VIRGINIA PREMIER MEDALLION 4.0

PRIOR AUTHORIZATION DETAIL

December 1, 2022

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.

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ABILIFY (ARIPIPRAZOLE)

Criteria for use for schizophrenia or acute bipolar mania (bullet points below are all inclusive unless otherwise noted):

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

-AND-

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

References

1. Virginia Premier

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

******For any request for OXAYDO or ROXYBOND: partially approve the EOC and submit to the PA Hub Client Sign-off queue. Send an email to COPTeam@elixirsolutions.com noting the EOC # and requested indication for use. A COP Team member will forward the supporting documentation to the medical team at VPHP for final coverage determination******

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 Virgnia 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
- 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 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 quantitites
    - 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

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**

ACTEMRA (TOCILIZUMAB)

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

ELIXR IS NOT TO REVIEW ANY CASES FOR ACTHAR AND CORTROPHIN. ALL CASES MUST BE REVIEWED BY THE CLIENT

PARTIALLY APPROVE AND MOVE TO THE **CLIENT SIGN OFF QUEUE** FOR REVIEW BY THE PLAN DIRECTLY. **EMAIL COPTEAM DISTRIBUTION at COPTeam@elixirsolutions.com** WITH EOC # AND INDICATION FOR USE ONCE THE EOC HAS BEEN MOVED TO THE CLIENT QUEUE

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.
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**
3. Member's atopic dermatitis involves 10% BSA or more; **AND**
4. Documented failure of phototherapy or systemic immunosuppressant treatment (e.g. cyclosporine, azathioprine), or failure of at least 2 of the following topical therapies:
    a. A moderate or higher potency topical corticosteroid for at least 2 consecutive weeks; OR
    b. A topical calcineurin inhibitor (tacrolimus or pimecrolimus) for 6 consecutive weeks; OR
    c. Eucrisa for 4 consecutive weeks; OR
5. Prescribed by or in conjunction with a dermatologist, allergist, or immunologist; **AND**
6. Member is not receiving Adbry in combination with another biologic medication indicated for atopic dermatitis or an oral JAK inhibitor indicate for atopic dermatitis or other inflammatory conditions.

Renewal therapy:

1. Confirmation of clinical improvement in signs and symptoms of atopic dermatitis; **AND**

2. Documentation of current disease severity; **AND**

Approval Duration: 6 months

Quantity Limit:

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

LAST REVISION: 5/1/22

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:
    - 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
- Prescriber used the DSM V and determined that criteria have been met (including documentation of impairment in more than 1 major setting) to make diagnosis of ADHD, AND
- Prescriber has reviewed the Virginia Prescription Monitoring Program on the date of this request, AND
- Prescriber has ordered and reviewed a urine drug screen (UDS) prior to initiating treatment with the requested stimulant within 30 days of this request and the drug screen is submitted with the request (checking for THC, benzodiazepines, amphetamine/methamphetamine, cocaine, heroin, and other prescription opiates) AND

RENEWAL

- The prescriber has checked the prescription monitoring program at least every three (3) months after the start of treatment (and date of most recent check is provided), AND
- Prescriber has ordered and reviewed a random urine drug screen at least every six (6) months (date of most recent check provided), AND

- Prescriber has regularly evaluated the patient for stimulant and/or other substance use disorder, and, if present, initiated specific treatment, consulted with appropriate health care provider, or referred the patient for evaluation for treatment if needed.

AUTHORIZATION

12 months

AEMCOLO (RIFAMYCIN)

CRITERIA FOR USE

- 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:
  - Sutent (sunitinib); OR
  - Nexavar (sorafenib), OR

- Patient has a diagnosis of Waldenstrom's macroglobulinemia (lymphoplasmacytic lymphoma) (NCCN), OR
- Patient has a diagnosis of Subependymal Giant Cell Astrocytoma (SEGA) associated with Tuberous Sclerosis (TS), OR

- Patient has a diagnosis of progressive neuroendocrine tumors of pancreatic origin that is unresectable, locally advanced, or metastatic, OR
- Patient has a diagnosis of lung neuroendocrine tumors. (NCCN), OR
- Patient has a diagnosis of hormone receptor-positive, HER2-negative metastatic breast cancer and prior therapy with a nonsteroidal aromatase inhibitor (e.g. Femara (letrozole),Arimidex (anastrozole)) (NCCN); **AND**
- Patient will be using Afinitor (everolimus) in combination with Aromasin (exemestane)(NCCN)

References

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)

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
- 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

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: 1/1/22

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
- 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

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: 9/26/22

ALFERON N (INTERFERON ALFA-N3)

- ≥18 years of age, AND
- External condylomata 27ysteine27 (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 acuminate. JAMA. 1988 Jan,22-29;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/.

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.

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 fampiridine 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
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 is participating in a behavioral management program (**NOTE**: **Not applicable if a Psychiatrist**), AND
- Patient has received a developmentally-appropriate, comprehensive psychiatric assessment with diagnoses, impairments, treatment target, and treatment plan clearly identified and documented (**NOTE**: **Not applicable if a Psychiatrist**), AND
- Patient has had inadequate response to at least 12 weeks of psychosocial treatment and psychosocial treatment will continue with parent/guardian involvement for the duration of medication therapy (**NOTE**: **Not applicable if a Psychiatrist**).

Authorization: 6 months

References

1. Virginia Premier

ANZEMET (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/. .
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 Interleukn-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 (Interleuckin-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.
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

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 malingnancy 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

AUBAGIO (TERIFLUNOMIDE)

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

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

OR

- Failure with Avonex (IFN Beta-1a) or Betaseron (IFN Beta-1b)
- Patient must have been compliant with treatment
- Patient must meet at least one of the following conditions:
  - Two disabling relapses within a 12-month period

- Secondary progression with an observable increase in disability over a six-month period
- Loss of ability to walk for a period longer than six months

Criteria for continuation of therapy:

- Continued response – decrease in number of, or no relapses

Contraindication:

- Severe hepatic impairment
- 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

AUSTEDO (DEUTETRABENAZINE)

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 Chorea associated with Huntington's Disease **OR**

- Member has a diagnosis of Tardive Dyskinesia, **AND**
- Medication is prescribed by, or in consultation with, a Neurologist or Psychiatrist, **AND**
- Meber has attempted an alternative method to manage the condition such as dose reduction, tapering, discontinuation of the offending agent, switching to an alternative agent **AND**
- For diagnosis of Chorea associated with Huntington's Disease: Member has an intolerance or treatment failure of tetrabenazine **AND**
- Member is not receiving concurrent therapy with MAOI or VMAT2 inhibitors **AND**
- Member does not have any suicidal thoughts/behaviors or untreated or inadequately treated depression

FOR RENEWAL:

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

DURATION:

Initial – 3 months, Renewal 12 months

AUVI-Q (EPINEPHRINE)

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

- Must be used for treatment of anaphylaxis
- Must have ***clinical*** trial and failure of ***all*** of the following (chart notes/medical record documenting trial and failure history required):
  - Epinephrine Auto-Injector (generic EpiPen)
  - Epinephrine Injection (generic AdrenaClick)
  - AdrenaClick
  - EpiPen (requires Prior authorization and trial and failure of all previously listed) ***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: 6/1/2021

References

Virginia Premier

AVASTIN (BEVACIZUMAB)

- Metastatic colorectal cancer, in combination with oxaliplatin and capecitabine, OR

- Metastatic carcinoma of the colon or rectum and used in combination with a 5-fluorouracil-based chemotherapy regimen, OR
- Metastatic carcinoma of the colon or rectum and used in combination with irinotecan, OR
- 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
- 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. Inravitreal 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 37ysteine37d, 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 vevacizumab. 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.
19. Rizzo S, Genovesi-Ebert F, Di Bartolo E, Vento A, Miniaci S, Williams G. Injection of intravitreal bevacizumab (Avastin) as a preoperative adjunct before vitrectomy surgery in the treatment of severe proliferative diabetic retinopathy (PDR). Graefes Arch Clin Exp Ophthalmol. 2008 Jun;246(6):837-842.
20. Roh MI, Byeon SH, Kwon OW. Repeated intravitreal injection of bevacizumab for clinically significant diabetic macular edema. Retina, the Journal of Retinal and Vitreous Diseases. 2008; 28(9): 1314-1318.
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.
23. Yazdani S, Hendi K, Pakravan M, et al. Intravitreal bevacizumab for neovascular glaucoma: a randomized controlled trial. J Glaucoma. October-November 2009;18(8):632-637.
24. Weigert G, Michels S, Sacu S, et al. Intravitreal bevacizumab (Avastin) therapy versus photodynamic therapy plus intravitreal triamcinolone for neovascular age-related macular degeneration: 6-month results of a prospective, 37ysteine37d, controlled clinical study. Br J Ophthalmol. 2008 Mar;92(3):356-360.
25. Wright JD, Rader JS, Viviano D, et al. Bevacizumab combination therapy in recurrent, platinum-refractory, epithelial ovarian carcinoma. Cancer. 2006;107 (1) :83-89.

AVSOLA, REMICADE, INFLECTRA (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 Renflexis.

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 Renflexis.

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 Renflexis 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 Renflexis 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 Renflexis and Humira or Enbrel.

Approval Duration

- Initial – 12 months
- Renewal – 12 months

LAST REVISION: 7/1/21

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

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.
- 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 18 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**
- 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

Age Limitations: SLE: 5 years of age or older LUPUS NEPHRITIS: 18 years of age or older

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 1/1/22

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
    - 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.

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. Boniva. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
3. Ibandronate. 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. National Osteoporosis Foundation. The Clinician's Guide to Prevention and Treatment of Osteoporosis. Available from http://www.nof.org/professionals/clinical-guidelines.
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.

BOTOX (ONABOTULINUMTOXINA)

- Dystonia, Spasticities, and Neuro-opthalmological 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 oromandibulary 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:
    - 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 pervious pneumatic dilatation

        - Epiphrenic diverticulum or hiatial hernia
        - Previous esophageal perforation
        - Sigmoid-shaped esophagus
        - Tried/failed/intolerance to isosorbide dinitrate, nifedipiine, 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
- 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**
- Botox wil **NOT** be used in combination with another CGRP inhibitor indicated for migraine prevention.

LAST REVISWION: 8/1/2022

References

1. Aurora SK et al. Botulinum toxin type A as prophylactic treatment of episodic migraine headache: A randomized, placebo controlled, exploratory trial. Headache April 2007 47:486-499.
2. Biglan AW, et al. Management of strabismus with botulinum A toxin. Ophthalmology 1989;96(7): 935-943
3. Biglan AW, et al., Management of facial spasm with Clostridium botulinum toxin type A (Oculinum). Arch Otolaryngol Head Neck Surg. 1998; 114(12): 1407-1412.
4. Blumenfeld AM et al. Botulinum toxin type A and divalproex sodium for prophylactic treatment of episodic or chronic migraine. Headache February 2008 48:210-220.
5. Boghen Dr. Disorders of facial motor function. Curr Opin Ophthalmol. 1996 Dec;7(6): 48-52.
6. Botox. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.

7. Daelen B, Thorwirth V, Koch A. Treatment of recurrent dislocation of the temporomandibular joint with type A botulinum toxin. Int J Oral Maxillofac Surg. 1997; 26(6): 458-460.
8. Ernberg M, Hedenberg-Magnusson B, List T, Svensson P. Efficacy of botulinum toxin type A for treatment of persistent myofascial TMD pain: a randomized, controlled, double-blind multicenter study. Pain, 2011; 152:1988-96.
9. Freund B, Schwartz M, Symington JM. The use of botulinum toxin for the treatment of temporomandibular disorders: preliminary findings. J Oral Maxillofac Surg. 1999; 57(8): 916-921.
10. Freund B, Schwartz M. The use of botulinum toxin for the treatment of temporomandibular disorder. Oral Health. 1998; 88(2):32-37.
11. Gordon JMI, Eager ELY. Prospective study of esophageal botulinum toxin in high-risk achalasia patients. Am J Gastroenterol; 1997; 92: 1812-1817.
12. Heckmann M, Breit S, Ceballos-Baumann A, et al., Side-controlled intradermal injection of botulinum toxin A in recalcitrant axillary hyperhidrosis. J Am Acad Dermatol. 1999; 41(6): 987-990.
13. Hobson DE, Gladish DF. Botulinum toxin injection for cervicogenic headache. Headache. 1997:37(4):253-255.
14. Jordan DR, Anderson RL, Thiese SM. Intractable orbicularis myokymia: treatment alternatives. Ophthalmic Surg. 1989; 20(4): 280-283.
15. Kalra HK, et al., Side effects of the use of botulinum toxin for treatment of benign essential blepharospasm and hemifacial spasm. Ophthalmic Surg. 1990;21(5): 335-338.
16. Karamfilov T, Konrad H, Karte K, et al., Lower relapse rate of botulinum toxin A therapy for axiallary hyperhidrosis by dose increase. Arch Dermatol. 2000; 136(4): 487-490.
17. Kolbasnik J, Waterfall WE, Fachnie B, Chen Y, et al., Long term efficacy of botulinum toxin in classical achalasia: a prospective study. Am J Gastroenterol 1999; 94(12): 3434-39.
18. Muehldorfer SM, Schneider TH, et al., Esophageal achalasia: intrasphincteric injection of botulinum toxin, A versus balloon dilation. Endoscopy 1999; 31(7): 231-34.
19. Munchau A, Bhatia KP. Uses of botulinum toxin injection in medicine today. BMJ. 2000;320:161-165.
20. Naver H, Swartling C, Aquilonius SM. Palmar and axillary hyperhidrosis treated with botulinum toxin: one-year clinical follow-up. Eur J Neurol. 2000; 7(1): 55-62.
21. Nixdorf DR, Heo G, Major PW. Randomized controlled trial of botulinum toxin A for chronic myogenous orofacial pain. Pain, 2002; 99:465-73.
22. Odderson IR. Hyperhidrosis treated by botulinum A exotoxin. Dermatol Surg. 1998; 24(11): 1237-1241.
23. Onabotulinumtoxina. 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.
24. Pasricha PJ, Ravich WJ, Henrix TR, et al., Intraspincteric botulinum toxin for the treatment of achalasia. N Engl J Med 1995;322: 774-78.
25. Pasricha PJ, Rai R, Ravich WJ, et al., Botulinum toxin for achalasia: Long term outcome and predictors of response. Gastroenterol 1996; 110: 1410-1415.
26. Richter MF. American College of Gastroenterology Practice. Diagnosis and Management of Achalasia. Practice Guidelines. Am J of Gastroenterol 1999; 94(12): 3406-3412.
27. Ruusuvaara P, Setala K. Long term treatment of involuntary facial spasms using botulinum toxin. Acta Ophthalmol (Copenh). 1990 Jun; 68(3): 331-8.
28. Schulte-Mattler WJ, Wieser T, Zierez S. Treatment of tension-type headache with botulinum toxin: a pilot study. Eur J Med Res. 1999; 4(5): 183-186.
29. Sedano MJ, Trejo JM, Macarron JL, Polo JM, Berciano J, Calleja J. Continuous facial myokymia in multiple sclerosis: treatment with botulinum toxin. Eur Neurol. 2000; 43(3): 137-40.
30. Solomon BA, Hayman R. Botulinum toxin type A therapy for palmar and digital hyperhidrosis. J Am Acad Dermatol. 2000; 42(6):1026-1029.
31. Vaezi MF, Richter JE, Wilcox M, et al., Botulinum toxin versus pneumatic dilation in the treatment of achalasia: A randomized trial. Gut 1999, 44: 231-239.
32. Wheeler A.H., Botulinum toxin A. adjunctive therapy for refractory headaches associated with pericranical muscle tension. Headache. 1998;38(6):468-471.
33. Zwart JA, Bovim G, Sand T, Sjaastad O. Tension headache: botulinum toxin paralysis of temporal muscles. Headache. 1994; 34 (8): 458-462.

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

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 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

References

1. Virginia Premier

BUTORPHANOL (GENERIC STADOL)

Migraine Headaches (bullet points below are all inclusive unless otherwise noted)

- • Failed / intolerant to VPHP-preferred Triptans
- • Failed / intolerant to Fioricet
- • Prophylactic therapy is currently being used at a sufficient dose.

Or

- • Prophylaxis with at least two different therapy classes was either ineffective or not tolerated.

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

- • Evaluation of chronic pain has been documented.
- • Failed other opioid pain management regimens including but not limited to: morphine extended release and Duragesic patches.
- • Patient is NPO.

• Criteria for use for greater than 2 canisters per month:

- •Clinical documentation and/ or treatment plan to support the need for greater than 2 canisters per month.

References

1. Virginia Premier

BYLVAY (ODEVIXIBAT)

Initial 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

CALQUENCE (ACALABRUTINIB)

- Patient is diagnosed with mantle cell lymphoma

- Patient has received at least 1 prior therapy
- Patient is 18 years of age or older
- Prescribed by an Oncologist
- Medication is being used as a single agent OR
- Patient is diagnosed with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- Patient is 18 years of age or older
- Prescribed by an Oncologist
- Medication is being used as a single agent or in combination with obinutuzumab

Warnings, Precautions, and other Clinical Information:

- Calquence (acalabrutinib) has not been evaluated in patients with severe hepatic impairment (Child-Pugh Class C or total bilirubin between 3-10x ULN and any AST)
- Monitor for bleeding and manage appropriately
- Monitor patients for signs and symptoms of infection and treat as needed, consider prophylaxis in patients at risk for opportunistic infections
- Infections due to hepatitis B virus reactivation and progressive multifocal leukoencephalopathy (PML) have occurred
- Monitor complete blood counts monthly for thrombocytopenia and neutropenia
- Secondary primary malignancy can occur, especially skin cancer, advise patients to use sun protection
- Interrupt and reduce Calquence dose with third occurrence of an adverse effect
- Discontinue Calquence with fourth occurrence of an adverse reaction
- Avoid use with strong CYP3A inhibitor, if inhibitor use is to be < 7 days, interrupt dose of Calquence
- With moderate CYP3A inhibitor use, reduce Calquence dose to 100 mg once daily
- Avoid use with strong CYP3A inducers, if unable to avoid, adjust dose of Calquence to 200 mg twice daily
- Avoid use with proton pump inhibitors, separation of doses does not eliminate the interaction
- Stagger dosing with H2-receptor antagonists and antacids
- Woman who is breast feeding an infant or child should stop breast feeding
- The mean absolute bioavailability of Calquence (acalabrutinib) is 25%, solubility decreases with increasing pH

CAMZYOS (MAVACAMTEN)

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

INITIAL:

- Clinically diagnosed with Obstructive Hypertrophi 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 pVO_2 since initiation of therapy and a reduction or stabilization in NYHA class; **AND**
- 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

References:

1. CAMZYOS (mavacameten) [prescribing information]. Brisbane, CA: Myokardia, Inc..; May 2022.
2. Bristol Myers Squibb. CAMZYOS (mavacameten) REMS: Education Program for Healthcare Providers and Pharmacies. https://www.camzyosrems.com/assets/commercial/us/camzyosrems/en/pdf/Camzyos-Prescriber-Education-Program.pdf
3. Olivotto, I., Oreziak, A., Barriales-Villa, R., Abraham, T. P., Masri, A., Garcia-Pavia, P., Saberi, S., Lakdawala, N. K., Wheeler, M. T., Owens, A., Kubanek, M., Wojakowski, W., Jensen, M. K., Gimeno-Blanes, J., Afshar, K., Myers, J., Hegde, S. M., Solomon, S. D., Sehnert, A. J., Zhang, D., … EXPLORER-HCM study investigators (2020). Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet (London, England), 396(10253), 759–769. https://doi.org/10.1016/S0140-6736(20)31792-X

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
  - 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
    - 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.
2. Bonilla FA, et al. "Practice parameter for the diagnosis and management of primary immunodeficiency." Ann Allergy Asthma Imunol. 2005;94:S1-63.
3. Carimune NF. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
4. Chu Y-Waye et al. "Idiopathic thrombocytopenia purpura." Pediatrics Review 2000; 21(3):94-105.
5. Cook S et al. "Intravenous gamma globulin in progressive MS." Acta Neurol Scand 1992;86:171-175.
6. Crenier L. "Low response to high-dose intravenous immunoglobulin in the treatment of acquired factor VIII inhibitor." Br J Haematol 1996;95(4):750-3.
7. 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.
8. Dalakais MC. "Intravenous immune globulin therapy for neurologic diseases." Ann Intern Med 1997;126(9):721-30.
9. Dalakas MC et al. "High-dose intravenous immune globulin for stiff-person syndrome." N Engl J Med 2001;345(26):1870-6.
10. Fasano MB. "Risks and benefits of intravenous immunoglobulin treatment in children." Curr Opin Pediatr 1995;7:688-94.
11. Francis G et al. "Failure of intravenous immunoglobulin to arrest progression of multiple sclerosis: a clinical MRI based study." Multiple Sclerosis 1997;3:370-6.
12. Gajdos P, et al. Intravenous immunoglobulin for myasthenia gravis. Cochrane Database of Systematic Reviews 2006, Issue 2. Art. No.: CD002277.
13. 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; 58:169-78.
14. Hughes RAC, et al. Practice parameter: immunotherapy for Guillain-Barre syndrome. Neurology 2003:61-736-40.

15. Immune Globulin. 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.
16. Jordan SC, et al. Evaluation of intravenous immunoglobulin as an agent to lower allosensitization and improve transplantation in highly sensitized adults patients with end-stage renal disease: report of the NIH IG02 trial. J Am Soc Nephrol 2004 15:3256-62.
17. Kiehl MG et al. "A controlled trial of intravenous immune globulin for the prevention of serious infections in adults with advanced human immunodeficiency virus infection." Arch Intern Med 1996;156:2545-50.
18. Lafferty TE et al. "Treatment of acquired factor VIII inhibitor using intravenous immunoglobulin in two patients with systemic lupus erythematosus." Arthritis 1997; 40(4):775-8.
19. Laosombat V. "Intravenous gamma globulin for treatment of chronic idiopathic thrombocytopenic purpura in children." J Med Assoc Thai 2000;83(2):160-8.
20. Medeiros, Desiree et al. "Current controversies in the management of idiopathic thrombocytopenic purpura during childhood." Pediatric Clin N Amer 1996;43(3):757-73.
21. Orange J, Hossny E, Weiler C et al. Use of intravenous immunoglobulin in human disease: A review of evidence by members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology. J Allergy Clin Immunol 2006;117:S525-S53.
22. Pehlau D et al. "Intravenous immunoglobulin (IVIG) treatment for patients with primary or secondary progressive multiple sclerosis – outline of a double-blind randomized, placebo-controlled trial." Multiple Sclerosis 1997;149-52.
23. Petz LP. "Treatment of autoimmune hemolytic anemias". Curr Opin Hematol 2001;8:411-16.
24. Report of the WHO Scientific Group. "Primary immunodeficiency diseases". Clin Exper Immunol 1997;109(suppl 1):1-28.
25. Sansome A, Dubowitz V. "Intravenous immunoglobulin in juvenile dermatomyositis: four year review of nine cases." Arch Dis Child 1995;72:25-8.
26. Schwarz RS, et al. A prospective study of treatment of acquired (autoimmune) factor VIII inhibitors with high-dose intravenous gammaglobulin. Blood 1995;86(2):797-804.
27. Scott-Timperley LJ et al. "Life-threatening complications of autoimmune disease: Autoimmune coagulation disorders." Rheum Dis Clin N Amer 1997;23(2):411-23.
28. Shah S. Pharmacy considerations for the use of IGIV therapy. Am J Health-Syst Pharmacy 2005;62:S5-S11.
29. Sultan Y. "Acquired hemophilia and its treatment." Blood Coagul Fibrinolysis 1997;8 (suppl 1):S15-8.
30. Zulay JP et al. "Long term follow up of multifocal motor neuropathy with conduction block under treatment." J Neurol 1997;62(4):391-4.

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

LAST UPDATED: 6/1/2021

CHENODAL (CHENODIOL)

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

References

1. Berginer VM, Salen g, Shefer S. Long-term treatment of cerebrotendinous xanthomatosis with chenodeoxycholic acid. N Engl J Med. 1984;331(26):1649-1652.
2. Chenodal. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
3. Chenodiol. 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. Petroni ML, Jazrawi RP, Pazzi P, et. Al. Ursodeoxycholic acid alone or with chenodeoxycholic acid for dissolution of cholesterol gallstones: a randomized 57ysteine57d57 trial. Aliment Pharmacol Ther. 2001;15:123-128.
5. Podda M, Zuin M, Battezzati PM, et. Al. Efficacy and safety of a combination chenodeoxycholic acid and ursodeoxycholic acid for gallstone dissolution: A comparison with ursodeoxycholic acid alone. Gastroenterology, 1989;96:222-229.
6. Schoenfield LJ, Lachin JM. Chenodiol (chenodeoxycholic acid) for dissolution of gallstones: the National Cooperative Gallstone Study. A controlled trial of efficacy and safety. Ann Intern Med. 1981;95(3):257-282.
7. Watts GF, Mitchell WD, Bending JJ, et. Al. Cerebrotendinous xanthomatosis: a family of sterol 27-hydroxylase mutations and pharmacotherapy. Q J Med. 1996;89:55-63.

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
- 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.
- Prescirber attests that Cibinqo 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 (Azulfindine)
  - 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**
  - 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:**
    - Achievement of clinical response
- **Cimzia** (certolizumab pegol) **may NOT be approved** for individuals with any of the following:
    - Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections; **or**
    - Individuals who have not had a tuberculin skin (TST), or a CDC-recommended equivalent, to evaluate for latent tuberculosis; **or**
    - Using in combination with other TNF antagonists; **or**
    - Using in combination with the following non-TNF immunomodulatory drugs: abatacept (Orencia), anakinra (Kineret), natalizumab (Tysabri), or rituximab (Rituxan).
- **Note**: Cimzia (certolizumab pegol) has a black box warning related to the increased risk of developing serious infections that could result in hospitalization or death. Individuals should be closely monitored for the development of infection during and after treatment with discontinuation of therapy if the individual develops a serious infection or sepsis. Reported infections include: Tuberculosis, invasive fungal infections (including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis), and infections (bacterial, viral, or other) due to opportunistic pathogens (including Legionella and Listeria). The risks and benefits of treatment with Cimzia should be considered prior to initiating in individuals with chronic or recurrent infection. Cimzia is not indicated for the use in pediatric

individuals due to reports of lymphoma and other malignancies developing in children and adolescents treated with tumor necrosis factor (TNF) blockers.

References

1. Virginia Premier

CINQAIR (RESLIZUMAB)

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

Initial Authorization Criteria: Must meet all of the criteria listed below:

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

Reauthorization Criteria:

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

Authorization

- Initial – 6 months
- Renewal – 1 year

References

1. Cinqair [Prescribing Information]. Frazer, PA: Teva Respiratory LLC; March 2016.

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 availability. Also, generally, compounded medications do not have standardized dosages and duration for use; likewise, there are no standardized protocols to prepare each compound. For these reasons compounded preparations are more likely to have batch-to-batch variability and their sterility/purity cannot be guaranteed relative to the commercially available products.

POLICY STATEMENT

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

AUTHORIZATION CRITERIA

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

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

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

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

Initial Authorization for compounds and bulk powders will <u>only</u> 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 **<u>NOT</u>** be approved for any of the following:

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	Pentoxyifylline
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 leuprolide when prescribed for off-label use (refer to leuprolide policy for criteria)

OR

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

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:

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

    - Must currently be prescribed by a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g. hepatologist) or a physician who has consulted with one of these specialists; AND
    - **Requests for concomitant use of two or more of the following; Incivek (telaprevir), Victrelis (boceprevir), Olysio (simeprevir), or Sovaldi (sofosbuvir) will not be approved.**
      Child Pugh Classification
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 >/=70,000/mm

6. Serum creatinine should be normal or near normal.
7. HCV RNA
8. genotype
9. Early Virological Response (EVR)
10. Liver Function Tests
11. Child Pugh Score Interpretation

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	<2mg/Dl	2-3 mg/Dl	>3 mg/Dl
Serum Albumin	>3.5 g/Dl	2.8-3.5 g/Dl	<2.8 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 < 50ml/min.
7. Coverage is not recommended

References

1. Ghany MG, Strader DB, et al. Diagnosis, management, and treatment of Hepatitis C: An Update. AASLD Practice Guidelines. Hepatology 2009. 1335-1373.
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.
3. Smith RA. Mechanisms of action of ribavirin. In: Smith RA, Kirkpatrick W, eds. Ribavirin: a broad spectrum antiviral agent. New York: Academic Press; 1980:99-118.
4. Ghany MG, Nelson DR, Strader DB et al. An update on treatment of genotype 1 chronic hepatitis C virus infection: 2011 practice guideline by the American Association for the Study of Liver Diseases. Hepatology. 2011; 54:1433-44.
5. European Association for the Study of the Liver. EASL Clinical Practice Guidelines: management of hepatitis C virus infection. J Hepatol. 2011; 55:245-64.
6. Yee HS, Chang MF, Pocha C et al. Update on the management and treatment of hepatitis C virus infection: recommendations from the Department of Veterans Affairs Hepatitis C Resource Center Program and the National Hepatitis C Program Office. Am J Gastroenterol. 2012; 107:669-89; quiz 690.
7. van den Berk GE, Arends JE. Sustained viral response after only 6 weeks of peginterferon and ribavirin treatment for acute hepatitis C in a HIV-1-infected patient. AIDS. 2011; 25:1553-4.
8. Hillyard IW. The preclinical toxicology and safety of ribavirin. In: Smith RA, Kirkpatrick W, eds. Ribavirin: a broad spectrum antiviral agent. New York: Academic Press; 1980:59-71.
9. Sidwell RW, Robins RK, Hillyard IW. Ribavirin: an antiviral agent. Pharmacol Ther. 1979; 6:123-46.
10. Allen LB. Review of in vivo efficacy of ribavirin. In: Smith RA, Kirkpatrick W eds. Ribavirin: a broad spectrum antiviral agent. New York: Academic Press; 1980:43-58.
11. Vertex Pharmaceuticals Incorporated. Incivek® (telaprevir) film-coated tablets prescribing information. Cambridge, MA; 2012 Jun.
12. Merck & Co. Victrelis® (boceprevir) capsules prescribing information. Whitehouse Station, NJ; 2012 Apr.
13. Isaacs D, Moxon ER, Harvey D et al. Randomized trials and ribavirin. Arch Dis Child. 1988; 63:989-90.
14. Isaacs D. Ribavirin. Pediatrics. 1987; 79:289-91.
15. Schvarcz R, Ando Y, Sonnerborg A et al. Combination treatment with interferon alfa-2b and ribavirin for chronic hepatitis C in patients who have failed to achieve sustained response to interferon alone: Swedish experience. J Hepatol. 1995; 23(Suppl 2): 17-21.
16. Reichard O, Norkrans G, Fryden A et al et al. Randomised, double-blind, placebo-controlled trial of interferon α-2b with and without ribavirin for chronic hepatitis C. Lancet. 1998; 351:83-7.
17. Brown JL. Efficacy of combined interferon and ribavirin for treatment of hepatitis C. Lancet. 1998; 351:78-9.
18. Chemello L, Cavalletto L, Bernardinello E et al. The effect of interferon alfa and ribavirin combination therapy in naive patients with chronic hepatitis C. J Hepatol. 1995; 23(Suppl 2):8-12.
19. Schalm SW, Hansen BE, Chemello L et al. Ribavirin enhances the efficacy but not the adverse effects of interferon in chronic hepatitis C. Meta-analysis of individual patient data from European centers. J Hepatol. 1997; 26:961-6.
20. Lai MY, Kao JH, Yang PM et al. Long-term efficacy of ribavirin plus interferon alfa in the treatment of chronic hepatitis C. Gastroenterology. 1996; 111:1307-12.
21. Centers for Disease Control and Prevention. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. MMWR Morb Mortal Wkly Rep. 1998; 47(No. RR-19):14-5.
22. Poynard T, Marcellin P, Lee SS st al. Randomised trial of interferon α2b plus ribavirin for 48 weeks or for 24 weeks versus interferon α2b plus placebo for 48 weeks for treatment of chronic infection with hepatitis C virus. Lancet. 1998; 352:1426-32.
23. McHutchison JG, Gordon SC, Schiff ER et al. Interferon alfa-2b alone or in combination with ribavirin as initial treatment for chronic hepatitis C. N Engl J Med. 1998; 339:1485-92.
24. Davis GL, Esteban-Mur R, Rustgi V et al Interferon alfa-2b alone or in combination with ribavirin for the treatment of relapse of chronic hepatitis C. N Engl J Med. 1998; 339:1493-9.
25. Hoofnagle JH. Management of hepatitis C: current and future perspectives. J Hepatol. 1999; 31(Suppl 1):264-8.
26. Booth JCL, O'apos;Grady J, Neuberger J for the Royal College of Physicians of London and the British Society of Gastroenterology. Clinical guidelines on the management of hepatitis C. Gut. 2001; 49(Suppl):1-21.
27. European Association for the Study of the Liver (EASL) Consensus Panel. EASL international consensus conference on hepatitis C; Paris, 26-28 February 1999. J Hepatol. 1999; 30:956-61.
28. Manns MP, McHutchison JG, Gordon SC et al. Peginterferon alfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a 67ysteine67d trial. Lancet. 2001; 358:958-65.
29. Merck & Co. Rebetol® (ribavirin) capsules, oral solution prescribing information. Whitehouse Station, NJ; 2012 Jul.
30. Zylberberg H, Benhamou Y, Lagneaux JL et al. Safety and efficacy of interferon-ribavirin combination therapy in HCV-HIV coinfected subjects: an early report. Gut. 2000; 47:694-7.
31. Genentech. Copegus® (ribavirin) tablets prescribing information. South San Francisco, CA; 2012 Nov.

32. McHutchison JG, Lawitz EJ, Shiffman ML et al. Peginterferon alfa-2b or alfa-2a with ribavirin for treatment of hepatitis C infection. N Engl J Med. 2009; 361:580-93.
33. Hadziyannis SJ, Sette H, Morgan TR et al. Peginterferon-alpha2a and ribavirin combination therapy in chronic hepatitis C: a randomized study of treatment duration and ribavirin dose. Ann Intern Med. 2004; 140:346-55.
34. Fried MW, Shiffman ML, Reddy KR et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection. N Engl J Med. 2002; 347:975-82.
35. Torriani FJ, Rodriguez-Torres M, Rockstroh JK et al. Peginterferon Alfa-2a plus ribavirin for chronic hepatitis C virus infection in HIV-infected patients. N Engl J Med. 2004; 351:438-50.
36. Wirth S, Ribes-Koninckx C, Calzado MA et al. High sustained virologic response rates in children with chronic hepatitis C receiving peginterferon alfa-2b plus ribavirin. J Hepatol. 2010; 52:501-7.
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 ≤ 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)
- 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)
- 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 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 amophotericin 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 atleast 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
  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 documentated 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 phospaturic 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

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

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**
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 contolled 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
    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

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 recoreds 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
        - Cimzia
        - Orencia
        - Kineret
        - Remicade
        - Rituxan
- Must have tried and failed, or been intolerant to formulary alternative Depen Titra (Prior Authorization Required)

Approval Duration:

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

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

Not approved if:
Any of the above contraindications are present

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

Additional considerations:

- Two types of patients with Wilson's disease should be treated. Those with symptomatic disease and those with asymptomatic disease that is presumed to progress if patient is not treated.
- In patients with Wilson's disease noticeable improvement may take up to three months. During initial treatment, neurologic symptoms may worsen. It is important that the drug is continued as interruption of therapy can increase the likelihood of developing a hypersensitivity reaction to the medication.

- Pregnant patients receiving penicillamine for Wilson's disease should have dose decreased to ≤ 1 g and if cesarean is planned, dose should be reduced to 250 mg for the 6 weeks prior to delivery.
- Treatment with penicillamine for RA can take three months to see a clinical benefit due to slow titration of the medication. It is recommended that drug is not discontinued during that time due to increased sensitivity upon re-initiation of therapy.
- Dose increases for RA should be in 125 mg or 250 mg increments over one to three month intervals.
- Dose of penicillamine in cystinuria should limit 77ysteine 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 77ysteine 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.
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 severed 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)

- Member has a diagnosis of one of the following:
  - Acute Malaria
  - Chemoprophylaxis of Malaria
  - Pneumocystis Pneumonia Prophylaxis
  - Toxoplasmosis
  - Toxoplasmosis Infection in HIV-infected patients
  - Toxoplasmic Encephalitis AND
- If being used to treat toxoplasmosis in HIV-infected patients, therapy will include sulfadiazine and leucovorin, AND
- If being used to treat toxoplasmosis in HIV-infected patients, the patient's CD4 count is greater than 200 cells/mm^3, AND
- Patient must not have either of the following:
  - Known hypersensitivity to pyrimethamine or any component of the formulation
  - Documented megaloblastic anemia due to folate deficiency, AND
- If being used to prevent Pneumocystis Pneumonia, patient has tried and failed all of the following:
  - Trimethoprim/sulfamethoxazole (TMP/SMX)

    - Dapsone
    - Pentamidine
    - Atovaquone, AND
- Prescriber has informed the patient about the importance of, and will monitor, adherence to antiretroviral therapy, AND
- For renewal for treatment of toxoplasmic encephalitis, the patient's CD4 count has remained above 200 cells/mm^3 for six months.

LAST REVISION: 5/1/22

DARAPRIM (PYRIMETHAMINE)

INITIAL:

Diagnosis of Toxoplasmosis – prophylaxis:

- Member has a diagnosis of HIV/AIDS; **AND**
- Member has a CD4 count < 100 cells/mm^3; **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 Cystoisoporiasis:

- Member has a diagnosis or exposure to HIV; **AND**
- 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
- 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:
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 82ulticen 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**
- 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, Pancrelipase; OR
- Diagnosis of pancreatic insufficiency due to pancreatectomy and a trial and failure of two (2) of the following preferred alternatives: Zenpep, Creon, Pancrelipase. If request is for patient with Cystic Fibrosis, trial and failure of preferred alternatives not required (Zenpep, Creon, Pancrelipase are preferred)

DRONABINOL

- Diagnosis of severe, chemotherapy induced nausea and vomiting OR

- Diagnosis of Nausea or vomiting related to radiation therapy, moderate to highly emetogenic chemotherapy, or post-operative nausea and vomiting AND
- Has the member tried and failed therapeutic doses of, or has adverse effects or contraindications to, TWO different conventional antiemetics (e.g., promethazine, prochlorperazine, meclizine, metoclopramide, dexamethasone, etc.) OR
- 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: Initial 6 months, Renewal 12 months.

APPROVAL CRITERIA

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

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

INITIAL

1. Must be at least 6 months old~~years of age~~ or older AND
2. Must have a diagnosis of atopic dermatitis 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. One (1) topical calcineurin inhibitors (tacrolimus or pimecrolimus); AND
    c. A trial and failure of Eucrisa

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 OR with oral corticosteroid dependent asthma, AND
3. Prescribed by, or in consultation with an allergist or pulmonologist, AND
4. Member has experienced at least 2 exacerbations, within the last 12 months, requiring any of the following despite adherent use of controller therapy (i.e., high dose inhaled corticosteroid (ICS) plus either a long acting beta-2 agonist (LABA) or leukotriene modifier (LTRA) if LABA contraindicated/intolerance):
    a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid)
    b. Urgent care visit or hospital admission
    c. Intubation; OR

4. For patients without oral corticosteroid dependent asthma:
    a. Eosinophilic phenotype defined as EITHER of the following:
        i. Blood eosinophils greater than or equal to 150 cells/mcl within the previous 6 weeks OR
        i. History of blood eosinophils greater than or equal to 300 cells/mcl , AND
        ii. Continued use of an inhaled corticosteroid AND another controller therapy (for example, long-acting beta-agonist, leukotriene receptor)
5. 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
2. Medication will be used as add on therapy, AND
3. Member is at least 18 years of age or older, AND
4. Member has had an inadequate response, intolerance, or contraindication to **ONE** medication from each of the following classes:
    a. Nasal Corticosteroid spray (Mometasone, Fluticasone, Nasacort OTC, Rhinocrot OTC
    b. Oral corticosteroid (i.e. prednisone)

RENEWAL

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

-OR- INITIAL

1. Diagnosis of eosinophilic esophagitis, AND
2. Member is 12 years of age or older and weighs at least 40 kg, AND
3. Member has 2 or more episodes of dysphagia per week, 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.

LAST REVISION: ~~10/1/22~~11/22/22

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

Not approved if:

• Does not meet the above-stated criteria

Caution:

• 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 and1000 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
- 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 ≥ 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

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:

- 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 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: 10/1/21

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
- 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

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 AND
- Medication is prescribed by or in conjunction with a neurologist or epileptologist appropriate for patient age

Auth Duration: 12 months
LAST REVISION: 1/1/22

EPOGEN (EPOETIN ALFA)

Criteria for approval is ONE of the following:

1. Erythropoietin Stimulating Agent (ESA) is being prescribed to reduce the possibility of allogeneic blood transfusion in a surgery patient **AND** patient's hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL **OR**
2. ESA is being prescribed for anemia due to chemotherapy for a non-myeloid malignancy AND ***BOTH*** of the following:

a. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy or stabilized on therapy (measured within the previous four weeks) **AND**
b. Patient is being concurrently treated with chemotherapy, with or without radiation (treatment period extends to eight weeks post chemotherapy) **OR**

3. ESA is prescribed for a patient with anemia associated with chronic renal failure in a patient NOT on dialysis **AND** patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy or stabilized on therapy (measured within the previous 4 weeks) **AND BOTH** of the following:
   a. Rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion **AND**
   b. Goal is to reduce risk of alloimmunization and/or other RBC transfusion related risks **OR**
4. ESA is prescribed for a patient with anemia due to myelodysplastic syndrome or a patient with anemia resulting from zidovudine treatment of HIV infection **AND** patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy or less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous four weeks) **OR**
5. ESA is prescribed for another indication **AND BOTH** of the following:
   a. There is clinical evidence supporting therapy with an ESA for the intended use or the prescriber has submitted documentation in support of the requested therapeutic use for the requested agent **AND**
   b. Patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy or less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous four weeks)

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

Authorization Requirements for Erythropoiesis Stimulating Agents by Indication
Chronic Kidney Disease *not* on Dialysis (erythropoietin or darbepoietin):
Initial or continuation:
Documentation of diagnosis; submission of lab findings confirming HgB level < 10 g/dL; serum ferritin ≥100 ng/mL or transferrin saturation of ≥ 20%; and that ESA therapy is required to raise HgB to a level necessary to reduce the need for RBC transfusion.

Re-authorization is required at 3 month intervals
Chronic Kidney Disease on Dialysis (erythropoietin or darbepoietin):
Initial:
Documentation of diagnosis; submission of lab findings confirming HgB level < 10 g/dL; serum ferritin ≥100 ng/mL or transferrin saturation of ≥ 20%.
Continuation:
Submission of lab findings confirming HgB level ≤ 11 g/dL, serum ferritin ≥100 ng/mL or transferrin

saturation of ≥ 20%.

Re-authorization is required at 3 month intervals
Chemotherapy-Induced Anemia in Cancer Patients (erythropoietin or darbepoietin):
Initial:
Documentation of non-myeloid malignancy and chemotherapy regimen, symptomatic anemia; submission of lab findings confirming HgB level < 10 g/dL; serum ferritin ≥100 ng/mL or transferrin saturation of ≥ 20%.
Continuation:
Submission of lab findings confirming HgB level ≤10 g/dL, serum ferritin ≥100 ng/mL or transferrin
saturation of ≥ 20%.

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

Re-authorization is required at 3 month intervals
Myelodysplastic Disease (erythropoietin):
Initial:
Documentation of diagnosis, submission of laboratory findings confirming HgB level < 10 g/dL, serum ferritin ≥100 ng/mL or transferrin saturation ≥ 20%.
Continuation:
Submission of lab findings confirming HgB level ≤ 12 g/dL, serum ferritin ≥100 ng/mL or transferrin saturation of ≥ 20%, and documentation that the member HgB levels have increased by at least 1 g/dL from pretreatment baseline.

Re-authorization is required at 3 month intervals
Hepatitis C Patients with anemia secondary to combination peginterferon/ribavirin therapy (erythropoietin):
Initial:
Documentation of diagnosis and concurrent use peginterferon / ribavirin therapy confirmed by review of prescription claims, submission of laboratory findings confirming HgB level < 10 g/dL and serum ferritin ≥ 100 ng/mL, or transferrin saturation ≥ 20%.
Continuation:

Submission of lab findings confirming HgB level ≤ 12 g/dL, serum ferritin ≥100 ng/mL or transferrin saturation of ≥ 20%, *documentation* that previous ribavirin dose did not require reduction due to symptomatic anemia; and documentation that the member HgB levels have increased by at least 1 g/dL
from pretreatment baseline.

Re-authorization is required at 3 month intervals

Anemia of Chronic Disease – Rheumatoid Arthritis, Crohn's Disease, Ulcerative Colitis (erythropoietin):

Initial:

Documentation of the underlying chronic disease, submission of laboratory findings confirming HgB level < 10 g/dL, serum ferritin ≥100 ng/mL or transferrin saturation ≥ 20%.

Continuation:

Submission of lab findings confirming HgB level ≤ 12 g/dL, serum ferritin ≥100 ng/mL or transferrin saturation of ≥ 20%, and documentation that the member HgB levels have increased by at least 1 g/dL from pretreatment baseline.

Re-authorization is required at 3 month intervals

Pre-Surgery (erythropoietin):

Initial:

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

EXCLUSIONS

1. *Anemia associated with cancer in patients not receiving cancer chemotherapy.*
   Epoetin is not indicated in cancer patients who are not receiving cancer chemotherapy. The ASCO/ASH guidelines for the use of epoetin and darbepoetin in adult patients with cancer recommend that ESAs not be used in treatment of anemia associated with malignancy in those who are not receiving concurrent myelosuppressive chemotherapy.
2. *Anemia associated with acute myelogenous leukemias (AML), chronic myelogenous leukemias (CML) or other myeloid cancers.*
   Epoetin is indicated for use in non-myeloid cancers when chemotherapy is given. AML and CML are examples of myeloid cancers.
3. *Anemia associated with radiotherapy in cancer.*
   Epoetin is not indicated for use in cancer patients who are given only radiation therapy.
4. *To enhance athletic performance.*
   Epoetin is not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.
5. *Anemia in patients due to acute blood loss.*

Use of Epoetin is not appropriate in these types of situations.

References

1. Rizzo JD, Somerfield MR, Hagerty KL, et al. American Society of Hematology / American Society of Clinical Oncology 2007 clinical practice guideline update on the use of epoetin and darbepoetin. Journal of Clinical Oncology, 26 (1), 2008: p.132-149.
2. Prescribing Information. Epogen, epoetin alfa. Amgen Inc., Thousand Oaks, CA 81320-1799. November 2012
3. Prescribing Information. Procrit, epoetin alfa. Ortho Biotech Products LP, Raritan, NJ 08869-0670. November 2012.
4. Eschbach JW, Egrie JC, Downing MR et al. Correction of the anemia of end-stage renal disease with recombinant human erythropoietin: results of a combined phase I and II clinical trial. N Engl J Med. 1987; 316:73-78.
5. Lim VS, DeGowin RL, Zavala D et al. Recombinant human erythropoietin treatment in pre-dialysis patients: a double-blind placebo-controlled trial. Ann Intern Med. 1989; 110:108-14.
6. Means RT, Olsen NJ, Krantz SB et al. Treatment of the anemia of rheumatoid arthritis with recombinant human erythropoietin: clinical and in vitro studies. Arth Rheum. 1989; 32:638-42.
7. Stevens JM, Strong CA, Oliver DO et al. Subcutaneous erythropoietin and peritoneal dialysis. Lancet. 1989; 1:1388-9.
8. Eschbach JW. The anemia of chronic renal failure: pathophysiology and the effects of recombinant erythropoietin. Kidney Int. 1989; 35:134-48.
9. Wine.dtd CG. Treatment of anaemia in haemodialysis patients with recombinant erythropoietin. Nephron. 1989; 51:26-8.
10. Verbeelen D, Bossuyt A, Smitz J et al. Hemodynamics of patients with renal failure treated with recombinant human erythropoietin. Clin Nephrol. 1989; 31:6-11.
11. Erslev A. Erythropoietin coming of age. N Engl J Med. 1987; 316:101-3.
12. 15. Freedman BI, Barbour GL. Correction of the anemia of end- stage renal disease with recombinant human erythropoietin. N Engl J Med. 1987; 317:249-50.
13. Levin N. Management of blood pressure changes during recombinant human erythropoietin therapy. Semin Nephrol. 1989; 9(Suppl 2):16-20.
14. Walker RE, Parker RI, Kovacs JA et al. Anemia and erythropoiesis in patients with the acquired immunodeficiency syndrome (AIDS) and Kaposi sarcoma treated with zidovudine. Ann Intern Med. 1988; 108:372-376.
15. Flaharty KK, Grimm AM, Vlasses PH. Epoetin: recombinant human erythropoietin. Clin Pharm. 1989; 8:769-82.
16. Finch CA. Erythropoiesis, erythropoietin, and iron. Blood. 1982; 60:1241-6.
17. Levine EA, Gould SA, Rosen RL et al. Perioperative recombinant human erythropoietin. Surgery. 1989; 106:432-8.
18. Eschbach JW, Adamson JW. Guidelines for recombinant human erythropoietin therapy. Am J Kidney Dis. 1989; 14(Suppl 1):2-8.
19. Brown AL, Tucker B, Baker LRI et al. Seizures related to blood transfusion and erythropoietin treatment in patients undergoing dialysis. BMJ. 1989; 299:1258-9.
20. Goodnough LT, Marcus RE. Erythropoietin and perioperative blood donation. N Engl J Med. 1990; 322:1158-9.
21. Fischl M, Galpin JE, Levine JD et al. Recombinant human erythropoietin for patients with AIDS treated with zidovudine. N Engl J Med. 1990; 322:1488-93.
22. 25. Miller CB, Jones RJ, Piantadosi S et al. Decreased erythropoietin response in patients with the anemia of cancer. N Engl J Med. 1990; 322:1689-92.
23. Ludwig H, Fritz E, Kotzmann H et al. Erythropoietin treatment of anemia associated with multiple myeloma. N Engl J Med. 1990; 322:1693-9.
24. Mintz PD, Popovsky MA, Ness P. Erythropoietin and perioperative blood donation. Lancet. 1990; 1:1157-8.
25. Thomas M, Saker BM, Thatcher GN et al. Cost- effectiveness of weekly and fortnightly subcutaneous erythropoietin. Lancet. 1990; 1:1533-4.
26. Pincus T, Olsen NJ, Russell IJ et al. Multicenter study of recombinant human erythropoietin in correction of anemia in rheumatoid arthritis. Am J Med. 1990; 89:161-8.
27. Scott WC. The abuse of erythropoietin to enhance athletic performance. JAMA. 1990; 264:1660.
28. Adamson JW, Vapnek D. Recombinant erythropoietin to improve athletic performance. N Engl J Med. 1991; 324:698-9.
29. Shepp DH, Agins BD, Farber BF. Erythropoietin for zidovudine-induced anemia. N Engl J Med. 1990; 323:1069-70.
30. Eschbach JW. Erythropoietin-associated hypertension. N Engl J Med. 1990; 323:999-1000.
31. Oster W, Herrmann F, Gamm H et al. Erythropoietin for the treatment of anemia of malignancy associated with neoplastic bone marrow infiltration. J Clin Oncol. 1990; 8:956-62.
32. Bunn HF. Recombinant erythropoietin therapy in cancer patients. J Clin Oncol. 1990; 8:949-51.
33. Henry DH. Erythropoietin therapy in AIDS. Prog Clin Biol Res. 1990; 338:113-20.
34. Erslev AJ. Erythropoietin. N Engl J Med. 1991; 324:1339-44.
35. Takashina N, Kondon H, Kashwazaki S. Suppressed serum erythropoietin response to anemia and the efficacy of recombinant erythropoietin in the anemia of rheumatoid arthritis. J Rheumatol. 1990; 17:885-7.

36. Krantz SP. Erythropoietin. Blood. 1991; 77:419-34.
37. Graber SE, Krantz SB. Erythropoietin: biology and clinical use. Hematol/Oncol Clin NA. 1989; 3:369-400.
38. Henry DH, Jemsek JG, Levin AS et al. Recombinant human erythropoietin and the treatment of anemia in patients with AIDS or advanced ARC not receiving ZDV. J Acquir Immune Defic Syndr. 1992; 5:847- 52.
39. Platanias LC, Miller CB, Mick R et al. Treatment of chemotherapy-induced anemia with recombinant human erythropoietin in cancer patients. J Clin Oncol. 1991; 9:2021-6.
40. Abels RI. Use of recombinant human erythropoietin in the treatment of anemia in patients who have cancer. Semin Oncol. 1992; 19(3 Suppl 8):29-35.
41. Stein RS, Abels RI, Krantz SB. Pharmacologic doses of recombinant human erythropoietin in the treatment of myelodysplastic syndromes. Blood. 1991; 78:1658-63.
42. Schouten HC, Vellenga E, van Rhenen DJ et al. Recombinant human erythropoietin in patients with myelodysplastic syndromes. Leukemia. 1991; 5:432-6.
43. Kurzrock R, Talpaz M, Estey E et al. Erythropoietin treatment in patients with myelodysplastic syndrome and anemia. Leukemia. 1991; 5:985-90.
44. de Campos ES, Radford JA, Steward WP et al. The effect of RHU erythropoietin (EPO) on levels of hemoglobin and number of red cell and platelet transfusions during intensive chemotherapy for small cell lung carcinoma (SCLC). Br J Cancer. 1991; 63(Suppl 13):9.
45. Henry DH, Staddon AP, Mason BA et al. Prevention of anemia in breast cancer patients receiving 97ulticente-containing chemotherapy with recombinant human erythropoietin (r-HuEPO). Blood. 1991; 78(Suppl 1):92A.
46. Henry DH, Beall GN, Benson CA et al. Recombinant human 97ulticenter97y97 in the treatment of anemia associated with human immunodeficiency virus (HIV) infection and zidovudine therapy: overview of four clinical trials. Ann Intern Med. 1992; 117:739-48.
47. Strauss RG. Erythropoietin and neonatal anemia. N Engl J Med. 1994; 330:1227-8.
48. Meyer MP, Meyer JH, Commerford A et al. Recombinant human erythropoietin in the treatment of the anemia of prematurity: results of a double-blind, placebo-controlled study. Pediatrics. 1994; 93:918-23.
49. Macdougall IC, Cavill I, Hulme B et al. Detection of functional iron deficiency during epoetin alfa treatment: a new approach. BMJ. 1992; 304:225-6.
50. Witzig TE, Silberstein PT, Loprinzi CL et al. Phase III, randomized, double-blind study of epoetin alfa versus placebo in anemic patients with cancer undergoing chemotherapy. J Clin Oncol. 2004;
51. Singh KA, Szczech L, Tang KL et al for the CHOIR Investigators. Correction of anemia with epoetin alfa in chronic kidney disease. N Engl J Med. 2006; 355:2085-98.
52. Remuzzi G, Ingelfinger JR. Correction of anemia — payoffs and problems. N Engl J Med. 2006; 355:2144-6.
53. Drueke TB, Locatelli F, Clyne N et al for the CREATE Investigators. Normalization of hemoglobin level in patients with chronic kidney disease and anemia. N Engl J Med. 2006; 355:2071-84.
54. Henke M, Laszig R, Rube C et al. Erythropoietin to treat head and neck cancer patients with anaemia undergoing radiotherapy: 97ulticente, double-blind, placebo-controlled trial. Lancet. 2003;362(Oct 18):1255-60.
55. Unger EF, Thompson AM, Blank M J et al. Erythropoiesis-stimulating agents—time for a reevaluation. N Engl J Med. 2010 Jan 21; 362:189-92.
56. Food and Drug Administration. FDA drug safety communication: modified dosing recommendations to improve the safe use of erythropoiesis-stimulating agents (ESAs) in chronic kidney disease . Rockville, MD; Jun 24, 2011. From FDA website.

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
- Chormdoma 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

References

1. Basal Cell and Squamous Cell 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.
2. 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.
3. Cascino, S, Berardi R, Labianca R, et al. Cetuximab plus gemcitabine and cisplatin compared with gemcitabine and cisplatin alone in patients with advanced pancreatic cancer: a randomized , multicenter, phase II trial. Lancet Oncology. 2008:9: 39-44.
4. Cetuximab. 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. 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.
6. Cunningham D, Humblet Y, Siena S, et al. Cetuximab alone or in combination with irinotecan in patients with epidermal growth-factor (EGFR)-positive, irinotecan-refractory metastatic colorectal cancer. Proc Am Soc Clin Oncol. 22: page 252, 2003.
7. Erbitux. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
8. 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.
9. 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.
10. Prewett MC, et al. Enhanced antitumor activity of anti-epidermal growth factor receptor monoclonal antibody IMC-255 in combination with irinotecan (CPT-11) against human colorectal tumor xenografs. Clin Cancer Res. 2002;8:994-1003.
11. Xiong H, Rosenberg A, Lobuglio A. Cetuximab, a monoclonal antibody targeting the epidermal growth factor receptor, in combination with gemcitabine for advanced pancreatic cancer: A multicenter phase II trial. J Clin Oncology. 2004;22:2610-6.

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 8 weeks for each trial (or contraindication of):
    a. One (1) topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) AND
    b. One (1) topical calcineurin inhibitors (tacrolimus or pimecrolimus); AND

Authorization Duration:

Initial approval: 12 months
Renewal approval: 12 months

LAST REVISION: 1/1/22

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

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.
4. Corrado EM, Peluso GF, Gigliotti S. The effects of intra-articular administration of hyaluronic acid on osteoarthritis of the knee: A clinical study with immunological and biochemical evaluations. Eur J Rheumatol Inflamm. 1995;15:47-56.
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. Euflexxa. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
7. 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.
8. 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.
9. Huskisson EC, Donnelly S. Hyaluronic acid in the treatment of osteoarthritis of the knee. Rheumatology. 1999;38(7):602-607.
10. Kirwan JR, Rankin E. Intra-articular therapy in osteoarthritis. Baillieres Clin Rheumatol. 1997;11(4):769-794.
11. Lohmander LS, Dalen N, Englund G, H, et al. Intra-articular hyaluronan injections in the treatment of osteoarthritis of the knee: A 100ulticente, double blind, placebo controlled 100ulticenter trial. Hyaluronan Multicentre Trial Group. Ann Rheum Dis. 1996;55(7):424-431.
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.

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.

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
    - 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/.
2. www.Evzio.com. Accessed 12/24/2014.
3. Evzio® [package insert]. Richmond (VA): Kaleo Inc.; April 2014.
4. Naloxone Access: A Practical Guideline for Pharmacists. College of Psychiatric and Neurologic Pharmacists. February 2015. Available at: http://cpnp.org/guideline/naloxone

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 dectected 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 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.
2. Exjade. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
3. Porter JB. Practical management of iron overload. Br J Haematol. 2001;115:239-252.
4. Thalassemia Providers Conference. (n.d.). Clinical Practice Guidelines For the Management of Thalassemia Patients California Consensus. Available from http://www.thalassemia.com/Thal_SOC_guide.pdf
5. 1. Product Information. Exjade® (deferasirox). Novartis Pharmaceuticals Corporation. East Hanover, New Jersey 07936. January 2013.

6. 2. Schrier, S, Bacon, B. Chelation therapy for iron overload states. UptoDate® Accessed 2014 Feb; available from http://uptodate.com
7. 3. Kwiatkowski JL. Management of transfusional iron overload – differential properties and efficacy of iron chelating agents. Journal of Blood Medicine 2011:2 135-149
8. 4. Ferriprox (package insert). Rockville, MD: ApoPharma USA, Inc; October 2011
9. 5. Deferiprone (Ferriprox); for iron overload. The Medical Letter 2012; 54:1384
10. 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.
11. 7. Hoffbrand AV et al. Role of deferiprone in chelation therapy for transfusional iron overload. Blood 2003;102:17-24.

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 Viltepso 53
    - Exon 45 skipping for Amondys 45 **AND**
- Provider has submitted clinical documentation of a baseline evaluation, including a standardize 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 ventalitory 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
    - Viltepso is initiated before the age of 10 **AND**
- 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 and REBIF are the preferred drugs. Member must have tried/failed Betaseron or Copaxone first unless contraindicated.******

EXCLUSIONS

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

1. Concurrent use of interferon beta-1b with interferon beta-1a (Avonex®, 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.
3. Patient is concurrently receiving fingolimod. Use of interferon beta-1b SC with fingolimod has not been studied or established.

References

1. Janeway CA, Travers P, Walport M et al eds. Immunology. 5th ed. New York, NY: Garland Publishing; 2001. From the National Library of Medicine website.
2. Panitch HS. Interferons in multiple sclerosis: a review of the evidence. *Drugs*. 1992; 44: 946-62.
3. Arnason BGW. Interferon beta in multiple sclerosis. *Neurology*. 1993; 43:641-3.
4. Herndon RM. Medical hypothesis: why secondary progressive multiple sclerosis is a relentlessly progressive illness. *Arch Neurol*. 2002; 59:301-4.
5. Compston A, Coles A. Multiple sclerosis. *Lancet*. 2002; 359:1221-31.

6. Goodin DS, Frohman EM, Garmany GP Jr 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.
7. Goodin DS. Interferon-β therapy in multiple sclerosis: evidence for a clinically relevant dose response. *Drugs*. 2001; 61:1693-1703.
8. McDonald WI, Compston A, Edan G et al. Recommended diagnostic criteria for multiple sclerosis: guidelines from the International Panel on the diagnosis of multiple sclerosis. *Ann Neurol*. 2001; 50:121-7.
9. Bayas A, Rieckmann P. Managing the adverse effects of interferon-beta therapy in multiple sclerosis. *Drug Saf*. 2000; 22:149-59.
10. Coyle PK, Hartung HP. Use of interferon beta in multiple sclerosis: rationale for early treatment and evidence for dose- and frequency-dependent effects on clinical response. *Mult Scler*. 2002; 8:2-9.
11. The IFNB Multiple Sclerosis Study Group. Interferon beta-1b is effective in relapsing remitting multiple sclerosis. I. Clinical results of a multicenter, randomized, double-blind, placebo-controlled trial. *Neurology*. 1993; 43:655-61.
12. Paty DW, Li DKB. Interferon beta-1b is effective in relapsing remitting multiple sclerosis. II. MRI analysis of a multicenter, randomized, double-blind, placebo-controlled trial. *Neurology*. 1993; 43: 627-7.
13. Durelli L, Verdun E, Barbero P et al. Every-other-day interferon beta-1b versus once-weekly interferon beta-1a for multiple sclerosis: results of a 2-year prospective 105ulticente 105ulticenter study (INCOMIN). *Lancet*. 2002; 359:1453-60.
14. Neilley LK, Goodin DS, Goodkin DE et al. Side effect profile of interferon beta-1b in MS: results of an open label trial. *Neurology*. 1996; 46:552-4.
15. Lublin FD, Whitaker JN, Eidelman BH et al. Management of patients receiving interferon beta-1b for multiple sclerosis: report of a consensus conference. *Neurology*. 1996; 46:12-8.
16. European Study Group on interferon beta-1b in secondary progressive MS. Placebo-controlled 105ulticenter 105ulticente trial of interferon beta-1b in treatment of secondary progressive multiple sclerosis. *Lancet*. 1998; 352:1491-7.
17. Molyneux PD, Barker GJ, Barkhof F et al. Clinical-MRI correlations in a European trial of interferon beta-1b in secondary progressive MS. *Neurology*. 2001; 57:2191-7.
18. Bramanti P, Sessa E, Rifici C et al. Enhanced spasticity in primary progressive MS patients treated with interferon beta-1b. *Neurology*. 1998; 51:1720-3.
19. Khan OA, Dhib-Jalbut SS. Neutralizing antibodies to interferon beta-1a and interferon beta-1b in MS patients are cross-reactive. *Neurology*. 1998; 51:1698-1702.
20. The IFNB Multiple Sclerosis Study Group and the University of British Columbia MS/MRI Analysis Group. Neutralizing antibodies during treatment of multiple sclerosis with interferon beta-1b: experience during the first three years. *Neurology*. 1996; 47:889-94.
21. Deisenhammer F, Reindl M, Harvey J et al. Bioavailability of interferon beta-1b in MS with and without neutralizing antibodies. *Neurology*. 1999; 52:1239-43.
22. Product Information: EXTAVIAI subcutaneous injection, interferon beta-1b subcutaneous injection. Novartis Pharmaceuticals Corporation, East Hanover, NJ, 2009.
23. Anon: Placebo-controlled 105ulticenter 105ulticente trial of interferon beta-1b in treatment of secondary progressive multiple sclerosis. Lancet 1998; 352(9139):1491-1497.
24. Sibley WA: Clinical efficacy of interferon beta-1b in multiple sclerosis: the US/Canadian Multicentre Trial evidence. Clin Immunother 1996; 5(suppl 1):41-46.
25. Paty DW & Li DKB: Interferon beta-1b is effective in relapsing-remitting multiple sclerosis. II. MRI analysis results of a multicenter, randomized, double-blind, placebo-controlled trial. Neurology 1993; 43:662-667.
26. Miller DH, Molyneux PD, Barker GJ, et al: Effect of interon-beta1b on magnetic resonance imaging outcomes in secondary progressive multiple sclerosis: results of a European multicenter, randomized, double-blind, placebo-controlled trial. Ann Neurol 1999; 46(6):850-859.
27. Weber F, Polak T, Gunther A, et al: Synergistic immunomodulatory effects of interferon-beta 1b and the phosphodiesterase inhibitor pentoxifylline in patients with relapsing-remitting multiple sclerosis. Ann Neurol 1998; 44(1):27-34.
28. Kappos L, Polman CH, Freedman MS, et al: Treatment with interferon beta-1b delays conversion to clinically definite and McDonald MS in patients with clinically isolated syndromes. Neurology 2006; 67(7):1242-1249.
29. Kappos L, Freedman MS, Polman CH, et al: Long-term effect of early treatment with interferon beta-1b after a first clinical event suggestive of multiple sclerosis: 5-year active treatment extension of the phase 3 BENEFIT trial. Lancet Neurol 2009; 8(11):987-997.
30. McDonald ND & Pender MP: Autoimmune hypothyroidism associated with interferon beta-1b treatment in two patients with multiple sclerosis. Aust N Z J Med 2000; 30:278-279.
31. Anon: Study Group: Interferon beta-1b is effective in relapsing-remitting multiple sclerosis. I. Clinical results of a multicenter, randomized, double-blind, placebo-controlled trial. Neurology 1993; 43:655-661.

32. Lublin FD, Whitaker JN, Eidelman BH, et al: Management of patients receiving interferon beta-1b for multiple sclerosis: report of a consensus conference. Neurology 1996; 46:12-18.
33. Bramanti P, Sessa E, Rifici C, et al: Enhanced spasticity in primary progressive MS patients treated with interferon beta-1b. Neurology 1998; 51:1720-1723.
34. Khan OA, Xia Q, Bever CT, et al: Interferon beta-1b serum levels in multiple sclerosis patients following subcutaneous administration. Neurology 1996; 46:1639-1643.
35. Anon: Study Group: Interferon beta-1b is effective in relapsing-remitting multiple sclerosis. I. Clinical results of a multicenter, randomized, double-blind, placebo-controlled trial. Neurology 1993; 43:655-661.
36. Durelli L, Verdun E, Barbero P, et al: Every-other-day interferon beta-1b versus once-weekly interferon beta-1a for multiple sclerosis: results of a 2-year prospective 106ulticente 106ulticenter study (INCOMIN). Lancet 2002; 359:1453-1460.
37. Barbero P, Bergui M, Versino E, et al: Every-other-day interferon beta-1b versus once-weekly interferon beta-1a for multiple sclerosis (INCOMIN Trial) II: analysis of MRI responses to treatment and correlation with Nab. Mult Scler 2006; 12(1):72-76.

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

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)

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

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
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.

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
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.
7. Hoffbrand AV et al. Role of deferiprone in chelation therapy for transfusional iron overload. Blood 2003;102:17-24.

LAST REVISION: 11/1/21

FIRDAPSE (AMIFAMPRIDINE)

CRITERIA FOR USE

- The indicated diagnosis must be Lambert-Eaton myathenic gravis (LEMS) in adults
  AND
- Patient must be 18 years of age or greater
  AND
- Prescribed by or in conjunction with a neurologist or rheumatologist
  AND
- Prescriber attests patient does not have a history of seizures
  AND
- Prescriber attests that small cell lung cancer (SCLC) diagnosis has been ruled out OR if patient has a diagnosis of SCLC, patient is being treated for SCLC unless intolerant or contraindications exist
  AND

- Patient has moderate to severe muscle weakness (i.e. proximal weakness affecting legs, eyes, face, or throat) that interferes with daily function
  AND
- Prescriber has a baseline evaluation of muscle strength in patient

Criteria for Renewal

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

Not approved if:

- 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.

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.
5. Rubin LJ. Primary pulmonary hypertension. N Engl J Med. 1997;336:111-117
6. Barst RJ, Rubin LJ, Long WA, et al. A comparison of continuous intravenous Epoprostenol with conventional therapy for primary pulmonary hyperetension N Engl J Med 1996;334:296-301.
7. McLaughlin V V G, Barst R J, Oudiz R, et al. Efficacy and safety of treprostinil: an Epoprostenol analog for primary pulmonary hypertension. Journal of Cardiovascular Pharmacology (2003), 41: pp. 293-299.

FORTEO (TERIPARATIDE)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Criteria for approval are ALL of the following:

1. ONE of the following:
    a. Patient has a diagnosis of osteoporosis defined as a T-score that is –2.5 or lower (2.5 or more standard deviations below the mean bone mineral density (BMD) value for a young adult) AND ONE of the following:
        i. Patient has a very low BMD defined as a T-score that is –3.5 or lower **OR**
        ii. Patient has a history of prevalent vertebral fracture(s) or low trauma or fragility fracture(s) [e.g., prior fracture from minor trauma such as falling from standing height or less] **OR**
        iii. Patient's medication history includes a first-line agent (bisphosphonate or SERM for women, bisphosphonate for men) **OR**
        iv. Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to SERM and bisphosphonate (bisphosphonate only if male) **OR**

    b. Patient has a history of prevalent vertebral fracture(s) or low trauma or fragility fracture(s) (without a diagnosis of osteoporosis) AND ONE of the following:
        i. Patient's medication history includes a first-line agent (bisphosphonate or SERM for women, bisphosphonate for men) **OR**
        ii. Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to SERM and bisphosphonate (bisphosphonate only if male) **AND**
2. Patient is not receiving concomitant bisphosphonate, SERM, or Prolia (denosumab) therapy **AND**
3. Total duration of treatment with Forteo has not exceeded 2 years

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

EXCLUSIONS

Coverage of Forteo is not recommended in the following circumstances:

- Prevention of osteoporosis (women and men).

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

References

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 113ulticenter 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

FYCOMPA™ (PERAMPANEL)

- Patient must be ≥12 years old for tonic-clonic seizures, or 4 years of age or older for partial-onset seizures
- Being used in one of the following:
    - Treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy OR
    - Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients with epilepsy
- Patient must have a history of trial and failure of:
- At least 2 concomitant Antiepileptic Drugs OR
- At least 3 different Antiepileptic Drugs OR
- History Vagal Nerve Stimulator (VNS) implantation or lobectomy.
- Serious or life-threatening psychiatric and behavioral adverse reactions including aggression, hostility, irritability, anger, and homicidal ideation and threats have been reported in patients taking FYCOMPA (5.1)
    - Monitor patients for these reactions as well as for changes in mood, behavior, or personality that are not typical for the patient, particularly during the titration period and at higher doses
- Maximum recommended daily dose is 12 mg once daily.

References

1. Virginia Premier.

FYLNETRA (PEGFILGRASTIM-PBBK)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Cancer patients receiving myelosuppressive chemotherapy.

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

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

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: 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.
3. Hollinad 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.
4. Gabrilove JL. Colony-stimulating factors: clinical status. In: DeVita VT, Hellman S, Rosenberg SA, eds. Biologic therapy of cancer. JB Lippincott; 1991:445-63.
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.
6. Welte K, Bonilla MA, Gabrilove JL et al. Recombinant human granulocyte-colony stimulating factor: in vitro and in vivo effects on myelopoiesis. *Blood Cells*. 1987; 13:17-30.
7. Anon. Pegfilgrastim (Neulasta) for prevention of febrile neutropenia. Med Lett Drugs Ther 2002; 44:44-5.
8. Curran MP, Goa KL. Pegfilgrastim. *Drugs*. 2002; 62:1207-13.

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

9. Holmes FA, O'Shaughnessy JA, Vukelja S et al. Blinded, randomized, multicenter study to evaluate single administration pegfilgrastim once per cycle versus daily filgrastim as an adjunct to chemotherapy in patients with high-risk stage II or stage III/IV breast cancer. *J Clin Oncol*. 2002; 20:727-31.
10. Micromedex Web Site. Available at: http://www.thomsonhc.com. Accessed Nov. 2012.
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

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

- 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

References

1. Berger M. Subcutaneous immunoglobulin replacement in primary immunodeficiency. Clin Immunol. 2004;112:1-7.
2. Bonilla FA, et al. "Practice parameter for the diagnosis and management of primary immunodeficiency." Ann Allergy Asthma Imunol. 2005;94:S1-63.
3. Chu Y-Waye et al. "Idiopathic thrombocytopenia purpura." Pediatrics Review 2000; 21(3):94-105.
4. Cook S et al. "Intravenous gamma globulin in progressive MS." Acta Neurol Scand 1992;86:171-175.
5. Crenier L. "Low response to high-dose intravenous immunoglobulin in the treatment of acquired factor VIII inhibitor." Br J Haematol 1996;95(4):750-3.
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.
7. Dalakais MC. "Intravenous immune globulin therapy for neurologic diseases." Ann Intern Med 1997;126(9):721-30.
8. Dalakas MC et al. "High-dose intravenous immune globulin for stiff-person syndrome." N Engl J Med 2001;345(26):1870-6.
9. Fasano MB. "Risks and benefits of intravenous immunoglobulin treatment in children." Curr Opin Pediatr 1995;7:688-94.
10. Francis G et al. "Failure of intravenous immunoglobulin to arrest progression of multiple sclerosis: a clinical MRI based study." Multiple Sclerosis 1997;3:370-6.
11. Gajdos P, et al. Intravenous immunoglobulin for myasthenia gravis. Cochrane Database of Systematic Reviews 2006, Issue 2. Art. No.: CD002277.
12. Gamunex. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
13. Gamunex – C. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
14. 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; 58:169-78.
15. Hughes RAC, et al. Practice parameter: immunotherapy for Guillain-Barre syndrome. Neurology 2003:61-736-40.
16. Immune Globulin. 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

17. Jordan SC, et al. Evaluation of intravenous immunoglobulin as an agent to lower allosensitization and improve transplantation in highly sensitized adults patients with end-stage renal disease: report of the NIH IG02 trial. J Am Soc Nephrol 2004 15:3256-62.
18. Kiehl MG et al. "A controlled trial of intravenous immune globulin for the prevention of serious infections in adults with advanced human immunodeficiency virus infection." Arch Intern Med 1996;156:2545-50.
19. Lafferty TE et al. "Treatment of acquired factor VIII inhibitor using intravenous immunoglobulin in two patients with systemic lupus erythematosus." Arthritis 1997; 40(4):775-8.
20. Laosombat V. "Intravenous gamma globulin for treatment of chronic idiopathic thrombocytopenic purpura in children." J Med Assoc Thai 2000;83(2):160-8.
21. Medeiros, Desiree et al. "Current controversies in the management of idiopathic thrombocytopenic purpura during childhood." Pediatric Clin N Amer 1996;43(3):757-73.
22. Orange J, Hossny E, Weiler C et al. Use of intravenous immunoglobulin in human disease: A review of evidence by members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology. J Allergy Clin Immunol 2006;117:S525-S53.
23. Pehlau D et al. "Intravenous immunoglobulin (IVIG) treatment for patients with primary or secondary progressive multiple sclerosis – outline of a double-blind randomized, placebo-controlled trial." Multiple Sclerosis 1997;149-52.
24. Petz LP. "Treatment of autoimmune hemolytic anemias". Curr Opin Hematol 2001;8:411-16.
25. Report of the WHO Scientific Group. "Primary immunodeficiency diseases". Clin Exper Immunol 1997;109(suppl 1):1-28.
26. Sansome A, Dubowitz V. "Intravenous immunoglobulin in juvenile dermatomyositis: four year review of nine cases." Arch Dis Child 1995;72:25-8.
27. Schwarz RS, et al. A prospective study of treatment of acquired (autoimmune) factor VIII inhibitors with high-dose intravenous gammaglobulin. Blood 1995;86(2):797-804.
28. Scott-Timperley LJ et al. "Life-threatening complications of autoimmune disease: Autoimmune coagulation disorders." Rheum Dis Clin N Amer 1997;23(2):411-23.
29. Shah S. Pharmacy considerations for the use of IGIV therapy. Am J Health-Syst Pharmacy 2005;62:S5-S11.
30. Sultan Y. "Acquired hemophilia and its treatment." Blood Coagul Fibrinolysis 1997;8 (suppl 1):S15-8.
31. Zulay JP et al. "Long term follow up of multifocal motor neuropathy with conduction block under treatment." J Neurol 1997;62(4):391-4.

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

Requests for continuing 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 criteria:

- 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, 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-antifunglas, cobicistat, HIV protease inhibitors, imatinib, boceprevir,

etc); if therapy is unavoidable, the member will be monitored for adverse reaction and/or dose modification

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
- 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

References

1. Acute Lymphocytic 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. 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.
3. 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.
4. Dermatofibrosarcoma Protuberans. 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. Gleevec. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
6. Imatinib. 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
7. Melanoma. 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. 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.

GOCOVRI (AMANTADINE)

- Patient is experiencing dyskinesia or "off" episodes associated with a Diagnosis of Parkinson's Disease
- Patient is 18 years of age or older
- Patient is currently on concomitant levodopa-based therapy
- Patient has had an adequate trial of, or is intolerant to, amantadine immediate-release

Requests for continuing 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 end-stage renal disease (creatinine clearance <15 mL/min/1.73m2)
- Patient will NOT receive live vaccines during treatment (inactivated vaccines may be utilized)

Authorization Dates:

Renewal – 12 months

INFORMATIONAL:
Quantity Limit:
68.5 mg = 34 capsules/34 days
137 mg = 68 capsules/34 days

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

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

Testicular Cancer				X	X	X	
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, laproscopy, 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.

Requests for continuing 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 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.

Continuation of Therapy:

- Member is still symptomatic with pain after the intial 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**
    - 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
    - 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:

Requests for continuing 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 vascular cancer.

LAST REVISION: 2/1/22

References

1. American College of Obstetricians and Gynecologists (ACOG). Management of endometriosis. Available from http://www.guideline.gov/summary/summary.aspx?doc_id=3961&nbr=3099&string=endometriosis.
2. Augustovski F, Colantonio L, Pichon Riviere A. Androgen deprivation treatment (hormonal therapy) for the management of prostate cancer [summary]. Report ITB No. 30. Buenos Aires, Argentina: Institute for Clinical Effectiveness and Health Policy (IECS); 2006.
3. Badawy A, Elnashar A, El-Ashry M, Shahat M. Gonadotropin-releasing hormone agonists for prevention of chemotherapy-induced ovarian damage: Prospective randomized study. Fertil Steril. 2009;91(3):694-697.
4. Clowse ME, Behera MA, Anders CK, et al. Ovarian preservation by GnRH agonists during chemotherapy: A meta-analysis. J Womens Health (Larchmt). 2009;18(3):311-319.
5. Eligard. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
6. Friedman AJ, Harrison-Atlas D, Barbieri RL, et al. A randomized, placebo-controlled, double-blind study evaluating the efficacy of leuprolide acetate depot in the treatment of uterine leiomyomata. Fertil Steril 1989;51:251-256.
7. Furr BA, Woodburn JR. Luteinizing hormone-releasing hormone and its analogues: A review of biological properties and clinical uses. J Endocrinol Invest. 1988;11:535-537.
8. Goldhirsch A, Wood WC, Senn HJ, et al. Meeting highlights: International consensus panel on the treatment of primary breast cancer (commentary). J Natl Cancer Inst. 1995;87(19):1441-1445.
9. Goserelin Acetate. 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. Hornstein MD, Surrey ES, Weisberg GW, et al. Leuprolide acetate depot and hormonal addback in endometriosis: a 12-month study. Lupron Add-Back Study Group. Obstet Gynecol1998;91:16-24.
11. Kletter, G. B. (2008). How should we diagnosis and monitor central precocious puberty? Journal of Pediatric Endocrinology & Metabolism, 21 (12), 1105-1106.
12. Korman LB. Treatment of prostate cancer. Clin Pharm. 1989;8:412-424.
13. Leuprolide Acetate. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
14. Leupron. 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.
15. Leuprolide Acetate. 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.
16. Lu PY, Ory SJ. Endometriosis: Current management. Mayo Clin Proc. 1995;70:453-463.
17. Oerter KE, Manasco PK, Barnes KM, Jones J, Hill S, Culter GB. Effects of luteinizing hormone-releasing hormone agonists on final height in luteinizing hormone-releasing hormone-dependent precocious puberty. Act Paed. 1993: Suppl 388:62-68.
18. Ohyama K, Tanaka T, Tachibana K, et al. Timing for discontinuation of treatment with along-acting gonadotropin-releasing hormone analog in girls with central precocious puberty. TAP-144SR CPP Study Group. Endocr J 1998;45:351-356.
19. 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.
20. Partsch CJ, Sippell WG. Treatment of central precocious puberty. Best Pract Res Clin Endocrinol Metobol 2002;16:165-189.
21. Prostate 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. Vercellini P, Fedele L, Maggi R, et al. Gonadotropin releasing hormone agonist for chronic anovulatory uterine bleeding and severe anemia. J Reprod Med. 1993;38(2):127-129.

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

23. Zoladex. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
24. Virginia Premier Health Plan

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:

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.

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
Drug	Children	Adults						

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

Accretropin	X					X		
Genotropin	X	X		X	X			
Humatrope	X	X				X		
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

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 Deficieny

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

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

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 132ulticenter132y 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 (OmnitropeI, SaizenI, Tev-TropinI, ZorbtiveI)
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, ZorbtiveI)
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

References

1. Genotropin prescribing information. Pharmacia & Upjohn Company. May 2008.
2. Humatrope prescribing information. Eli Lilly and Company. March 2009.
3. Norditropin prescribing information. Novo Nordisk Pharmaceuticals, Inc. September 2008.
4. Nutropin prescribing information. Genentech, Inc. June 2006.
5. Nutropin AQ prescribing information. Genentech, Inc. January 2008.
6. Omnitrope prescribing information. Sandoz Inc. March 2009.
7. Saizen prescribing information. Serono, Inc. October 2007.
8. Serostim prescribing information. Serono, Inc. September 2007.
9. Skytrofa (lonapegsomatropin) [prescribing information]. Palo Alto, CA: Ascendis Pharma Inc; August 2021.
10. Tev-Tropin prescribing information. Gate Pharmaceuticals. October 2007.
11. Zorbtive prescribing information. Serono, Inc. January 2004.
12. AACE Guidelines. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children2003 Update. *Endocrine Practice* 2003;9 (1):65-76.
13. Wilson TA, Rose SR, Cohen P, et al. Update of guidelines for the use of growth hormone in children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. *J of Pediatr* 2003;143:415-421.
14. Cohen P, Rogol AD, Deal CL, et al. on behalf of the 2007 ISS Consensus Workshop participants. Consensus statement on the diagnosis and treatment of children with Idiopathic Short Stature: A summary of the Growth Hormone Researche Society, The Lawson Wilkins Pediatric Endocrine Society and the European Society for Pediatric Endocrinology Workshop. *J Clin Endocrin Metab*. 2008.
15. Attanasio AF, Howel S, Bates PC, et al. Body composition, IGF-I and IGFBP-3 concentrations as outcome measures in severely GH-deficient (GHD) patients after childhood GH treatment: A comparison with adult onset GHD patients. *J Clin Endocrinol Metab* 2002;87(7):3368-3372.
16. Bryant J, Cave C, Mihaylova B, Chase D, McIntyre L, Gerard K, et al. Clinical effectiveness and cost-effectiveness of growth hormone in children: a systematic review and economic evaluation. *Health Technol Assess* 2002;6(18).
17. Wood A, Vance M, Mauras N. Growth hormone therapy in adults and children. *N Engl J Med*.1999;341(16):1206-1215.
18. Evaluation and treatment of adult growth hormone deficiency: An endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2011 Jun;96(6):1587-609.
19. American association of clinical endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children – 2003 update. Endocrine practice; Vol 9 (1), Jan/Feb 2003.

LAST REVISION: 1/1/22

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

- Medication must be prescribed by or in conslation with a gastroenterologist, hepatologist, transplant specialist, or infectious disease specialist
- Member must have a diagnosis of Acute or Chronic Hepatitis C with or without, Compenstaed cirrhosis, Hepatocellular Carcinoma, Decompenstated cirrhosis (child-pugh class b or c,) or status post-liver transplant AND
- Genotype and polymorphism (if available), must be documented
- Must be utilized for an FDA approved treatment regimen
- If member has decompensated chirrosis (child pugh score greater than 6) or history of severe renal impairment (eGFR<30mL/min/1.73m^2) or ESRD requiring hemodialysis then details must be provided

Requests for continuing 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
- 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: 8/1/21

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).
    - CinryzeTM: 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

- 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

References

1. Berger M. Subcutaneous immunoglobulin replacement in primary immunodeficiency. Clin Immunol. 2004;112:1-7.
2. Bonilla FA, et al. "Practice parameter for the diagnosis and management of primary immunodeficiency." Ann Allergy Asthma Imunol. 2005;94:S1-63.
3. Chu Y-Waye et al. "Idiopathic thrombocytopenia purpura." Pediatrics Review 2000; 21(3):94-105.
4. Cook S et al. "Intravenous gamma globulin in progressive MS." Acta Neurol Scand 1992;86:171-175.
5. Crenier L. "Low response to high-dose intravenous immunoglobulin in the treatment of acquired factor VIII inhibitor." Br J Haematol 1996;95(4):750-3.
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.
7. Dalakais MC. "Intravenous immune globulin therapy for neurologic diseases." Ann Intern Med 1997;126(9):721-30.
8. Dalakas MC et al. "High-dose intravenous immune globulin for stiff-person syndrome." N Engl J Med 2001;345(26):1870-6.
9. Fasano MB. "Risks and benefits of intravenous immunoglobulin treatment in children." Curr Opin Pediatr 1995;7:688-94.

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

10. Francis G et al. “Failure of intravenous immunoglobulin to arrest progression of multiple sclerosis: a clinical MRI based study.” Multiple Sclerosis 1997;3:370-6.
11. Gajdos P, et al. Intravenous immunoglobulin for myasthenia gravis. Cochrane Database of Systematic Reviews 2006, Issue 2. Art. No.: CD002277.
12. 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; 58:169-78.
13. Hizentra. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
14. Hughes RAC, et al. Practice parameter: immunotherapy for Guillain-Barre syndrome. Neurology 2003:61-736-40.
15. Immune Globulin. 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.
16. Jordan SC, et al. Evaluation of intravenous immunoglobulin as an agent to lower allosensitization and improve transplantation in highly sensitized adults patients with end-stage renal disease: report of the NIH IG02 trial. J Am Soc Nephrol 2004 15:3256-62.
17. Kiehl MG et al. “A controlled trial of intravenous immune globulin for the prevention of serious infections in adults with advanced human immunodeficiency virus infection.” Arch Intern Med 1996;156:2545-50.
18. Lafferty TE et al. “Treatment of acquired factor VIII inhibitor using intravenous immunoglobulin in two patients with systemic lupus erythematosus.” Arthritis 1997; 40(4):775-8.
19. Laosombat V. “Intravenous gamma globulin for treatment of chronic idiopathic thrombocytopenic purpura in children.” J Med Assoc Thai 2000;83(2):160-8.
20. Medeiros, Desiree et al. “Current controversies in the management of idiopathic thrombocytopenic purpura during childhood.” Pediatric Clin N Amer 1996;43(3):757-73.
21. Orange J, Hossny E, Weiler C et al. Use of intravenous immunoglobulin in human disease: A review of evidence by members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology. J Allergy Clin Immunol 2006;117:S525-S53.
22. Pehlau D et al. “Intravenous immunoglobulin (IVIG) treatment for patients with primary or secondary progressive multiple sclerosis – outline of a double-blind randomized, placebo-controlled trial.” Multiple Sclerosis 1997;149-52.
23. Petz LP. “Treatment of autoimmune hemolytic anemias”. Curr Opin Hematol 2001;8:411-16.
24. Report of the WHO Scientific Group. “Primary immunodeficiency diseases”. Clin Exper Immunol 1997;109(suppl 1):1-28.
25. Sansome A, Dubowitz V. “Intravenous immunoglobulin in juvenile dermatomyositis: four year review of nine cases.” Arch Dis Child 1995;72:25-8.
26. Schwarz RS, et al. A prospective study of treatment of acquired (autoimmune) factor VIII inhibitors with high-dose intravenous gammaglobulin. Blood 1995;86(2):797-804.
27. Scott-Timperley LJ et al. “Life-threatening complications of autoimmune disease: Autoimmune coagulation disorders.” Rheum Dis Clin N Amer 1997;23(2):411-23.
28. Shah S. Pharmacy considerations for the use of IGIV therapy. Am J Health-Syst Pharmacy 2005;62:S5-S11.
29. Sultan Y. “Acquired hemophilia and its treatment.” Blood Coagul Fibrinolysis 1997;8 (suppl 1):S15-8.
30. Zulay JP et al. “Long term follow up of multifocal motor neuropathy with conduction block under treatment.” J Neurol 1997;62(4):391-4.

HORIZANT (GABAPENTIN EXTENDED RELEASE)

*****Partially approve the EOC and submit to the PA Hub Client Sign-off queue. Send an e-mail to COPTeam@elixirsolutions.com and the “CC” the CDPharmacist e-mail distribution box, noting the EOC # and requested indication for use.**
Generic name: gabapentin extended release **Brand name:** Horizant

Requests for continuing 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 class: anticonvulsant

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

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

Duration of therapy: indefinite

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

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

Contraindication:

- None reported at this time.

Not approved if:

- Does not meet the above stated criteria.

Special considerations:

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

References

1. Virginia Premier.

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

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.

Requests for continuing 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. 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.
4. Corrado EM, Peluso GF, Gigliotti S. The effects of intra-articular administration of hyaluronic acid on osteoarthritis of the knee: A clinical study with immunological and biochemical evaluations. Eur J Rheumatol Inflamm. 1995;15:47-56.
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. Hyalgan. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
10. Kirwan JR, Rankin E. Intra-articular therapy in osteoarthritis. Baillieres Clin Rheumatol. 1997;11(4):769-794.
11. Lohmander LS, Dalen N, Englund G, H, et al. Intra-articular hyaluronan injections in the treatment of osteoarthritis of the knee: A 140ulticente, double blind, placebo controlled 140ulticenter trial. Hyaluronan Multicentre Trial Group. Ann Rheum Dis. 1996;55(7):424-431.
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.

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

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

ILARIS (CANAKINUMAB)

- Prescribed by a Rheumatologist or Immunologist, AND
- Diagnosed with one of the following:
- Cryopyrin-Associated Periodic Syndromes (CAPS) disorder in adult or child 4 years of age and older, including:
    - Familial Cold Autoinflammatory Syndrome, OR
    - Muckle-Wells Syndrome; OR
- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS); OR
- Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD); OR
- Familial Mediterranean Fever (FMF); OR
- 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

References

1. Canakinumab. 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. Ilaris. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
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.

ILUMYA (TILDRAKIZUMAB-ASMN)

Requests for continuing 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 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
    - 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.

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.

Appendix 1

ECOG Performance status:

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

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

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

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

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

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

Grade 5 : Dead

IMCIVREE (SETMELANOTIDE)

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

- Treatment of obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency :
    - Prescriber attest that patient has confirmed obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) gene variants interpreted as pathogenic, likely pathogenic, or of uncertain significance confirmed by genetic testing AND
    - Member is 6 years of age or older AND
    - Prescriber attest patient's obesity is ≥30 kg/m2 (adults) or ≥95th percentile (pediatric patients) AND
    - Prescriber attest alternative weight management options have failed to provide at least a 10% weight reduction; such as diet, exercise, bariatric surgery AND
    - Prescriber provides baseline body weight and BMI AND
    - Prescribed by or in conjunction with a provider specializing in metabolic disorders and genetic obesity

RENEWAL:

- Prescriber attest to a reduction in 5% baseline body weight or 5% of baseline BMI and provides body weight and BMI for initial renewal OR
- Prescriber attest to sustained weight loss or BMI reduction from baseline while taking IMCIVREE.

Authorization Dates:
Initial – 4 months
Renewal – 12 months

INCRELEX (MECASERMIN)

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

Reauthorization.continuing therapy:

- Increase in height velocity > 2.5cm total growth in 1 yr, AND
- No evidence of epiphyseal closure, AND
- Patient has not met their expected final adult height or targeted height based on min-parental height calculation or their current absolute height is <= the 25th percentile (defined as 68 inches in males and 63 inches in females).

References

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 therapoy 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
  - Increase in hemoglobin; OR
  - Decrease in transfusions (if transfusion dependent); 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 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 x 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 x 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
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, dislking 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, dislking the taste of Exjade, etc. are not considered failure).***
2. Patient must be >10 years of age on the date of request for Jadenu.
3. Documentation of iron overload related to anemia found in patient's medical conditions, progress notes, and/or discharge notes.

4. Serum ferritin and liver iron concentration (LIC) must have been measured within 30 days of initiation (copy lab results must be submitted).
5. Serum ferritin levels must be >300mcg/L.
6. Liver iron concentration (LIC) must be >5 mg Fe/g dried weight (dw)
7. Starting dose is 7mg/kg/day. Calculate dose to the nearest whole tablet (90 mg, 180 mg, or 360 mg)

Non-Transfusional Iron Overload continuation of therapy:

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

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/1.73m^2; 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
- 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. constellatus), and Enterococcus faecalis (vancomycin-susceptible isolates only), **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 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. Rilonocept 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.

Deficiency of Interlukin-1 Receptor Antagonist
Approve 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

Other Uses with Supportive Evidence

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

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

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

In a small open-label trial (n = 9), patients with active systemic onset JIA who were unresponsive to conventional treatment (corticosteroids and MTX) responded (clinical and 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), in one time series trial and several case studies. Symptoms of fever, rash, headache, arthralgia, vomiting, hepatomegaly, and lymphadenopathy; neurologic complications (eg,

papilledema, sensorineural hearing loss, cochlear enhancement); and laboratory parameters (eg, serum levels of amyloid A, C-reactive protein, erythrocyte sedimentation rate) showed rapid and marked improvement following initiation of anakinra. A mutation in the cold-induced auto-inflammatory syndrome 1 gene, which may regulate inflammation caused by interleukin-1-beta and nuclear factor-kappa B, is seen in approximately 60% of patients with a clinical diagnosis, but did not appear to predict anakinra response to treatment. Adverse events reported include injection site reactions, upper respiratory infection, urinary tract infection, and nonbacterial diarrhea leading to hospitalization.

Ankylosing spondylitis.

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

Etanercept, infliximab, golimumab, and adalimumab are FDA-approved for ankylosing spondylitis. According to the Assessment in Ankylosing Spondylitis (ASAS) working group and the European League Against Rheumatism (EULAR) recommendations for ankylosing spondylitis, all patients should have an adequate trial of at least 2 NSAIDs for pain and stiffness. Recommendations for other therapies before receiving etanercept, infliximab, golimumab, or adalimumab vary according to the manifestations of the disease, level of current symptoms, clinical findings, etc. According to these recommendations, patients with only axial manifestations do not have to try traditional DMARDs before using anti-TNF therapy; patients with symptomatic peripheral arthritis should have an insufficient response to at least one local corticosteroid injection, if appropriate; patients with persistent peripheral arthritis must have a trial of sulfasalazine; and patients with enthesitis should try appropriate local therapy (corticosteroid injection in selected cases). Anti-TNF agents (adalimumab, etanercept, golimumab, infliximab) should be used in patients with persistently high disease activity despite conventional therapy.

Anakinra has been beneficial in a few patients with ankylosing spondylitis, but results are not consistent. In a small (n = 20) open-label study, patients with active ankylosing spondylitis who were refractory to NSAIDs received anakinra 100 mg daily. The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score decreased over a 6-month period but was not significant (5.8 at baseline vs. 5.0 at week 12 [$P > 0.05$], and 4.8 at week 24 [$P > 0.05$]). No significant change was found in Bath Ankylosing Spondylitis Functional Index (BASFI), patients' and physicians' global assessment or general pain during the study. After 12 weeks, both the ASAS 20 and 40 responses improved in 10.5% of patients (intent-to-treat analysis). After 24 weeks, ASAS 20 was attained in 26% of patients, ASAS 40 in 21%, and ASAS 70 in 10.5% of patients.

Adult with Still's Disease.

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

Muckle-Wells Syndrome (MWS).

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

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

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

Schnitzler's syndrome.
Approve for 12 months if patient has tried one other prescription medication for Schnitzler's syndrome. In several individual case reports, anakinra has been effective in producing complete remission of Schnitzler's syndrome.[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.

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 Mediterannean 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 155ulticenter155y (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 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

1. 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 (Arthritis Care & Research). Vol. 59, No. 6. June 15, 2008, pp. 762-784.
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*
3. Calabrese LH. Anakinra treatment of patients with rheumatoid arthritis. *Ann Pharmacother*. 2002; 36:1204-9.
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:

- 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 (creatine 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

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

KUVAN (SAPROPTERIN DIHYDROCHLORIDE)

• Hyperphenylalaninemia due to 159ulticenter159y159terin- (BH4-) responsive phenylketonuria, AND
• Tried/failed/intolerance to a phenylalanine restricted diet alone, AND
• Phe levels > 6 mg/dL for ≤ 12 years of age, OR
• Phe levels >15 mg/dL on average for >12 years of age.

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

References

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

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

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:
        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.

Requests for continuing 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. 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/mm^3.***

NOTE: Approve if undergoing cyclic chemotherapy and ANC not < 1000 cells/mm^3.

References

1. Bayer HealthCare. Leukine® (sargramostim) prescribing information. Seattle, WA; November 2012.
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.
14. Kaplan LD, Kahn JO, Crowe S et al. Clinical and virologic effects of recombinant human granulocyte-macrophage colony-stimulating factor in patients receiving chemotherapy for human immunodeficiency virus-associated non-Hodgkin's lymphoma: results of a randomized trial. *J Clin Oncol*. 1991; 9:929-40.
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.
18. Antmann KS, Griffin JD, Elias A et al. Effect of recombinant human granulocyte-macrophage colony-stimulating factor on chemotherapy-induced myelosuppression. *N Engl J Med*. 1988; 319:593-8.
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.
20. Mitsuyasu RT. Use of recombinant interferons and hematopoietic growth factors in patients infected with human immunodeficiency virus. *Rev Infect Dis*. 1991; 13:979-84.
21. Levine JD, Allan JD, Tessitore JH et al. Recombinant human granulocyte-macrophage colony-stimulating factor ameliorates zidovudine-induced neutropenia in patients with acquired immunodeficiency syndrome (AIDS)/AIDS-related complex. *Blood*. 1991; 78:3148-54.
22. Cheson BD. The myelodysplastic syndromes: current approaches to therapy. *Ann Intern Med*. 1990; 112:932-41.

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

23. Herrmann F, Lindemann A, Klein H et al. Effect of recombinant human granulocyte-macrophage colony-stimulating factor in patients with myelodysplastic syndrome with excess blasts. *Leukemia*. 1989; 3:335-8.
24. Thompson JA, Lee DJ, Kidd P et al. Subcutaneous granulocyte-macrophage colony-stimulating factor in patients with myelodysplastic syndrome: toxicity, pharmacokinetics, and hematological effects. *J Clin Oncol*. 1989; 7:629-37.
25. Vadhan-Raj S, Keating M, Le Maistre A et al. Effects of recombinant human granulocyte-macrophage colony-stimulating factor in patients with myelodysplastic syndromes. *N Engl J Med*. 1987; 317:1545-52.
26. Cannistra SA, DiCarlo J, Groshek P et al. Simultaneous administration of granulocyte-macrophage colony-stimulating factor and cytosine arabinoside for the treatment of relapsed acute myeloid leukemia. *Leukemia*. 1991; 5:230-8.
27. Champlin RE, Nimer SD, Ireland P et al. Treatment of refractory aplastic anemia with recombinant human granulocyte-macrophage-colony-stimulating factor. *Blood*. 1989; 73:694-9.
28. Ganser A, Ottmann OG, Erdmann H et al. The effect of recombinant human granulocyte-macrophage colony-stimulating factor on neutropenia and related morbidity in chronic severe neutropenia. *Ann Intern Med*. 1989; 111:887-92.
29. Furman WL, Crist WM. Potential uses of recombinant human granulocyte-macrophage colony-stimulating factor in children. *Am J Pediatr Hematol/Oncol*. 1991; 13:388-99.
30. Morstyn G, Burgess AW. Hemopoietic growth factors: a review. *Cancer Res*. 1988; 48:5624-37.
31. Mitsuyasu RT, Golde DW. Clinical role of granulocyte-macrophage colony-stimulating factor. *Hematol/Oncol Clin N Am.* 1989; 3:411-25.
32. Metcalf D. The colony stimulating factors: discovery, development, and clinical applications. *Cancer*. 1990; 65:2185-95.
33. Groopman JE, Molina JM, Scadden DT. Hematopoietic growth factors: biology and clinical applications. *N Engl J Med*. 1989; 321:1449-59.
34. 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.
35. Lieschke GJ, Burgess AW. Granulocyte colony-stimulating factor and granulocyte-macrophage colony-stimulating factor. (Second of two parts.) *N Engl J Med*. 1992; 327:99-106.
36. Vadhan-Raj S, Buescher S, Broxmeyer HE et al. Stimulation of myelopoiesis in patients with aplastic anemia by recombinant human granulocyte-macrophage colony-stimulating factor. *N Engl J Med*. 1988; 319:1628-34.
37. Scadden DT. The clinical applications of colony-stimulating factors in acquired immunodeficiency syndrome. *Semin Hematol*. 1992; 29:33-7.
38. Groopman JE, Feder D. Hematopoietic growth factors in AIDS. *Semin Oncol*. 1992; 19:408-14.
39. Gerhartz HH, Stern AC, Wolf-Hornung B et al. Intervention treatment of established neutropenia with human recombinant granulocyte-macrophage colony-stimulating factor (rhGM-CSF) in patients undergoing cancer chemotherapy. *Leuk Res*. 1993; 17:175-85.
40. Singer JW. Role of colony-stimulating factors in bone marrow transplantation. *Semin Oncol*. 1992; 19:27-31.

LEVALBUTEROL (GENERIC XOPENEX)

- Asthma or COPD, AND
- Tried/failed/intolerance to albuterol

References

1. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Executive Summary. Updated 2009.
2. Levalbuterol. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
3. Levalbuterol. 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. National Heart, Lung, and Blood Institute (NHLBI), National Education and Prevention Program (NAEPP). Expert panel report(EPR-3). Guidelines for the diagnosis and management of asthma. NIH publication No. 07-4051. Bethesda, MD: U.S. Department of Health and Human Services, 2007.

LINZESS (LINACLOTIDE)

Requests for continuing 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 Idiopathic Chronic Constipation or Constipatioin-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); ORStimulant 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 years 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;
    - Gramma 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
- 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

Requests for continuing 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: 1/1/22

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 foscamet; **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
- 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:

Requests for continuing 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: 6 months
Renewal approval: 12 months

LAST REVISION: 1/1/22

LOTRONEX (ALOSETRON)

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

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

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

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)

Requests for continuing 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: ONE MONTH. May renew 6 months at a time with clinical notes demonstrating adequate control of IBS symptoms. (see underlined note above).
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
- 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.
3. Comparison of Age-related Macular Degeneration Treatments Trials (CATT) Research Group, Martin DF, Maguire MG, Fine SL, Ying GS, Jaffe GJ, et al. Ranibizumab and Bevacizumab for Treatment of Neovascular Age-related Macular Degeneration: Two-Year Results. Ophthalmology; 2012;7:1388-98.
4. Weigert G, Michels S, Sacu S, et al. Intravitreal bevacizumab (Avastin) therapy versus photodynamic therapy plus intravitreal triamcinolone for neovascular age-related macular degeneration: 6-month results of a prospective, 166ulticente, controlled clinical study. Br J Ophthalmol. 2008 Mar;92(3):356-360.
5. 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;145:249256.
6. Yazdani S, Hendi K, Pakravan M, et al. Intravitreal bevacizumab for neovascular glaucoma: a randomized controlled trial. J Glaucoma. October-November 2009;18(8):632-637.

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

7. 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.
8. 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.
9. Vedula, SS, Krzystolik, MG. Antiangiogenic therapy with anti-vascular endothelial growth factor modalities for neovascular age-related macular degeneration. Cochrane Database Syst Rev. 2008(2):CD005139. PMID: 18425911
10. Martin, DF, Maguire, MG, Ying, GS, Grunwald, JE, Fine, SL, Jaffe, GJ. Ranibizumab and bevacizumab for neovascular age-related macular degeneration. The New England journal of medicine. 2011 May 19;364(20):1897-908. PMID: 21526923
11. Martin, DF, Maguire, MG, Fine, SL, et al. Ranibizumab and bevacizumab for treatment of neovascular age-related macular degeneration: two-year results. United States, 2012. P. 1388-98.
12. American Academy of Ophthalmology Retina/Vitreous Panel Preferred Practice Pattern: Age related Macular Degeneration. [cited 08/10/2015]; Available from: http://one.aao.org/preferredpractice-pattern/agerelated-macular-degeneration-ppp--september-200
13. National Institutes for Health and Care Excellence (NICE) Technology Assessment: Ranibizumab and pegaptanib for the treatment of age-related macular degeneration. [cited 08/10/2015]; Available from: http://publications.nice.org.uk/ranibizumab-and-pegaptanib-for-the-treatment-ofage-related-macular-degeneration-ta155/guidance

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. therascreen KRAS RGQ PCR Kit; Guardant360® 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

LUNESTA (ESZOPICLONE)

PA criteria for FDA age indications:

- Breathing-related sleep disorder; Diagnosis – Polysomnography
- Generalized anxiety disorder – Insomnia
- Insomnia
- Insomnia – Major depressive disorder

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

- Insomnia – Menopause
- Patient must have tried and failed:
    - Zolpidem and benzodiazepine or trazodone

References

1. Virginia Premier

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 $\geq$ 45mL/min/1.73m^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**
    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 treatement; 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
• 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

Requests for continuing 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 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 treatement; 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 evalution 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 >= 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)
- 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 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 monthsRenewal – 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:
    - Single entity immediate release or extended release opioids,
    - Benzodiazepines,
    - Barbiturates
    - Carisoprodol
    - Meprobamate, **AND**

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

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

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.
4. Corrado EM, Peluso GF, Gigliotti S. The effects of intra-articular administration of hyaluronic acid on osteoarthritis of the knee: A clinical study with immunological and biochemical evaluations. Eur J Rheumatol Inflamm. 1995;15:47-56.
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.

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

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. Hyalgan. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
10. Kirwan JR, Rankin E. Intra-articular therapy in osteoarthritis. Baillieres Clin Rheumatol. 1997;11(4):769-794.
11. Lohmander LS, Dalen N, Englund G, H, et al. Intra-articular hyaluronan injections in the treatment of osteoarthritis of the knee: A 174ulticente, double blind, placebo controlled 174ulticenter trial. Hyaluronan Multicentre Trial Group. Ann Rheum Dis. 1996;55(7):424-431.
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.

MOTEGRITY (PRUCALOPRIDE)

CRITERIA FOR USE

Documentation of the following:

1. Diagnosis of Chronic Idiopathic Constipation
   AND
2. Age is 18 years or older;
   AND
3. An inadequate response to ≥ 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
   - A. Linzess OR
   - B. Amitiza OR
   - C. Trulance

Not Approved if:

- Does not meet above criteria
- Any contraindication to treatment

Approval Duration: 6 months

MOVEMENT DISORDERS (AUSTEDO, INGREZZA, TETRABENAZINE, XENAZINE)

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**

Requests for continuing 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:

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

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

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 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

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: 11/1/21

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.
2. Brashear A et al. Safety and efficacy of NeuroBloc (botulinumtoxin type B) in type A-responsive cervical dystonia. Neurology 1999;53:1439-46.
3. Brashear A et al. Treatment with botulinum toxin type B for upper limb spasticity. Arch Phys Med Rehabil 2003;84:103-07.
4. Brin MF et al. Safety and efficacy of NeuroBloc (botulinum toxin type B) in type A-resistant cervical dystonia. Neurology 1999;53:1431-8.
5. ComellaCL et al. Teaching tape for the motor section of the Toronto Western Spasmodic TorticollisScale. MovDisord 1997;12(4):570-5.
6. Ghei M, et al. Effects of botulinum toxin B on refractory detrusor overactivity: a randomized, double-blind, placebo controlled, crossover trial. J Urol. 2005;174:1873-7.
7. Boghen Dr. Disorders of facial motor function. Curr Opin Ophthalmol. 1996 Dec;7(6): 48-52.
8. Hirst GR et al. Botulinum toxin B is not an effective treatment of refractory overactive bladder. Urology 2007;69:69-73.
9. Jackson CE, Gronseth G, Rosenfeld J, Barohn RJ, Dubinsky R, et al.; Muscle Study Group. Randomized double-blind study of botulinum toxin type B for sialorrhea in ALS patients. Muscle Nerve. 2009;39(2):137-43.
10. Lagalla G, Millevolte M, Capecci M, Provinciali L, Ceravolo MG. Long-lasting benefits of botulinum toxin type B in Parkinson's disease-related drooling. J Neurol. 2009 Apr;256(4):563-7. Epub 2009 Apr 23.
11. LewMF et al. Botulinum toxin type B: a double-blind, placebo-controlled, safety and efficacy study in cervical dystonia. Neurology 1997;49:701-7.
12. OndoWG, Hunter C, Moore W. A double-blind placebo-controlled trial of botulinum toxin B for sialorrhea in Parkinson's disease. Neurology 2004;62(1):37-40.
13. Myobloc. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
14. Rimabotulinumtoxin B. 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.

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**

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

- 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

NASONEX (MOMETASONE)

- Diagnosis of Allergic Rhinitis, Nasal Congestion associated with seasonal rhinitis, or Nasal Polyps
- Must have tried and failed Nasacort OTC allergy spray and one other formulary nasal corticosteroid

References

1) Virginia Premier

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 anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
6. ***ANC must be < 1000 cells/mm^3.***

NOTE: Approve if undergoing cyclic chemotherapy and ANC not < 1000 cells/mm^3.

Other Uses with Supportive Evidence

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

FDA Approval: Adult, no; Pediatric, no

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

Efficacy: Adult, Evidence favors efficacy
Recommendation: Adult, Class Iia
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.

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.

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.
3. Hollinad 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.

Requests for continuing 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. Gabrilove JL. Colony-stimulating factors: clinical status. In: DeVita VT, Hellman S, Rosenberg SA, eds. Biologic therapy of cancer. JB Lippincott; 1991:445-63.
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.
6. Welte K, Bonilla MA, Gabrilove JL et al. Recombinant human granulocyte-colony stimulating factor: in vitro and in vivo effects on myelopoiesis. *Blood Cells*. 1987; 13:17-30.
7. Anon. Pegfilgrastim (Neulasta) for prevention of febrile neutropenia. Med Lett Drugs Ther 2002; 44:44-5.
8. Curran MP, Goa KL. Pegfilgrastim. *Drugs*. 2002; 62:1207-13.
9. Holmes FA, O'Shaughnessy JA, Vukelja S et al. Blinded, randomized, multicenter study to evaluate single administration pegfilgrastim once per cycle versus daily filgrastim as an adjunct to chemotherapy in patients with high-risk stage II or stage III/IV breast cancer. *J Clin Oncol*. 2002; 20:727-31.
10. Micromedex Web Site. Available at: http://www.thomsonhc.com. Accessed Nov. 2012.
11. American Hospital Formulary Service Drug Information. Available at: http://www.medicinescomplete.com/mc/ahfs/current/. Accessed Nov. 2012.

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/mm^3.***

NOTE: Approve if undergoing cyclic chemotherapy and ANC not < 1000 cells/mm^3.

Other FDA Approved Indications include:

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

Neutropenic disorder, chronic (Severe), Symptomatic

Requests for continuing 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. Amgen. Neupogen® (filgrastim) prescribing information. Thousand Oaks, CA; November 2012.
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.
3. Bronchud MH, Scarffe JH, Thatcher N et al. Phase I/II study of recombinant human granulocyte colony-stimulating factor in patients receiving intensive chemotherapy for small cell cancer. *Br J Cancer*. 1987; 56:809-13.
4. Bronchud MH, Howell A, Crowther D et al. The use of granulocyte colony-stimulating factor to increase the intensity of treatment with doxorubicin in patients with advanced breast and ovarian cancer. *Br J Cancer*. 1989; 60:121-5.
5. Crawford J, Ozer H, Stoller R et al. Reduction by granulocyte colony-stimulating factor of fever and neutropenia induced by chemotherapy in patients with small-cell lung cancer. *N Engl J Med*. 1991; 315:164-70.
6. . Morstyn G, Campbell L, Lieschke G et al. Treatment of chemotherapy-induced neutropenia by subcutaneously administered granulocyte colony-stimulating factor with optimization of dose and duration of therapy. *J Clin Oncol*. 1989; 7:1554-62.
7. Gabrilove JL. Colony-stimulating factors: clinical status. In: DeVita VT, Hellman S, Rosenberg SA, eds. Biologic therapy of cancer. JB Lippincott; 1991:445-63.
8. Hammond WP, Price TH, Souza LM et al. Treatment of cyclic neutropenia with granulocyte colony-stimulating factor. *N Engl J Med*. 1989; 320:1306-11. Ridan WP, Morstyn G, Wolf M et al. Granulocyte colony-stimulating factor and neutrophil recovery after high-dose chemotherapy and autologous bone marrow transplantation.
9. Metcalf D. The colony stimulating factors: discovery, development, and clinical applications. *Cancer*. 1990; 65:2185-95.
10. 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.
11. Cheson BD. The myelodysplastic syndromes: current approaches to therapy. *Ann Intern Med*. 1990; 112: 932-41.
12. Soutar RL. Acute myeloblastic leukaemia and recombinant granulocyte colony stimulating factor. *BMJ*. 1991; 303:123-4.
13. Sheridan WP, Begley CG, Juttner CA et al. Effect of peripheral-blood progenitor cells 182ulticent by filgrastim (G-CSF) on platelet recovery after high-dose chemotherapy. *Lancet*. 1992; 339:640-4.
14. 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.
15. Lieschke GJ, Burgess AW. Granulocyte colony-stimulating factor and granulocyte-macrophage colony-stimulating factor. (Second of two parts.) *N Engl J Med*. 1992; 327:99-106.
16. Morstyn G, Campbell L, Souza LM et al. Effect of granulocyte colony stimulating factor on neutropenia induced by cytotoxic chemotherapy. *Lancet*. 1988; 1:667-72.
17. Lindemann A, Herrmann F, Oster W et al. Hematologic effects of recombinant human granulocyte colony-stimulating factor in patients with malignancy. *Blood*. 1989; 74:2644-51.
18. Stahel RA, Jost LM, Cerny T et al. Randomized study of recombinant human granulocyte colony-stimulating factor after high-dose chemotherapy and autologous bone marrow transplantation for high-risk lymphoid malignancies. *J Clin Oncol*. 1994; 12:1931-8.
19. Maher DW, Lieschke GJ, Green M et al. Filgrastim in patients with chemotherapy-induced febrile neutropenia: a double-blind, placebo-controlled trial. *Ann Intern Med*. 1994; 121:492-501.
20. Anon. Drugs for AIDS and associated infections. *Med Lett Drugs Ther*. 1993; 35:79-86.
21. Hermans P, Rozenbaum W, Jou A et al. Filgrastim to treat neutropenia and support myelosuppressive medication dosing in HIV infection. G-CSF 92105 Study Group. *AIDS*. 1996; 10:1627-33.
22. Riikonen P, Rahiala J, Salonvaara M et al. Prophylactic administration of granulocyte colony-stimulating factor (Filgrastim) after conventional chemotherapy in children with cancer. *Stem Cells*. 1995; 13:289-94.
23. Heil G, Hoelzer D, Sanz MA et al. A randomized, double-blind, placebo-controlled, phase III study of filgrastim in remission induction and consolidation therapy for adults with de novo acute myeloid leukemia: the International Acute Myeloid Leukemia Study Group. *Blood*. 1997; 90(12):4710-4718.
24. Moore JO, Dodge RK, Amrein PC et al. Granulocyte-colony stimulating factor (filgrastim) accelerates granulocyte recovery after intensive postremission chemotherapy for acute myeloid leukemia with aziridinyl benzoquinone and mitoxantrone: Cancer and Leukemia Group B study 9022. *Blood*. 1997; 89(3)780-788.
25. Micromedex Web Site. Available at: http://www.thomsonhc.com. Accessed Nov. 2012.
26. American Hospital Formulary Service Drug Information. Available at: http://www.medicinescomplete.com/mc/ahfs/current/. Accessed Nov. 2012.

NEXAVAR (SORAFENIB)

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

Reauthorization/continuing treatment:

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

References

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. Clinical Cancer Advances 2005: Major Research and Advances in Cancer Treatments-Prevention and Screening-A report from ASCO (American Society of Clinical Oncology) Journal of Clinical Oncology January 2006; 24; 190-205.
3. 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.
4. Nexavar. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
5. Sorafenib. 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. 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.
7. Thyroid 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.

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

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

    - 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)
        - 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 attach (TIA)
- Corornary 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
    - 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 myopthay, vitamin D deficiency, or primary muscle disease; OR
    - The member has been diagnosed with statin-induced rhabdomyolysis

CONTINUNG 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 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:

- 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

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

- Has 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***
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
- 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-Rh_o[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

1. George JN WS, Raskob GE, et al. Idiopathic thrombocytopenic purpura: a practice guideline developed by explicit methods for the American Society of Hematology. Blood. 1996;88:3-40.
2. Guidelines for the investigation and management of idiopathic thrombocytopenic purpura in adults, children and in pregnancy. British Journal of Hematology. 2003;120:574-96.
3. Kojouri K GJ. Recent advances in the treatment of chronic refractory immune thrombocytopenic purpura. Int J Hematol. 2005;81(2):119-25.
4. Kuter DJ, Rummel M, Boccia R, Macik BG, Pabinger I, Selleslag D, Rodeghiero F, Chong BH, Wang X, Berger DP. Romiplostim or standard of care in patients with immune thrombocytopenia. N Engl J Med. 2010 Nov 11;363(20):1889-99.
5. Newland C SM, Bourgeois E, et al. Evaluating the long-term efficacy of romiplostim (AMG 531) in patients with chronic immune thrombocytopenic purpura (ITP) during an open-label extension study. Haematologica. 2008;93(suppl 1)(377 Abstract 0945.).
6. Nplate. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
7. Romiplostim. 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

NUBEQA (DAROLUTAMIDE)

- Diagnosis of non-metastatic castration-resistant prostate cancer
- Must use concurrently with a gonadotropin-releasing hormone (GnRH) analog unless the patient has had a bilateral orchiectomy
- Must not be used with P-gp and strong or moderate CYP3A inducers (i.e. rifampin)
- Must be prescribed by an Oncologist or Urologist

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:
    - 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, Fasenra, or Xolair; AND
12. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist.

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

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

- 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

NUEDEXTA (DEXTROMETHORPHAN/QUINIDINE)

- Diagnosed with pseudobulbar affect

References:

1. Virginia Premier

NUVIGIL (ARMODAFINIL)

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

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

OR

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

- Clinically diagnosed shift work sleep disorder.
- Documentation of the patient work shift (defined as working "all night shift"), AND
- 17 years of age or older

OR

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

- Clinically diagnosed obstructive sleep apnea
- Diagnosis confirmed via sleep study or documentation that C-PAP has been maximized, AND
- 17 years of age or older

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

References

1. Virginia Premier

OLEPTRO (TRAZODONE EXTENDED RELEASE)

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

Requests for continuing 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.
- 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

ONFI (CLOBAZAM)

1. Patient must be ≥ 2 years of age; AND
2. Patient must have a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS); AND
3. Using as adjunctive therapy with other anticonvulsants; AND
4. For Non Formulary branded Onfi - Prescribing physician should submit documentation of an insufficient response to 2 other medications used for LGS

LAST UPDATED: 7/1/2021

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
- 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

Requests for continuing 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 – 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 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 cytogenic 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 Virgnia 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)**
    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<u>Criteria for both Preferred (75) and Non-Preferred (MR)(Non-Preferred must pass tollgate of 2 t/f above)</u>

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 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

- 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

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 quantitites
    - 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

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

        - 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
- 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, Hepatoxicity

- 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
- Percentage of BSA with atopic dermatitis involvement of 3% to 20%; 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 or at least 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
- Prescribed by or in consultation with a dermatologist or allergist/immunologist

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

Quantity Limit:
60 grams per week
8 week maximum

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

LAST REVISION: 8/1/22

ORACEA (DOXYCYCLINE) DELAYED-RELEASE

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

Approve for only 16 weeks max.

Requests for continuing 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

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.

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

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

Requests for continuing 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 endometreosis ***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 dysparenunia 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 ≥ 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

ORTHOVISC (HYALURONIC ACID DERIVATIVES, INTRA-ARTICULAR)

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

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

References

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.
4. Corrado EM, Peluso GF, Gigliotti S. The effects of intra-articular administration of hyaluronic acid on osteoarthritis of the knee: A clinical study with immunological and biochemical evaluations. Eur J Rheumatol Inflamm. 1995;15:47-56.
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.
10. Lohmander LS, Dalen N, Englund G, H, et al. Intra-articular hyaluronan injections in the treatment of osteoarthritis of the knee: A 206ulticente, double blind, placebo controlled 206ulticenter trial. Hyaluronan Multicentre Trial Group. Ann Rheum Dis. 1996;55(7):424-431.
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. Orthovisc. 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.

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 candidates 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

    - Risks from improper dosing: Mistaken daily use has led to fatal toxicity
    - Patients with impaired renal function, ascites, or pleural effusions: Elimination is reduced
- Dizziness and fatigue: May impair ability to drive or operate machinery
- Monitoring:
    - Effects on reproduction: May cause impairment of fertility, oligospermia and menstrual dysfunction
    - Laboratory tests: Monitor complete blood counts, renal function and liver function tests
- Contraindication:
    - Pregnancy; Avoid pregnancy if either partner is receiving Otrexup. Advise males to avoid pregnancy for a minimum of three months after therapy and females to avoid pregnancy for at least one ovulatory cycle after therapy
    - Nursing mothers
    - Alcoholism or liver disease
    - Immunodeficiency syndromes
    - Preexisting blood dyscrasias
    - Hypersensitivity to methotrexate
- Not approved if:
    - Does not meet above criteria
    - Has any contraindications to treatment
    - Being used for the treatment of neoplastic diseases
- Special considerations:
    - *Another formulation of methotrexate should be used for patients requiring doses less than 10mg per week, doses above 25mg per week, high-dose regimens, or dose adjustments of less than 5mg increments
    - Systemic exposure of methotrexate was found to be similar between Otrexup and intramuscular or subcutaneous administration of methotrexate injection at the same doses
    - Systemic exposure of methotrexate from Otrexup at doses of 10, 15, 20, and 25mg was higher than that of oral methotrexate by 17, 13, 31, and 36%, respectively.

OXANDRIN (OXANDROLONE)

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

- Must have one of the following diagnosis:
    - Used as an adjunctive therapy to promote weight gain following:

        - Extensive Surgery
        - Chronic Infection
        - Severe Trauma

Or

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

Or

- Treatment of bone pain associated with osteoporosis

Contraindications:

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

References

1. Virginia Premier

OXBRYTA (VOXELOTOR)

Initial Criteria:

- Patient is 4 years of age or older **AND**
- Medication prescribed by or in consultation with a hematologist **AND**
- Patient has been confirmed with a diagnosis of sickle cell disease of any genotype as determined by the following:
    - Identification of significant quantities of Hbs with or without an additional beta globin chain variant by hemoglobin assay **OR**
    - Identification of biallelic HBB pathogenic variants where at least one allele is the p.Glu6Val pathogenic variant on molecular genetic testing **AND**
- Trial of and inadequate response or intolerance to a minimum 3-month trial of hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced **AND**
- Confirmation that the member has symptomatic anemia with a baseline hemoglobin (Hb) level between ≥ 5.5 g/dl and ≤ 10 g/dl prior to start of therapy (lab documentation must be submitted) **AND**
- Confirmation that other causes of anemia have been ruled out **AND**
- Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy **AND**

- Patient is **NOT** concomitantly receiving Adakveo (crizanlizumab) or Endari (L-glutamine oral powder)

Renewal Criteria

- Patient continues to meet above criteria **AND**
- Patient is absent of medication toxicity **AND**
- Patient demonstrates disease response as evidenced by an increase in hemoglobin (Hb) of ≥ 1g/dl from baseline (lab documentation must be submitted)

Duration:

Initial 6 months

Reauthorization 12 months

LAST REVISION: 10/01/22

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
- Prescribed by or in consultation with a specialist (Allergist or Immunologist) AND
- Prescriber attests the patients 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 verifyhigh calcium levels, OR
- Osteolytic metastases and the patient is also diagnosed with multiple myeloma, OR
- Pagets 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
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

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

Initial: 3 months; 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 partents
            - 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
        - 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 – REPATHA OR PRALUENT
        - 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 attach (TIA)

- Corornary 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 myopthay, vitamin D deficiency, or primary muscle disease; OR
    - The member has been diagnosed with statin-induced rhabdomyolysis

CONTINUNG THERAPY

- 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

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

PDE-5 INHIBITORS (SILDENAFIL/ADCIRCA)

- Diagnosis of pulmonary artery hypertension, AND
- Prescribed by pulmonary specialist or cardiologist, AND
- 18 years of age or older for Adcirca

LAST REVISION: 11/1/21

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

Reauthorization:

- Patient has locally advanced or metastatic cholangiocarcinoma; 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; ANDEffective contraception is being followed (as outlined above) for both males and females through 1 week post therapy

PIZENSY (LACTITOL MONOHYDRATE)

CRITERIA FOR USE

1. Diagnosis of Chronic Idiopathic 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

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
5. An inadequate response/intolerance to ≥ 1 of the preferred products indicated for CIC
   - A. Linzess OR
   - 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:
  - Drug-sensitive TB
  - Latent infection due to Mycobacterium tuberculosis

- Extra-pulmonary infection due to Mycobacterium tuberculosis
- 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
- 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
- Documenation 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

Requests for continuing 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 a documented seropositivity for Cytomegalovirus; ***AND***
- Patient must have received an allegeneic hematopoietic stem cell transplant (HSCT) within the last 28 days (provider must provide transplant date); ***AND***
- Prescribed by, or in consultation with, a hematologist/oncologist or infectious disease specialist;

COVERAGE DURATION

- Up to day 100 post-transplant

EXCLUSION CRITERIA

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

PROCYSBI (CYSTEAMINE BITARTRATE)

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 signification 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

Requests for continuing 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

PRODIGY VOICE KIT METER AND TEST STRIPS

- Clinically diagnosed with Diabetes Mellitus
- Must have clinical need for a speaking meter and corresponding test strips (i.e. patient is blind)
- Quantity limit of 100 strips in 30 days

References

1. Virginia Premier

PROLIA (DENOSUMAB)

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 ≤ 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.

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

Contraindications:

- Uncorrected pre-existing hypocalcemia.

Not approved if:

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

Approval Duration of therapy: Indefinite

Special Considerations:

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

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

PROMACTA (ELTROMBOPAG)

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

Reauthorization/continuing treatment:

- 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

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

- 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.
2. Boellner SW, et al. Modafinil in children and adolescents with attention-deficit/hyperactivity disorder: a preliminary 8-week, open-label study. Curr Med Res Opinion. 2006;22(12):2457-65.
3. Biederman J, et al. Efficacy and safety of modafinil film-coated tablets in children and adolescents with attention-deficit/hyperactivity disorder: results of a randomized, double-blind, placebo-controlled, flexible-dose study. Pediatrics. 2005;116:777-84.
4. Greenhill LL, et al. A randomized, double-blind, placebo-controlled study of modafinil film-coated tablets in children and adolescents with attention-deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry. 2006;45(5):503-11.
5. Harsh JR, et al. The efficacy and safety of armodafinil as treatment for adults with excessive sleepiness associated with narcolepsy. Curr Med Res Opin. 2006 Apr;22(4):761-774.
6. Hirshkowitz M, et al. Adjunct armodafinil improves wakefulness and memory in obstructive sleep apnea/hypopnea syndrome. Respir Med. 2007 Mar;101(3):616-627.
7. Kingshott RN, Vennelle M, Coleman EL, et al. Randomized, double-blind, placebo-controlled crossover trial of modafinil in the treatment of residual excessive daytime sleepiness in the sleep/apnea/hypopnea syndrome. Am J Resp Crit Care Med. 2001;163:918-923.
8. Modafinil. 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
9. Pack AI, Black JE, Schwartz RL, Matheson JK. Modafinil as adjunct therapy for daytime sleepiness in obstructive sleep apnea. Am J Respir Crit Care Med. 2001;164:1675-1681.
10. Practice parameters for the treatment of narcolepsy: an update for 2000. Sleep. 2001;24 (4):451-466.
11. Provigil. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
12. Rammohan KW, et al. Efficacy and safety of modafinil (Provigil) for the treatment of fatigue in multiple sclerosis: a two centre phase 2 study. J Neurol Neurosurg Psychiatry. 2002;72:179-183.
13. Roth T, et al. Effects of armodafinil in the treatment of residual excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome: A 12-week, multicenter, double-blind, randomized, placebo-controlled study in nCPAP-adherent adults. Clin Ther. 2005;28(5):689-706.
14. Rugino TA et al. Modafinil in children with Attention Deficit Hyperactivity Disorder. Ped Neuro 2003; 29(2):136-42.
15. Stankoff B, Waubant E, Confavreux C, et al. Modafinil for fatigue in MS: a randomized placebo-controlled double-blind study. Neurology. 2005;64(7):1139-1143.
16. Swanson JM, et al. Modafinil film-coated tablets in children and adolescents with attention-deficit/hyperactivity disorder: results of a randomized, double-blind, placebo-controlled, fixed-dose study followed by abrupt discontinuation. J Clin Psychiatry. 2006;67:137-47.
17. US Modafinil in Narcolepsy Study Group. Randomized trial of modafinil as a treatment for the excessive daytime somnolence of narcolepsy. Neurology. 2000;54(5):1166-1175.

PYRUKYND (MITAPIVAT)

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 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**
- 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**

Requests for continuing 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 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
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 ulcerso 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:

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

- 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)

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**
- 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.

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

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

LAST REVISION: 11/1/21

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

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 >/=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:

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

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

Coverage of ribavirin is not recommended in the following circumstances:

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

References

1. Ghany MG, Strader DB, et al. Diagnosis, management, and treatment of Hepatitis C: An Update. AASLD Practice Guidelines. Hepatology 2009. 1335-1373.
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.
3. Smith RA. Mechanisms of action of ribavirin. In: Smith RA, Kirkpatrick W, eds. Ribavirin: a broad spectrum antiviral agent. New York: Academic Press; 1980:99-118.
4. Ghany MG, Nelson DR, Strader DB et al. An update on treatment of genotype 1 chronic hepatitis C virus infection: 2011 practice guideline by the American Association for the Study of Liver Diseases. Hepatology. 2011; 54:1433-44.
5. European Association for the Study of the Liver. EASL Clinical Practice Guidelines: management of hepatitis C virus infection. J Hepatol. 2011; 55:245-64.
6. Yee HS, Chang MF, Pocha C et al. Update on the management and treatment of hepatitis C virus infection: recommendations from the Department of Veterans Affairs Hepatitis C Resource Center Program and the National Hepatitis C Program Office. Am J Gastroenterol. 2012; 107:669-89; quiz 690.
7. van den Berk GE, Arends JE. Sustained viral response after only 6 weeks of peginterferon and ribavirin treatment for acute hepatitis C in a HIV-1-infected patient. AIDS. 2011; 25:1553-4.
8. Hillyard IW. The preclinical toxicology and safety of ribavirin. In: Smith RA, Kirkpatrick W, eds. Ribavirin: a broad spectrum antiviral agent. New York: Academic Press; 1980:59-71.
9. Sidwell RW, Robins RK, Hillyard IW. Ribavirin: an antiviral agent. Pharmacol Ther. 1979; 6:123-46.
10. Allen LB. Review of in vivo efficacy of ribavirin. In: Smith RA, Kirkpatrick W eds. Ribavirin: a broad spectrum antiviral agent. New York: Academic Press; 1980:43-58.
11. Vertex Pharmaceuticals Incorporated. Incivek® (telaprevir) film-coated tablets prescribing information. Cambridge, MA; 2012 Jun.
12. Merck & Co. Victrelis® (boceprevir) capsules prescribing information. Whitehouse Station, NJ; 2012 Apr.
13. Isaacs D, Moxon ER, Harvey D et al. Randomized trials and ribavirin. Arch Dis Child. 1988; 63:989-90.
14. Isaacs D. Ribavirin. Pediatrics. 1987; 79:289-91.
15. Schvarcz R, Ando Y, Sonnerborg A et al. Combination treatment with interferon alfa-2b and ribavirin for chronic hepatitis C in patients who have failed to achieve sustained response to interferon alone: Swedish experience. J Hepatol. 1995; 23(Suppl 2): 17-21.
16. Reichard O, Norkrans G, Fryden A et al et al. Randomised, double-blind, placebo-controlled trial of interferon α-2b with and without ribavirin for chronic hepatitis C. Lancet. 1998; 351:83-7.
17. Brown JL. Efficacy of combined interferon and ribavirin for treatment of hepatitis C. Lancet. 1998; 351:78-9.
18. Chemello L, Cavalletto L, Bernardinello E et al. The effect of interferon alfa and ribavirin combination therapy in naive patients with chronic hepatitis C. J Hepatol. 1995; 23(Suppl 2):8-12.
19. Schalm SW, Hansen BE, Chemello L et al. Ribavirin enhances the efficacy but not the adverse effects of interferon in chronic hepatitis C. Meta-analysis of individual patient data from European centers. J Hepatol. 1997; 26:961-6.

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

20. Lai MY, Kao JH, Yang PM et al. Long-term efficacy of ribavirin plus interferon alfa in the treatment of chronic hepatitis C. Gastroenterology. 1996; 111:1307-12.
21. Centers for Disease Control and Prevention. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. MMWR Morb Mortal Wkly Rep. 1998; 47(No. RR-19):14-5.
22. Poynard T, Marcellin P, Lee SS st al. Randomised trial of interferon α2b plus ribavirin for 48 weeks or for 24 weeks versus interferon α2b plus placebo for 48 weeks for treatment of chronic infection with hepatitis C virus. Lancet. 1998; 352:1426-32.
23. McHutchison JG, Gordon SC, Schiff ER et al. Interferon alfa-2b alone or in combination with ribavirin as initial treatment for chronic hepatitis C. N Engl J Med. 1998; 339:1485-92.
24. Davis GL, Esteban-Mur R, Rustgi V et al Interferon alfa-2b alone or in combination with ribavirin for the treatment of relapse of chronic hepatitis C. N Engl J Med. 1998; 339:1493-9.
25. Hoofnagle JH. Management of hepatitis C: current and future perspectives. J Hepatol. 1999; 31(Suppl 1):264-8.
26. Booth JCL, O'apos;Grady J, Neuberger J for the Royal College of Physicians of London and the British Society of Gastroenterology. Clinical guidelines on the management of hepatitis C. Gut. 2001; 49(Suppl):1-21.
27. European Association for the Study of the Liver (EASL) Consensus Panel. EASL international consensus conference on hepatitis C; Paris, 26-28 February 1999. J Hepatol. 1999; 30:956-61.
28. Manns MP, McHutchison JG, Gordon SC et al. Peginterferon alfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a randomised trial. Lancet. 2001; 358:958-65.
29. Merck & Co. Rebetol® (ribavirin) capsules, oral solution prescribing information. Whitehouse Station, NJ; 2012 Jul.
30. Zylberberg H, Benhamou Y, Lagneaux JL et al. Safety and efficacy of interferon-ribavirin combination therapy in HCV-HIV coinfected subjects: an early report. Gut. 2000; 47:694-7.
31. Genentech. Copegus® (ribavirin) tablets prescribing information. South San Francisco, CA; 2012 Nov.
32. McHutchison JG, Lawitz EJ, Shiffman ML et al. Peginterferon alfa-2b or alfa-2a with ribavirin for treatment of hepatitis C infection. N Engl J Med. 2009; 361:580-93.
33. Hadziyannis SJ, Sette H, Morgan TR et al. Peginterferon-alpha2a and ribavirin combination therapy in chronic hepatitis C: a randomized study of treatment duration and ribavirin dose. Ann Intern Med. 2004; 140:346-55.
34. Fried MW, Shiffman ML, Reddy KR et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection. N Engl J Med. 2002; 347:975-82.
35. Torriani FJ, Rodriguez-Torres M, Rockstroh JK et al. Peginterferon Alfa-2a plus ribavirin for chronic hepatitis C virus infection in HIV-infected patients. N Engl J Med. 2004; 351:438-50.
36. Wirth S, Ribes-Koninckx C, Calzado MA et al. High sustained virologic response rates in children with chronic hepatitis C receiving peginterferon alfa-2b plus ribavirin. J Hepatol. 2010; 52:501-7.
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.

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:

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

    - Age > 50 years old
    - Postmenopausal status in women
    - Hypogonadal status in men
    - Currently taking certain medications that can decrease BMD:
        - Glucocorticoids (equivalent of >5mg/day of prednisone for > 3 months), cyclosporine, chemotherapy, anticonvulsants, aluminum salts, gonadotropin-releasing hormone agonists, heparin, lithium, high doses of thyroxine
    - Concurrent disease state that increases the risk of osteoporosis:
        - Hypogonadal diseases, endocrine disorders, nutritional and gastrointestinal disorders, rheumatic disorders, hematologic/oncologic disorders, organ transplantation, selected inherited disorders, chronic obstructive pulmonary disease, pregnancy and lactation, scoliosis, multiple sclerosis, sarcoidosis, amyloidosis, acromegaly, diabetes mellitus type 1, chronic liver disease, or states of immobilization.
- Other risk factors:
    - Vitamin D or calcium deficiency, alcohol intake (3 or more drinks per day), parental history of hip fracture, small frame or stature, early menopause, and low body mass index (BMI in kg/m2; BMI for healthy weight is between 18.5 to 24.9 kg/m2, current smoking.
- Tried/failed/intolerance to alendronate, **OR**

- Paget's disease of bone with elevations in serum alkaline phosphatase (ALP) of ≥2 x ULN of the age-specific normal reference range with:
- Symptomatic disease (bone pain, hearing loss, bone deformities, fractures, arthritis), AND
- At risk of complications from Paget's disease (e.g., osteoarthritis, heart failure, kidney stones, broken bones), AND
- Concomitant treatment with calcium and vitamin D, AND
- Tried/failed/intolerance to alendronate and pamidronate, and generic zolendronic acid, OR
- Hypercalcemia of malignancy

    - Bone metastasis - Solid tumor configuration
    - Multiple myeloma
    - Osteopenia, Secondary to androgen-deprivation therapy in prostate cancer patients; Prophylaxis

References

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, Colsn-Emeric CS, Magaziner JS, et al. Zoledronic acid and clinical fractures and mortality after hip fracture. N Engl J Med. 2007;357:1799-809.

Requests for continuing 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. National Osteoporosis Foundation. The Clinician's Guide to Prevention and Treatment of Osteoporosis. Available from http://www.nof.org/professionals/clinical-guidelines.
5. Reclast. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
6. 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.
7. Reid DM, Devogelaer J, Saag K, et al. Zoledronic acid and resedronate in the prevention and treatment of glucocorticoid-induced osteoporosis (HORIZON): a multicenter, double-blind, double-dummy, randomized controlled trial. The Lancet. 2009; 373:1253-1263.
8. Siris ES, Lyles KW, et al. Medical management of Paget's disease of bone: indications for treatment and review of current therapies. J Bone Miner Res. 2006 Dec;21 Suppl 2:P94-8.
9. 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.
10. 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.

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

Requests for continuing 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

RECTIV (NITROGLYCERIN)

APPROVAL DURATION: 21 days
APPROVAL CRITERIA
Criteria for use (bullet points below are all inclusive unless otherwise noted):

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

Contraindication:

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

Not approved if:

- Does not meet the above stated criteria.
- 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

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

REGRANEX (BECAPLERMIN)

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

References

1. APhA Drug Treatment Protocols; Management of Foot Ulcers in Patients with Diabetes. Journal of the American Pharmaceutical Association July/August 2000 Vol 40, No.4.
2. Becaplermin. 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. Frykberg, RG et.al. Diabetic Foot Disorders: A Clinical Practice Guideline. J Foot Ankle Surg 2006 Sep-Oct;45(5):S2-66.
4. Regranex. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.

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/mm^3.***
   NOTE: Approve if undergoing cyclic chemotherapy and ANC not < 1000 cells/mm^3.

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

Requests for continuing 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. Amgen. Neupogen® (filgrastim) prescribing information. Thousand Oaks, CA; November 2012.
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.
3. Bronchud MH, Scarffe JH, Thatcher N et al. Phase I/II study of recombinant human granulocyte colony-stimulating factor in patients receiving intensive chemotherapy for small cell cancer. *Br J Cancer*. 1987; 56:809-13.
4. Bronchud MH, Howell A, Crowther D et al. The use of granulocyte colony-stimulating factor to increase the intensity of treatment with doxorubicin in patients with advanced breast and ovarian cancer. *Br J Cancer*. 1989; 60:121-5.
5. Crawford J, Ozer H, Stoller R et al. Reduction by granulocyte colony-stimulating factor of fever and neutropenia induced by chemotherapy in patients with small-cell lung cancer. *N Engl J Med*. 1991; 315:164-70.
6. . Morstyn G, Campbell L, Lieschke G et al. Treatment of chemotherapy-induced neutropenia by subcutaneously administered granulocyte colony-stimulating factor with optimization of dose and duration of therapy. *J Clin Oncol*. 1989; 7:1554-62.
7. Gabrilove JL. Colony-stimulating factors: clinical status. In: DeVita VT, Hellman S, Rosenberg SA, eds. Biologic therapy of cancer. JB Lippincott; 1991:445-63.
8. Hammond WP, Price TH, Souza LM et al. Treatment of cyclic neutropenia with granulocyte colony-stimulating factor. *N Engl J Med*. 1989; 320:1306-11. Ridan WP, Morstyn G, Wolf M et al. Granulocyte colony-stimulating factor and neutrophil recovery after high-dose chemotherapy and autologous bone marrow transplantation.
9. Metcalf D. The colony stimulating factors: discovery, development, and clinical applications. *Cancer*. 1990; 65:2185-95.
10. 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.
11. Cheson BD. The myelodysplastic syndromes: current approaches to therapy. *Ann Intern Med*. 1990; 112: 932-41.
12. Soutar RL. Acute myeloblastic leukaemia and recombinant granulocyte colony stimulating factor. *BMJ*. 1991; 303:123-4.
13. Sheridan WP, Begley CG, Juttner CA et al. Effect of peripheral-blood progenitor cells 232ulticent by filgrastim (G-CSF) on platelet recovery after high-dose chemotherapy. *Lancet*. 1992; 339:640-4.
14. 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.
15. Lieschke GJ, Burgess AW. Granulocyte colony-stimulating factor and granulocyte-macrophage colony-stimulating factor. (Second of two parts.) *N Engl J Med*. 1992; 327:99-106.
16. Morstyn G, Campbell L, Souza LM et al. Effect of granulocyte colony stimulating factor on neutropenia induced by cytotoxic chemotherapy. *Lancet*. 1988; 1:667-72.
17. Lindemann A, Herrmann F, Oster W et al. Hematologic effects of recombinant human granulocyte colony-stimulating factor in patients with malignancy. *Blood*. 1989; 74:2644-51.
18. Stahel RA, Jost LM, Cerny T et al. Randomized study of recombinant human granulocyte colony-stimulating factor after high-dose chemotherapy and autologous bone marrow transplantation for high-risk lymphoid malignancies. *J Clin Oncol*. 1994; 12:1931-8.
19. Maher DW, Lieschke GJ, Green M et al. Filgrastim in patients with chemotherapy-induced febrile neutropenia: a double-blind, placebo-controlled trial. *Ann Intern Med*. 1994; 121:492-501.
20. Anon. Drugs for AIDS and associated infections. *Med Lett Drugs Ther*. 1993; 35:79-86.
21. Hermans P, Rozenbaum W, Jou A et al. Filgrastim to treat neutropenia and support myelosuppressive medication dosing in HIV infection. G-CSF 92105 Study Group. *AIDS*. 1996; 10:1627-33.
22. Riikonen P, Rahiala J, Salonvaara M et al. Prophylactic administration of granulocyte colony-stimulating factor (Filgrastim) after conventional chemotherapy in children with cancer. *Stem Cells*. 1995; 13:289-94.
23. Heil G, Hoelzer D, Sanz MA et al. A randomized, double-blind, placebo-controlled, phase III study of filgrastim in remission induction and consolidation therapy for adults with de novo acute myeloid leukemia: the International Acute Myeloid Leukemia Study Group. *Blood*. 1997; 90(12):4710-4718.
24. Moore JO, Dodge RK, Amrein PC et al. Granulocyte-colony stimulating factor (filgrastim) accelerates granulocyte recovery after intensive postremission chemotherapy for acute myeloid leukemia with aziridinyl benzoquinone and mitoxantrone: Cancer and Leukemia Group B study 9022. *Blood*. 1997; 89(3)780-788.
25. Micromedex Web Site. Available at: http://www.thomsonhc.com. Accessed Nov. 2012.
26. American Hospital Formulary Service Drug Information. Available at: http://www.medicinescomplete.com/mc/ahfs/current/. Accessed Nov. 2012.

RELISTOR (METHYLNALTREXONE)

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

- 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
- 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

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, coadminsitration with either cyclosporine or glyburide
- New York Heart Association functional classification:
    - Class 1: No symptoms with ordinary physical activity.
    - Class 2: Symptoms with ordinary activity. Slight limitation of activity.
    - Class 3: Symptoms with less than ordinary activity. Marked limitation activity.
    - Class 4: Symptoms with any activity or event at rest.

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

infusion, depending on clinical response. There is little experience with doses >40 ng/kg/min.

References:

1. Remodulin full prescribing information United Therapeutics.
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.
5. Rubin LJ. Primary pulmonary hypertension. N Engl J Med. 1997;336:111-117
6. Simonneau G. Barst R J. Galie N, et al. Continuous subcutaneous infusion of treprostinil, a prostacyclin analogue, in patients with pulmonary arterial hypertension. American Journal of Respiratory and Critical Care Medicine (2002), 165: pp. 800-804.
7. McLaughlin V V G, Barst R J, Oudiz R, et al. Efficacy and safety of treprostinil: an Epoprostenol analog for primary pulmonary hypertension. Journal of Cardiovascular Pharmacology (2003), 41: pp. 293-299.

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
    - 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% noral) or ; detection of pathogenic mutations in the ADA gene by genetic testing

AND

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

AND

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

AND

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

Continuation of therapy

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

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

REVLIMID (LENALIDOMIDE)

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

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Myelodysplastic Syndromes (MDS):
    - Prescribed by an oncologist or a hematologist
    - Clinically diagnosed low to intermediate risk MDS associated with deletion 5q cytogenic abnormality with or without additional chromosomal abnormalities
    - Transfusion dependent anemia (2 or more units of RBC every 8 weeks).

  OR

    - Symptomatic anemia with hgb less than 10g/dl
    - Absolute neutrophil count (ANC) of at least 500/ml
    - Platelet count of at least 50,000/ml
    - Serum creatinine < 2.5 mg/dl.
- Multiple Myeloma (MM):
    - Prescribed by an oncologist or a hematologist.
    - Clinically diagnosed with Multiple Myeloma
    - Member has **ONE** of the following:
        - Medication will be used in combination with Dexamethasone, OR
        - Revlimid will be used as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT)
    - Absolute neutrophil count (ANC) of at least 500/ml.

Requests for continuing 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/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 Lmyphoma
    - 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.
        - Cytogenic 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 (BREXPIPRAZOLE)

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

1) Must have clinically diagnosed Major Depressive Disorder, AND
2) Must have tried and failed Quetiapine, Olanzapine, and Aripiprazole (Prior Authorization Required), 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) 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

RIBAPAK (RIBAVIRIN)

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

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Coverage of 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 >/=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.
5. Patients with a history of significant or unstable cardiac disease.
6. Creatinine clearance < 50ml/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

1. Ghany MG, Strader DB, et al. Diagnosis, management, and treatment of Hepatitis C: An Update. AASLD Practice Guidelines. Hepatology 2009. 1335-1373.
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.
3. Smith RA. Mechanisms of action of ribavirin. In: Smith RA, Kirkpatrick W, eds. Ribavirin: a broad spectrum antiviral agent. New York: Academic Press; 1980:99-118.
4. Ghany MG, Nelson DR, Strader DB et al. An update on treatment of genotype 1 chronic hepatitis C virus infection: 2011 practice guideline by the American Association for the Study of Liver Diseases. Hepatology. 2011; 54:1433-44.
5. European Association for the Study of the Liver. EASL Clinical Practice Guidelines: management of hepatitis C virus infection. J Hepatol. 2011; 55:245-64.
6. Yee HS, Chang MF, Pocha C et al. Update on the management and treatment of hepatitis C virus infection: recommendations from the Department of Veterans Affairs Hepatitis C Resource Center Program and the National Hepatitis C Program Office. Am J Gastroenterol. 2012; 107:669-89; quiz 690.
7. van den Berk GE, Arends JE. Sustained viral response after only 6 weeks of peginterferon and ribavirin treatment for acute hepatitis C in a HIV-1-infected patient. AIDS. 2011; 25:1553-4.
8. Hillyard IW. The preclinical toxicology and safety of ribavirin. In: Smith RA, Kirkpatrick W, eds. Ribavirin: a broad spectrum antiviral agent. New York: Academic Press; 1980:59-71.
9. Sidwell RW, Robins RK, Hillyard IW. Ribavirin: an antiviral agent. Pharmacol Ther. 1979; 6:123-46.
10. Allen LB. Review of in vivo efficacy of ribavirin. In: Smith RA, Kirkpatrick W eds. Ribavirin: a broad spectrum antiviral agent. New York: Academic Press; 1980:43-58.
11. Vertex Pharmaceuticals Incorporated. Incivek® (telaprevir) film-coated tablets prescribing information. Cambridge, MA; 2012 Jun.
12. Merck & Co. Victrelis® (boceprevir) capsules prescribing information. Whitehouse Station, NJ; 2012 Apr.
13. Isaacs D, Moxon ER, Harvey D et al. Randomized trials and ribavirin. Arch Dis Child. 1988; 63:989-90.
14. Isaacs D. Ribavirin. Pediatrics. 1987; 79:289-91.
15. Schvarcz R, Ando Y, Sonnerborg A et al. Combination treatment with interferon alfa-2b and ribavirin for chronic hepatitis C in patients who have failed to achieve sustained response to interferon alone: Swedish experience. J Hepatol. 1995; 23(Suppl 2): 17-21.
16. Reichard O, Norkrans G, Fryden A et al et al. Randomised, double-blind, placebo-controlled trial of interferon α-2b with and without ribavirin for chronic hepatitis C. Lancet. 1998; 351:83-7.
17. Brown JL. Efficacy of combined interferon and ribavirin for treatment of hepatitis C. Lancet. 1998; 351:78-9.
18. Chemello L, Cavalletto L, Bernardinello E et al. The effect of interferon alfa and ribavirin combination therapy in naive patients with chronic hepatitis C. J Hepatol. 1995; 23(Suppl 2):8-12.
19. Schalm SW, Hansen BE, Chemello L et al. Ribavirin enhances the efficacy but not the adverse effects of interferon in chronic hepatitis C. Meta-analysis of individual patient data from European centers. J Hepatol. 1997; 26:961-6.
20. Lai MY, Kao JH, Yang PM et al. Long-term efficacy of ribavirin plus interferon alfa in the treatment of chronic hepatitis C. Gastroenterology. 1996; 111:1307-12.
21. Centers for Disease Control and Prevention. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. MMWR Morb Mortal Wkly Rep. 1998; 47(No. RR-19):14-5.
22. Poynard T, Marcellin P, Lee SS st al. Randomised trial of interferon α2b plus ribavirin for 48 weeks or for 24 weeks versus interferon α2b plus placebo for 48 weeks for treatment of chronic infection with hepatitis C virus. Lancet. 1998; 352:1426-32.
23. McHutchison JG, Gordon SC, Schiff ER et al. Interferon alfa-2b alone or in combination with ribavirin as initial treatment for chronic hepatitis C. N Engl J Med. 1998; 339:1485-92.
24. Davis GL, Esteban-Mur R, Rustgi V et al Interferon alfa-2b alone or in combination with ribavirin for the treatment of relapse of chronic hepatitis C. N Engl J Med. 1998; 339:1493-9.
25. Hoofnagle JH. Management of hepatitis C: current and future perspectives. J Hepatol. 1999; 31(Suppl 1):264-8.
26. Booth JCL, O'apos;Grady J, Neuberger J for the Royal College of Physicians of London and the British Society of Gastroenterology. Clinical guidelines on the management of hepatitis C. Gut. 2001; 49(Suppl):1-21.
27. European Association for the Study of the Liver (EASL) Consensus Panel. EASL international consensus conference on hepatitis C; Paris, 26-28 February 1999. J Hepatol. 1999; 30:956-61.
28. Manns MP, McHutchison JG, Gordon SC et al. Peginterferon alfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a randomised trial. Lancet. 2001; 358:958-65.
29. Merck & Co. Rebetol® (ribavirin) capsules, oral solution prescribing information. Whitehouse Station, NJ; 2012 Jul.
30. Zylberberg H, Benhamou Y, Lagneaux JL et al. Safety and efficacy of interferon-ribavirin combination therapy in HCV-HIV coinfected subjects: an early report. Gut. 2000; 47:694-7.
31. Genentech. Copegus® (ribavirin) tablets prescribing information. South San Francisco, CA; 2012 Nov.

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

32. McHutchison JG, Lawitz EJ, Shiffman ML et al. Peginterferon alfa-2b or alfa-2a with ribavirin for treatment of hepatitis C infection. N Engl J Med. 2009; 361:580-93.
33. Hadziyannis SJ, Sette H, Morgan TR et al. Peginterferon-alpha2a and ribavirin combination therapy in chronic hepatitis C: a randomized study of treatment duration and ribavirin dose. Ann Intern Med. 2004; 140:346-55.
34. Fried MW, Shiffman ML, Reddy KR et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection. N Engl J Med. 2002; 347:975-82.
35. Torriani FJ, Rodriguez-Torres M, Rockstroh JK et al. Peginterferon Alfa-2a plus ribavirin for chronic hepatitis C virus infection in HIV-infected patients. N Engl J Med. 2004; 351:438-50.
36. Wirth S, Ribes-Koninckx C, Calzado MA et al. High sustained virologic response rates in children with chronic hepatitis C receiving peginterferon alfa-2b plus ribavirin. J Hepatol. 2010; 52:501-7.
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.

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)
    - Used in combination with any other biologic DMARD or targeted synthetic DMARD
    - Used in combination with potent immunosuppressants azathioprine or 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

    - 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 polyangiits in adults and pediatric patients 2 years and older OR
- Follicular or Marginal Zone Lymphoma, AND
- Is being used with Revlimid (lenalidomide), ORModerate to severe active rheumatoid arthritis with at least four of the following symptoms:
    - Morning stiffness.
    - Arthritis of three (3) or more joint areas.
    - Arthritis of hand joints.
    - Symmetric arthritis.
    - Rheumatoid nodules.

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

- 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
  - Hydroxychoroquine 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

References

1. American College of Rheumatology 2008 Recommendations for the Use of Nonbiological and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. Arthritis & Rheum. 2008; 59(6):762-784.
2. Arnett FC, Edworthy SM, Bloc DA, et al. The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. Arthritis Rheum.1988:31:315-324
3. Canninga-van Dijk MR, Van Der Straaten HM, Fijnheer R, et al. Anti-CD 20 monoclonal antibody treatment in 6 patients with therapy-refractory chronic graft-versus host disease. Blood. 2004; 104:2603-2606.
4. Cutler C, Miklos D, Kim HT, et al. Rituximab for steroid-refractory chronic graft-versus host disease. Blood. 2006; 108:756-762.
5. Edwards JC, Szczepanski l, Szechinski J, et al. Efficacy of B-cell-targeted therapy with rituximab in patients with rheumatoid arthritis. N Engl J Med. 2004; 350:2572-2581.
6. Keystone E, Fleischmann R, Emery P, et al. Safety and efficacy of additional courses of rituximab in patients with active rheumatoid arthritis. Arthritis Rheum. 2007;56:3896-3908.
7. Non-Hodgkins 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.
8. Ratanatharathorn V, Carson E, Reynolds C, et al. Anti-CD 20 chimeric monoclonal antibody treatment of refractory immune-mediated thrombocytopenia in a patient with chronic graft-versus host disease. Ann Intern Med. 2000; 133:275-279.
9. Rituxan. 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

10. Rituximab. 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.
11. Zaja F, Baccarani M, Mazza P, et al. Dexamethasone plus rituximab yields higher sustained response rates than dexamethasone monotherapy in adults with primary immune thrombocytopenia. Blood. 2010;115:2755-2762.

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)

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

Requests for continuing 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 provided for ALL of the following
    - Plasminogen activity level ≤ 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

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

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

Contraindication:

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

Not approved if:

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

References
1. Virginia Premier

SABRIL (VIGABATRIN)

- Prescribed by a neurologist, AND
- Adjunct therapy for Refractory complex partial seizures, AND
  - ≥ 2 years of age, AND
  - Tried/failed/intolerance to two formulary anticonvulsants, AND
  - Prescriber confirmation that potential benefit outweighs the potential risk of vision loss, AND
  - Vision tested at baseline before beginning treatment and will be tested every 3 months thereafter, OR
- Infantile spasms, AND.
  - ≥ 1 month to ≤2 years of age, AND.
  - Prescriber confirmation that potential benefit outweighs the potential risk of vision loss, AND
  - Vision tested, when possible, at baseline before beginning treatment and will be tested every 3 months therafter.

Reauthorization/continuing therapy:

- Demonstrate clinical benefit, AND
- Confirmation of vision test within the last 3 months

References
1. Harden CI, Meador KJ, Pennell PB, et al. Practice Parameter update: Management issues for women with epilepsy—Focus on pregnancy (an evidence-based review): Teratogenesis and perinatal outcomes. Report of the Quality Standards Subcommittee and Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and American Epilepsy Society. Neurology. 2009;73:133-41.
2. Hemming K, Maguire MJ, Hutton JL, Marson AG. Vigabatrin for refractory partial epilepsy. Cochrane Database Syst Rev. 2008 July 16; (3):CD007302.
3. Sabril. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
4. Steering Committee on Quality Improvement and Management, Subcommittee on Febrile Seizures. Febrile Seizures: Clinical proactive guideline for the long-term management of the child with simple febrile seizures. Pediatrics 2008;121:1281-6.
5. Vigabatgrin. 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.

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

Requests for continuing 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 able to sense and respond appropriately to thirst, AND
- Patient is not Anuric

References

1. Gheorghiade M, Gottlieb SS, Udelson JE, et al; Tolvaptan Investigators. Vasopressin v(2) receptor blockade with tolvaptan versus fluid restriction in the treatment of hyponatremia. Am J Cardiol. 2006;97(7):1064-7.
2. Ho, J. and J. Teerlink, Role of Tolvaptan in Acute Decompensated Heart Failure. Expert Rev Cardiovasc Ther, 2008. 6(5): p. 601-8.
3. Konstam M et al. Efficacy of vasopressin antagonism in heart failure outcome study with tolvaptan (EVEREST) investigators. JAMA 2007;297:1319-31.
4. Rossi J, Bayram M, Udelson JE, et al. Improvement in hyponatremia during hospitalization for worsening heart failure is associated with improved outcomes: insights from the Acute and Chronic Therapeutic Impact of a Vasopressin Antagonist in Chronic Heart Failure (ACTIV in CHF) trial. Acute Card Care. 2007;9(2):82-6.
5. Samsca. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
6. Schrier RW, Gross P, Gheorghiade M, et al; SALT Investigators. Tolvaptan, a selective oral vasopressin V2-receptor antagonist, for hyponatremia. N Engl J Med. 2006;355(20):2099-112.
7. Udelson, J., et al., Acute Hemodynamic Effects of Tolvaptan, a Vasopressin V2 Receptor Blocker, in Patients with Symptomatic Heart Failure and Systolic Dysfunction. J Am Coll Cardiol, 2008. 52(19): 1540-5
8. Verbalis JG, Goldsmith SR, Greenberg A et al. Hyponatremia treatment guidelines 2007: an expert panel report. The American Journal of Medicine 2007;120:S1-S21.
9. Tolvaptan. 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.

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

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

1. Virginia Premier

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, Anit-Sm, Anti-Ro/SSA, Anti-La/SSB) AND
- 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

Requests for continuing 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 7/1/21

SAVAYSA (EDOXABAN)

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

SAVELLA (MILNACIPRAN HYDROCHLORIDE)

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

Caution

- Can increase blood pressure and heart rate
- Serotonin syndrome has been reported with SNRIs and SSRIs. Concomitant use of serotonergic drugs such as triptans, tramadol and drugs that inhibit serotonin reuptake, including Savellla, 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 behavnior in patients with depression or other psychiatric disorders taking Savella

Contraindications

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

Not approved if:

- Being used for depression.
- Patient has End Stage Renal Disease.

References

1. American College of Rheumatology. Diagnostic Criteria for Fibromyalgia 2010. Available from http://www.rheumatology.org/practice/clinical/classification/fibromyalgia/2010_preliminary_diagnostic_criteria.pdf.

Requests for continuing 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. Arnold LM, Goldenberg DL, Stanford SB, Lalonde JK, Sandun HS, et al. Gabapentin in the treatment of fibromyalgia: A randomized, double-blind, placebo-controlled, multicenter trial. Arthritis Rheum. 2007;56(4):1336-44.
3. Bortolotti B, Menchetti M, Bellini F, Montaguti MB, Berardi D. Psychological interventions for major depression in primary care: a meta-analytic review of randomized controlled trials. Gen Hosp Psychiatry. 2008 Jul-Aug;30(4):293-302.
4. Buckhardt CS, Goldenberg D, Crofford L, Gerwin R, Gowens S, et al. Guideline for the management of fibromyalgia syndrome pain in adults and children. Glenview (IL): American Pain Society (APS); 2005. 109 p. (Clinical practice guideline; no. 4). Available from http://www.guidelinecentral.com/_webapp_1825321/Guideline_for_the_management_of_fibromyalgia_syndrome_pain_in_adults_and_children.
5. Cipriani A, Furukawa TA, Salanti G, et. al. Comparative efficacy and acceptability of 12 new-generation antidepressants: a multiple-treatments meta-analysis. Lancet. 2009 Feb 28;373(9665):746-58.
6. Clauw DJ, Mease P, Plamer RH. Milnacipran for the treatment of fibromyalgia in adults: a 15-week, multicenter, randomized, double-blind, placebo-controlled, multiple-dose clinical trial. Clin Ther. 2008;30(11):1988-2004.
7. Clauw DJ, Mease P, Palmer RH, Gendreau RM, Wang Y. Milnacipran for the treatment of fibromyalgia in adults: a 15-week, multicenter, randomized, double-blind, placebo-controlled, multiple-dose clinical trial. Clin Ther. 2008 Nov;30(11):1988-2004.
8. Gartlehner G, Hansen RA, Thieda P, DeVeaugh-Geiss AM, Gaynes BN, Krebs EE, Lux LJ, Morgan LC, Shumate JA, Monroe LG, Lohr KN. Comparative Effectiveness of Second-Generation Antidepressants in the Pharmacologic Treatment of Adult Depression. Comparative Effectiveness Review No. 7. (Prepared by RTI International-University of North Carolina Evidence-based Practice Center under Contract No. 290-02-0016.) Rockville, MD: Agency for Healthcare Research and Quality. January 2007. Available from http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=61.
9. Gartlehner G, Gaynes BN, Hansen RA, et. al. Comparative benefits and harms of second-generation antidepressants: background paper for the American College of Physicians. Ann Intern Med. 2008 Nov 18;149(10):734-50.
10. Goldenberg DL, Buckhardt C, Crofford L. Management of fibromyalgia syndrome. J Am Med Assoc. 2004;292:2388-95.
11. Guelfi JD, Ansseau M, Corruble E, Samuelian JC, Tonelli I, Tournoux A, Plétan Y. A double-blind comparison of the efficacy and safety of milnacipran and fluoxetine in depressed inpatients. Int Clin Psychopharmacol. 1998 May;13(3):121-8.
12. Hansen R, Gaynes B, Thieda P, et al. Meta-analysis of major depressive disorder relapse and recurrence with second-generation antidepressants. Psychiatr Serv. 2008 Oct;59(10):1121-30.
13. Milnacipran. 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.
14. Rush AJ, Trivedi MH, Wisniewski SR, et al. Bupropion-SR, sertraline, or venlafaxine-XR after failure of SSRIs for depression. N Engl J Med. 2006 Mar 23;354(12):1231-42.
15. Savella. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
16. Steen A, Den Boer JA. A double-blind six months comparative study of milnacipran and clomipramine in major depressive disorder. Int Clin Psychopharmacol. 1997 Sep;12(5):269-81.
17. Sechter D, Vandel P, Weiller E, Pezous N, Cabanac F, Tournoux A; study co-coordinators. A comparative study of milnacipran and paroxetine in outpatients with major depression. J Affect Disord. 2004 Dec;83(2-3):233-6.
18. Tignol J, Pujol-Domenech J, Chartres JP, Léger JM, Plétan Y, Tonelli I, Tournoux A, Pezous N. Double-blind study of the efficacy and safety of milnacipran and imipramine in elderly patients with major depressive episode. Acta Psychiatr Scand. 1998 Feb;97(2):157-65.
19. Trivedi MH, Fava M, Wisniewski SR, et al. ; STAR-D Study Team. Medication augmentation after the failure of SSRIs for depression. N Engl J Med. 2006 Mar 23;354(12):1243-52.
20. Watanabe N, Omori IM, Nakagawa A, et. al. Multiple Meta-Analyses of New Generation Antidepressants (MANGA) Study Group. Mirtazapine versus other antidepressants in the acute-phase treatment of adults with major depression: systematic review and meta-analysis. J Clin Psychiatry. 2008 Sep;69(9):1404-15.

SAXENDA (LIRAGLUTIDE)

CRITERIA FOR USE:

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

- Member is 18 years of age or older, AND
- Member currently has a BMI ≥ 30 kg/m^2 OR
- Member has a BMI ≥ 27 kg/m^2 for those with risk factors besides obesity (e.g. diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea OR
- Member is 12-17 years of age; AND
- Member has body weight above 60kg; AND
- Member has initial BMI corresponding to 30kg/m2 or greater for adults (obese) by international cut-offs; AND
- Member is currently engaged in behavioral modification and on a reduced calorie diet, AND
- Member has had a trial and failure, intolerance, or contraindication to at least one (1) of the following if indicated in members age:
    - Adipex-P (Phentermine)
    - Xenical
    - Contrave
    - Qsymia

RENEWAL:

- Member has lost at least 4% or baseline bodyweight OR
- Member has lost at least 1% of baseline bodyweight for age 12-17 years and older

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

Dosing:
Chronic weight management: SubQ: Initial: 0.6 mg once daily for one week; increase by 0.6 mg daily at weekly intervals to a target dose of 3 mg once daily. If the patient cannot tolerate an increased dose during dose escalation, consider delaying dose escalation for one week. If the 3 mg daily dose is not tolerated, discontinue use as efficacy has not been established at lower doses.

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

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**

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

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)

REFERENCES

1. Sensipar [package insert]. Thousand Oaks, CA: Amgen, Inc.; November 2014.
2. Micromedex Solutions [database online]. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: www.micromedexsolutions.com. Accessed November 18, 2016.
3. AHFS DI (Adult and Pediatric) [database online]. Lexi-Comp, Inc. Hudson, OH. Available at: http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed November 18, 2016.
4. Clinical Pharmacology [Internet]. Elsevier. Tampa (FL). Available from: http://www.clinicalpharmacology.com. Accessed November 18, 2016.
5. Evenepoel P, Cooper K, Holdaas H, et al. A randomized study evaluating cinacalcet to treat hypercalcemia in renal transplant recipients with persistent hyperparathyroidism. *Am J Transplant* 2014;14:2545-2555.
6. Kruse AE, Ensenberger U, Frey FJ, et al. The calcimimetic cinacalcet normalizes serum calcium in renal transplant patients with persistent hyperparathyroidism. *Nephrol Dial Transplant*. 2005;20:1311-1314.
7. Srinivas TR, Schold JD, Womer KL, et al. Improvement in hypercalcemia with cinacalcet after kidney transplantation. *Clin J Am Soc Nephrol*. 2006;1:323–326.
8. Shoback D. Hypoparathyroidism. *NEJM*. 2008;359: 391-403.

SGLT2 (FARXIGA/INVOKANA)

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

- Farxiga and Invokana Indications:
  - Must be clinically diagnosed with type 2 diabetes.
  - Must have tried and failed or had an inadequate response to metformin (HgbA1c signifies control, A1c greater than or equal to 7.6% qualifies for approval and A1c >9% does not require trial of metformin); **OR**
  - Patient is intolerant to Metformin
  - 18 years of age or older
- Farxiga Only
  - Is being used to reduce the risk of cardiovascular death and hospitalization for heart failure patients (NYHA II-IV) with reduced ejection fraction
  - 18 years of age or older
- Farxiga Only
  - To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in patients with chronic kidney disease of risk or progression
  - Patient is 18 years of age or older

Contraindication:

• History of serious hypersensitivity reaction to Invokana
• Severe renal impairment, ESRD, or on dialysis.

Not approved if:

• Have any contraindications to the use of Invokana
• Does not meet the above stated criteria.

Requests for continuing 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
Initial – 6 months, Renewal – 12 months

LAST REVISION: 11/1/21

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
        - 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.

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

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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

FDA-Approved Indications

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

- Member has a diagnosis of moderately to severely active ulcerative colitis; AND
- Member is 18 years of age or older; AND
- Member has trial and failure of a compliant regimen of oral or rectal aminosalicylates (i.e., sulfasalazine or mesalamine) for two consecutive months, AND
- 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
- 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 TNFα antagonist (e.g., adalimumab, certolizumab pegol (Cimzia®), etanercept, infliximab), anakinra, rituximab, abatacept, or tocilizumab (Actemra).**

Combination therapy with two biologic agents is not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy.

Requests for continuing 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. **Plaque psoriasis without psoriatic arthritis.**
Golimumab has been studied in patients with psoriatic arthritis who had plaque psoriasis. Plaque psoriasis improved in these patients with a PASI-75 being attained by 40% of patients on golimumab 50 mg every 4 weeks and by 58% in the golimumab 100 mg group at week 14. Golimumab is FDA-approved in patients with psoriatic arthritis, but not in patients with plaque psoriasis without psoriatic arthritis. Prospective, controlled trials are needed to determine safety and efficacy in plaque psoriasis. The other TNFα antagonists, adalimumab, etanercept and infliximab are FDA-approved for the treatment of plaque psoriasis.

3. **Asthma.**
In a double-blind trial, 309 patients with uncontrolled, severe asthma despite high-dose inhaled corticosteroids and long-acting beta-2 agonists were randomized to golimumab 50, 100, or 200 mg or to placebo for 52 weeks. No significant differences were observed for change in percent-predicted FEV_1 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

1. 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 (Arthritis Care & Research). Vol. 59, No. 6. June 15, 2008, pp. 762-784.
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*
3. Braun J, Pham T, Sieper J, et al. ASAS Working Group. International ASAS consensus statement for the use of anti-tumor necrosis factor agents in patients with ankylosing spondylitis. Ann Rheum Dis. 2003;62:817-824.
4. Janssen Biotech Inc. Simponi® (golimumab) injection prescribing information. Horsham, PA; 2011 Sep.
5. Smolen JS, Kay J, Doyle MK et al. Golimumab in patients with active rheumatoid arthritis after treatment with tumour necrosis factor alpha inhibitors (GO-AFTER study): a multicentre, randomised, double-blind, placebo-controlled, phase III trial. *Lancet*. 2009; 374:210-21.
6. Keystone EC, Genovese MC, Klareskog L et al. Golimumab, a human antibody to tumour necrosis factor alpha given by monthly subcutaneous injections, in active rheumatoid arthritis despite methotrexate therapy: the GO-FORWARD Study. *Ann Rheum Dis*. 2009; 68:789-96.
7. Emery P, Fleischmann RM, Moreland LW et al. Golimumab, a human anti-tumor necrosis factor alpha monoclonal antibody, injected subcutaneously every four weeks in methotrexate-naive patients with active rheumatoid arthritis: twenty-four-week results of a phase III, multicenter, randomized, double-blind, placebo-controlled study of golimumab before methotrexate as first-line therapy for early-onset rheumatoid arthritis. *Arthritis Rheum*. 2009; 60:2272-83.
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.
9. Inman RD, Davis JC, Heijde D et al. Efficacy and safety of golimumab in patients with ankylosing spondylitis: results of a randomized, double-blind, placebo-controlled, phase III trial. *Arthritis Rheum*. 2008; 58:3402-12.
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.
11. McCluggage LK, Scholtz JM. Golimumab: a tumor necrosis factor alpha inhibitor for the treatment of rheumatoid arthritis. *Ann Pharmacother*. 2010; 44:135-44.
12. Keystone E, Genovese MC, Klareskog L et al. Golimumab in patients with active rheumatoid arthritis despite methotrexate therapy: 52-week results of the GO-FORWARD study. *Ann Rheum Dis*. 2010; 69:1129-35.
13. Campas-Moya C. Golimumab: A novel anti-TNF-alpha human monoclonal antibody for rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. *Drugs Today (Barc)*. 2010; 46:13-22.

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

SKYRIZI (RISANKIZUMAB-RZAA)

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 ≥ 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 ≥ 1systemic 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

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 hemapoetic clones (Type III PNH red blood cells [RBC]) via flow cytometry **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 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

Requests for continuing 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: 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**
- 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.
2. Soliris. 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

SOLODYN (MINOCYCLINE) EXTENDED-RELEASE

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

- Clinically documented inflammatory lesions of non-nodular moderate to severe acne.
- Must be 12 years of age or older.
- Failed/intolerant to topical combinations.
- Intolerant to an excipient in the immediate release minocycline

Contraindications:

- Hypersensitivity to any of the tetracyclines

Not Approved if:

- Lesions are non-inflammatory.
- Have any contraindications to the use of Solodyne.
- Does not meet the above stated criteria.

Special Considerations:

- There is no evidence that Solodyne is superior to its generic minocycline for treating acne. For patients who require antibiotic treatment generic minocycline is a less expensive option.

Duration of Therapy: 12 weeks (safety beyond this point has not been established).

References

1. Virginia Premier

SONATA (ZALEPLON)

- FDA age indications
- Must have tried and failed Zolpidem, Rozerem and sedative benzodiazepines
- Should not be prescribed in quantities exceeding a 1-month supply and no refills allowed.

References

1. Virginia Premier

SORIATANE (ACITRETIN)

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

- Must be used for treatment of moderate to severe Psoriasis
- Trial and failure, intolerance, or contraindication to, 90 day trial of Methotrexate
- Trial and failure, intolerance, or contraindication to, 90 day trial of high dose topical steroid (i.e. betamethasone augmented, halobetasol)
- Prescribed by, or in consultation with, a Dermatologist

Requests for continuing 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 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)
  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

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

SPINRAZA (NUSINERSEN)

- **Note: covered through pharmacy benefit only at specified pharmacies, all other claims through Medical Benefit

Partially approve, move to client queue, and send email to COPTeam@elixirsolutions.com, to be forwarded to client for review by Medical Directors.

1. The treatment of **Spinal Muscular Atrophy (SMA)** in patients who meet **all** of the following criteria:

a. For **initial therapy**, **all** of the following:

(1) **One** of the following:

(a) Diagnosis of spinal muscular atrophy type I, II, or III by a neurologist with expertise in the diagnosis of SMA.

(b) Diagnosis of spinal muscular atrophy type I, II, or III by a physician in consultation with a neurologist with expertise in the diagnosis of SMA.

AND

(2) Submission of medical records (e.g., chart notes, laboratory values) confirming **both** of the following:

(a) The mutation or deletion of genes in chromosome 5q resulting in **one** of the following:

i. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13).1,2

OR

ii. Compound heterozygous mutation (e.g., deletion of SMN1 exon 7[allele 1] and mutation of SMN1 [allele 2])

AND

(b) Patient has at least 2 copies of SMN2

AND

(3) Patient is **not** dependent on **either** of the following:

(a) Invasive ventilation or tracheostomy

(b) Non-invasive ventilation for at least 6 hours per day

AND

(4) Submission of medical records (e.g., chart notes, laboratory values) of the baseline exam of at least **one** of the following exams (based on patient age and motor ability) to establish baseline motor ability:

(a) Hammersmith Infant Neurological Exam (**HINE**)1,8,12 (infant to early childhood)

(b) Hammersmith Functional Motor Scale Expanded (**HFMSE**)1,9,13-14

(c) Upper Limb Module (**ULM**) Test (Non ambulatory)1,9,

(d) Children's Hospital of Philadelphia Infant Test of Neuromucular Disorders (**CHOP INTEND**)1,8

AND

(5) One of the following:

(a) Spinraza is prescribed by a neurologist with expertise in the treatment of SMA

(b) Spinraza is prescribed by a physician in consultation with a neurologist with expertise in the treatment of SMA

AND

(6) Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures.

AND

(7) Spinraza dosing for SMA is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12mg for each loading dose.

AND

(8) Initial authorization will be for no more than 4 loading doses

Continuation of Therapy

For **continuation therapy**, **all** of the following:

(1) **One** of the following

(a) Diagnosis of spinal muscular atrophy type I, II, or III by a neurologist with expertise in the diagnosis of SMA.

(b) Diagnosis of spinal muscular atrophy type I, II, or III by a physician in consultation with a neurologist with expertise in the diagnosis of SMA.

AND

(2) Submission of medical records (e.g., chart notes, laboratory values) confirming **both** of the following:

(a) The mutation or deletion of genes in chromosome 5q resulting in **one** of the following:

i. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13).1,2

OR

ii. Compound heterozygous mutation (e.g., deletion of SMN1 exon 7[allele 1] and mutation of SMN1 [allele 2])

AND

(b) Patient has at least 2 copies of SMN2

AND

(3) Patient is **not** dependent on **either** of the following:

(a) Invasive ventilation or tracheostomy

(b) Non-invasive ventilation for at least 6 hours per day

AND

(4) Submission of medical records (e.g., chart notes, laboratory values) with the most recent results (< 1 month prior to request) documenting a positive clinical response **from pretreatment baseline status** to Spinraza therapy as demonstrated by at least **one** of the following exams:

(a) **HINE** milestones :

i. **One** of the following:

(i) Improvement or maintenance of previous improvement of at least 2 point (or maximal score) increase in ability to kick

(ii) Improvement or maintenance of previous improvement of at least 1 point increase in any other HINE milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp.

AND

ii. **One** of the following:
(i) The patient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement).
(ii) Achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk).

OR

(b) **HFMSE: One** of the following:
i. Improvement or maintenance of previous improvement of at least a 3 point increase in score from pretreatment baseline
ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

(c) **ULM: One** of the following:
i. Improvement or maintenance of previous improvement of at least a 2 point increase in score from pretreatment baseline
ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

(d) **CHOP INTEND: One** of the following:
i. Improvement or maintenance of previous improvement of at least a 4 point increase in score from pretreatment baseline
ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

AND

(5) **One** of the following:
(a) Spinraza is prescribed by a neurologist with expertise in the treatment of SMA
(b) Spinraza is prescribed by a physician in consultation with a neurologist with expertise in the treatment of SMA

AND

(6) Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures.

AND

(7) Spinraza dosing for SMA is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12mg every 4 months, starting 4 months after the last loading dose.

AND

(8) Reauthorization will be for no more than 3 maintenance doses (12 months).
Spinraza **is not proven or medically necessary** for spinal muscular atrophy without chromosome 5q mutations or deletions.

I. Length of Authorization

Coverage will be provided annually and may be renewed**.**

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Loading: 1 vial on D1, D15, D29, and D59
- Maintenance: 1 vial (5ml) every 112 days

Requests for continuing 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. Max Units (per dose and over time) [Medical Benefit]:

- Loading: 12 mg (1-vial-5ml) on D1, D15, D29, and D59
- Maintenance: 12 mg (1-vial-5ml) every 112 days

Store refrigerated at 2^0C to 8^0C; warm to room temperature prior to administration

References

1. Spinraza [package insert]. Cambridge, MA: Biogen, Inc, December 2016.
2. Markowitz JA, Singh P, Darras BT. Spinal Muscular Atrophy: A Clinical and Research Update. Pediatric Neurology 46 (2012) 1-12.
3. Sugarman EA, Nagan N, Zhu H, et al. Pan-ethnic carrier screening and prenatal diagnosis for spinal muscular atrophy: clinical laboratory analysis of >72,400 specimens. Eur J Hum Genet 2012;20:27-32.
4. Prior TW, Snyder PJ, Rink BD, et al. Newborn and carrier screening for spinal muscular atrophy. Am J Med Genet A. 2010 Jul;152A(7):1608-16.
5. United States Census Bureau. http://www.census.gov/popclock/. Accessed January 2017.
6. World Population Statistics. http://www.worldpopulationstatistics.com/poplation-of-europe/. Accessed January 2017.
7. Lunn MR, Wang CH. Spinal muscular atrophy. Lancet. 2008 Jun 21;371(9630):2120-33.
8. Ionis Pharmaceuticals, Inc. A Study to Assess the Efficacy and Safety of IONIS-SMN Rx in Infants With Spinal Muscular Atrophy. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2017 Jan 6]. Available from: https://clinicaltrials.gov/show/NCT02193074 NLM Identifier: NCT02193074.
9. Ionis Pharmaceuticals, Inc. A Study to Assess the Efficacy and Safety of IONIS-SMN Rx in Patients With Later-onset Spinal Muscular Atrophy. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2017 Jan 6]. Available from: https://clinicaltrials.gov/show/NCT02292537 NLM Identifier: NCT02292537.
10. Finkel RS, Chiriboga CA, Vajsar J, et al. Treatment of infantile-onset spinal muscular atrophy with nusinersen: a phase 2, open-label, dose-escalation study. Lancet. 2017 Dec 17;388(10063):3017-3026.
11. Chiriboga CA, Swoboda KJ, Darras BT, et al. Results from a phase 1 study of nusinersen (ISIS-SMN(Rx)) in children with spinal muscular atrophy. Neurology. 2016 Mar 8;86(10):890-7.
12. Haataja L, Mercuri E, Regev R, et al. Optimality score for the neurologic examination of the infant at 12 and 18 months of age. J Pediatr. 1999 Aug;135(2 Pt 1):153-61.
13. Glanzman AM, O'Hagen JM, McDermott MP, et al. Validation of the Expanded Hammersmith Functional Motor Scale in spinal muscular atrophy type II and III. J Child Neurol. 2011;26(12):1499-507.
14. O'Hagen JM, Glanzman AM, McDermott MP, et al. An expanded version of the Hammersmith Functional Motor Scale for SMA II and III patients. Neuromuscular disorders : NMD. 2007;17(9-10):693-7.

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

Requests for continuing 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 dermal fungal infections (not including onychomycosis) where topical antifungal agents are considered first line therapy:
  - Patient must have failed/intolerant to both an OTC and Rx topical antifungal agent used for an appropriate length of time

  Or
  - Patient has an extensive infection involving areas too large to reasonably use a topical agent

  Or
  - Patient has a chronic, recalcitrant infection

  Or
  - Patient is immunocompromised

Contraindications:

- Congestive heart failure
- Concomitant administration of itraconazole with drugs metabolized by CYP3A4: oral midazolam, pimozide, quinidine, dofetilide, tirazolam, lovastatin, and simvastatin.

Duration of Therapy:

Toenail onychomycosis -12 weeks

Fingernail onychomycosis – 5 weeks (2 treatment pulses for 1 week separated by 3 weeks)

References

1. Virginia Premier

SPRIX (KETOROLAC TROMETHAMINE) INTRANASAL

*****Partially approve the EOC and submit to the PA Hub Client Sign-off queue. Send an e-mail to COPTeam@elixirsolutions.com and the "CC" the CDPharmacist e-mail distribution box, noting the EOC # and requested indication for use.**

PA criteria for FDA age indications.

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

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Clinically documented acute pain
- Failed/intolerant to generic NSAID's
- Failed/intolerant to Celebrex (Celebrex requires a PA)
- Failed/intolerant to VPHP preferred opioids including morphine sulfate, Fentanyl patches
- Failed/intolerant to generic ketorolac tromethamine tablets (ketorolac tablets requires a PA)

Requests for continuing 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 combined duration of use of any form of ketorolac is not to exceed 5 days
- Total daily dose of Sprix not to exceed 126mg (1 bottle per day)

Not approved if:

- Patient is less than 18 years of age
- Patient has high risk of GI bleed
- Patient has any risk of bleed potential, including CVA, TIA
- Patient needs medication for a longer period than 5 days

Duration of therapy: Maximum of 5 days

References

1. Virginia Premier

STELARA (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 ≥ 5%.
   Exceptions can be made to the requirement for ≥ 5% BSA involvement in the following instances (i or ii):
   i. Patients with plaque psoriasis of the palms, soles, head and neck, nails, intertriginous areas or genitalia are not required to have a minimum BSA involvement OR
   ii. The patient who meets all four of the following conditions (bullet points) is not required to have a minimum BSA involvement:
   - Patient has had an inadequate response to a 3-month trial of either topical therapy OR localized phototherapy with ultraviolet B (UVB) or oral methoxsalen plus UVA light (PUVA) and
   - Patient has had an inadequate response to a 3-month trial of systemic therapy with one of the following: MTX, cyclosporine, or acitretin (Soriatane®) or has contraindications to all of these and
   - Patient has tried a tumor necrosis factor (TNF) antagonist [adalimumab (Humira®), etanercept, infliximab (Remicade®)] and
   - Patient has significant disability or impairment in physical or mental functioning, according to the treating physician.

Note: Patients who meet the criteria under 1bii are not required to meet 1c below.
AND

c. Patient has tried systemic therapy or phototherapy for 3 months with one of the following: acitretin (Soriatane®), cyclosporine, methotrexate, or phototherapy with UVB or PUVA for psoriasis. Rarely, a patient may have contraindications to nearly all of these other therapies and patients will be evaluated by a pharmacist and/or a physician on a case-by-case basis to determine a coverage recommendation for the client. (Due to its toxicity, ustekinumab therapy should be reserved for patients who have not responded well or are intolerant to other standard systemic therapy. In addition, the National Psoriasis Foundation Clinical Consensus, states that there currently are no prognostic factors that ascertain which therapies will be most efficacious and least toxic.)

AND

d. Patient has tried adalimumab, etanercept, or infliximab for plaque psoriasis.

2. **Psoriatic arthritis without plaque psoriasis.**
    1. Individual is 18 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 infusioin 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).

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

1. **Ustekinumab should not be given in combination with a TNFα antagonist (e.g., adalimumab [Humira®], certolizumab pegol [Cimzia®], etanercept [Enbrel®], golimumab [Simponi™], infliximab [Remicade®]), anakinra (Kineret®), or alefacept (Amevive®).**
   Combination therapy with two biologic agents is not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy.

2. **Children or adolescents ≤ 11 years of age.**
   Safety and efficacy in pediatric patients have not been established.

3. **Multiple sclerosis.**
   In a Phase II double-blind trial, 249 adult patients with relapsing-remitting multiple sclerosis were randomized to one of four different ustekinumab SC doses or placebo for 19 weeks. No statistically significant or clinically meaningful differences in the cumulative number of new lesions on serial cranial magnetic resonance imaging (MRI) through Week 23 between any of the ustekinumab dosage groups and placebo were observed.

Other indications. Exceptions not recommended. Case reports have documented some efficacy in the treatment of pityriasis rubra pilaris and variable efficacy for treatment of palmoplantar pustulosis with ustekinumab. Controlled clinical trials are needed to evaluate the safety and efficacy of ustekinumab in conditions not mentioned in the authorization criteria.

References

1. Chandler SKD, Griffiths CEM, Helliwell P. Guideline for anti-TNF-a therapy in psoriatic arthritis. *Rheumatology* 2005; 44:390-97

Requests for continuing 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. 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.
4. Griffiths CE, Strober BE, van de Kerkhof P et al. Comparison of ustekinumab and etanercept for moderate-to-severe psoriasis. *N Engl J Med*. 2010; 362:118-28.
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.

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

Requests for continuing 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 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 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

SUBOXONE (BUPRENORPHINE/NALOXONE)

Initial

- Clinically diagnosed with opioid dependence
    - FDA approved indication is for treatment of opioid dependence only, **NOT** pain management.
- Must be 16 years of age or older
- Patient must be participating in psychosocial counseling (individual or group) at least once per week
- Must provide name and phone number of behavioral health care provider that is providing counseling
- Prescriber must have reviewed the Virginia Controlled Substance Database Prescription Monitoring Program (PMP) **before the initiation of therapy** (https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx)
    - Must provide date of last opioid prescription
    - Must provide date of last benzodiazepine prescription
- Prescriber must confirm that the patient is **NOT** concurrently taking any stimulant medication
- Patient must not be taking a Benzodiazepine concurrently (if patient is taking, approve for one month only and prescriber must resubmit)

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

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

Maintenance

- Clinically diagnosed with opioid dependence
    - FDA approved indication is for treatment of opioid dependence only, **NOT** pain management.
- Must be 16 years of age or older
- Patient must be participating in psychosocial counseling (individual or group) at least once to twice per month
- Prescriber must review the PMP Web Site **on the date of the request for maintenance therapy**
- Prescriber must confirm that patient is **NOT** concurrently taking any of the following medications during Maintenance (These medications ***will not*** be allowed to be prescribed or taken concurrently with buprenorphine containing drugs)
    - Benzodiazepines, Tramadol (Ultram), Carisoprodol (Soma), other opiates, or stimulants
    - Prescriber must provide a tapering plan and document medical reasoning for co-prescribing these substances (may authorize up to a maximum of 3 months for tapering)
- Prescriber must check random urine drug screens
    - Urine drug screens must check for buprenorphine, norbuprenorphine, methadone, oxycodone, benzodiazepines, amphetamine/methamphetamine, cocaine, heroin, and other prescription opiates
- Prescriber must provide the **last 2 urine drug screens (with at least 1 of these screenings within the past month)**
    - Drug screens must be positive for buprenorphine/norbuprenorphine and negative for all other substances
    - If a drug screen is negative for buprenorphine/norbuprenorphine and/or positive for another substance, written documentation of steps being taken to address patient's possible diversion of buprenorphine and/or ongoing use of other substances including intensifying the counseling that patient is receiving and/or considering referral to higher level of care (such as

intensive outpatient, partial hospitalization, or residential treatment) **MUST** be provided
    - A 1x, 30 day supply will be allowed for failure of (positive) drug screens/UDS medical records/chart notes **for the drugs listed above.** Another prior authorization request would be needed for the next authorization and must include a new clean drug screen/UDS medical record/chart note (from the last EOC submission), otherwise will result in denial of request for continued therapy.
- A quantity limit is in place of 16mg of buprenorphine per day. Authorization can be provided for up to 24mg/day of buprenorphine if needed. Doses over 24mg per day cannot be approved. Authorization will be good for 6 months

- **Quantity Limits**
    - Suboxone SL Film 2-0.5 mg 3/day – 3 films per day
    - Suboxone SL Film 4-1 mg 1/day – 1 film per day
    - Suboxone SL Film 8-2 mg/day - 2 films per day
    - Suboxone SL Film 12-3 mg/day – 1 film per day

Block all other opioids from adjudictiong for the patient, when approving Suboxone

References

1. Buprenorphine. 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. Center for Substance Abuse Treatment. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) Series 40. DHS Publication No. (SMA) 04-3939. Rockville, Md: Substance Abuse and Mental Health Services Administration; 2004. Available from http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf. Accessed July 5, 2011.
3. Johnson RE, Jaffe JH, Fundala PJ. A controlled trial of buprenorphine treatment for opioid dependence. JAMA. 1992;267(20):2750-2755.
4. Ling W, Charuvastra C, Collins JF, et al. Buprenorphine maintenance treatment of opiate dependence: a multicenter, randomized clinical trial. Addiction.1998;93(4):475-486.
5. Mattick RP, Ali R, White J, O'Brien S, Wolk S, Danz C. Buprenorphine versus methadone maintenance therapy: a randomised double-blind with 405 opioid-dependent patients. Addiction. 2003;98:441-452.
6. Naloxone. 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.
7. Suboxone. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
8. The Management of Substance Use Disorders Working Group. VHA/DoD Clinical practice guideline for the management of substance use disorders. v. 2.0 Available from http://www.healthquality.va.gov/sud/sud_full_601f.pdf.
9. Virginia Premier

SUNOSI (Solriamfetol)

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
- 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
- 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.
4. Corrado EM, Peluso GF, Gigliotti S. The effects of intra-articular administration of hyaluronic acid on osteoarthritis of the knee: A clinical study with immunological and biochemical evaluations. Eur J Rheumatol Inflamm. 1995;15:47-56.
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.

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

10. Lohmander LS, Dalen N, Englund G, H, et al. Intra-articular hyaluronan injections in the treatment of osteoarthritis of the knee: A randomised, double blind, placebo controlled multicentre trial. Hyaluronan Multicentre Trial Group. Ann Rheum Dis. 1996;55(7):424-431.
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. Supartz. 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.

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
- 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 willl NOT be treated with interferon alfa (Roferon-A, Pegasys, Intron-A, Peg-Intron) or interleukin-2 (Proleukin) therapy in combination with Sutent treatment, AND
  - If the patient is female and of childbearing years (12 – 45 years of age), she is NOT pregnant, has NO plans for pregnancy and has been educated on the potential dangers of Sutent therapy in pregnancy.

Reauthorization/continuing therapy:

- If the patient has received previous Sutent therapy, he/she has no evidence of disease progression (tumor growth) since initiating Sutent therapy.

References

1. Barrios CH, Liu MC, Lee SC, et. al. Phase III randomized trial of sunitinib versus capecitabine in patients with previously treated HER2-negative advanced breast cancer. Breast Cancer Res Treat. 2010 May;121(1):121-31.
2. 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.
3. Burstein HJ, Elias AD, Rugo HS, et. al. Phase II study of sunitinib malate, an oral multitargeted tyrosine kinase inhibitor, in patients with metastatic breast cancer previously treated with an anthracycline and a taxane. J Clin Oncol. 2008 Apr 10;26(11):1810-6
4. Choueiri TK, Plantade A, Elson P, et al. Efficacy of sunitinib and sorafenib in metastatic papillary and chromophobe renal cell carcinoma. J Clin Oncol. 2008 Jan 1;26(1):127-31.
5. Chu TF, Rupnick MA, Kerkela R, et al. Cardiotoxicity associated with tyrosine kinase inhibitor sunitinib. Lancet. 2007 Dec 15;370(9604):2011-9.

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

6. Demetri GD, van Oosterom AT, Garrett CR, Blackstein ME, Shah MH, Verweij J, et al. Efficacy and safety of sunitinib in patients with advanced gastrointestinal stromal tumour after failure of imatinib: a randomized controlled trial. Lancet. 2006 Oct 14;368(9544):1329-38.
7. Desai J, Yassa L, Marqusee E, George S, Frates MC, Chen MH, Hypothyroidism after sunitinib treatment for patients with gastrointestinal stromal tumors. Ann Intern Med. 2006 Nov 7;145(9):660-4.
8. Dror Michaelson M, Regan MM, Oh WK, Kaufman DS, Olivier K, Michaelson SZ, Spicer B, Gurski C, Kantoff PW, Smith MR. Phase II study of sunitinib in men with advanced prostate cancer. Ann Oncol. 2009 May;20(5):913-20.
9. Escudier B, Roigas J, Gillessen S, et al. Phase II study of sunitinib administered in a continuous once-daily dosing regimen in patients with cytokine-refractory metastatic renal cell carcinoma. J Clin Oncol. 2009 Sep 1;27(25):4068-75.
10. Fiedler W, et al. "A phase 1 study of SU11248 in the treatment of patients with refractory or resistant acute myeloid leukemia (AML) or not amenable to conventional therapy for the disease." Blood. 2005;105:986-93.
11. Faivre S, Delbaldo C, Vera K, Robert C, Lozahic S, Lassau N, Safety, pharmacokinetic, and antitumor activity of SU11248, a novel oral multitarget tyrosine kinase inhibitor, in patients with cancer. J Clin Oncol. 2006 Jan 1;24(1):25-35.
12. Faivre S, Raymond E, Boucher E, Douillard J, Lim HY, Kim JS, Zappa M, Lanzalone S, Lin X, Deprimo S, Harmon C, Ruiz-Garcia A, Lechuga MJ, Cheng AL. Safety and efficacy of sunitinib in patients with advanced hepatocellular carcinoma: an open-label, multicentre, phase II study. Lancet Oncol. 2009 Aug;10(8):794-800.
13. Fountzilas G, Fragkoulidi A, Kalogera-Fountzila A, Nikolaidou M, Bobos M, Calderaro J, Andreiuolo F, Marselos M. A phase II study of sunitinib in patients with recurrent and/or metastatic non-nasopharyngeal head and neck cancer. Cancer Chemother Pharmacol. 2010 Mar;65(4):649-60.
14. George S, Blay JY, Casali PG, et. al. Clinical evaluation of continuous daily dosing of sunitinib malate in patients with advanced gastrointestinal stromal tumour after imatinib failure. Eur J Cancer. 2009 Jul;45(11):1959-68.
15. George S, Merriam P, Maki RG, Van den Abbeele AD, Yap JT, Akhurst T, Harmon DC, Bhuchar G, O'Mara MM, D'Adamo DR, Morgan J, Schwartz GK, Wagner AJ, Butrynski JE, Demetri GD, Keohan ML. Multicenter phase II trial of sunitinib in the treatment of nongastrointestinal stromal tumor sarcomas. J Clin Oncol. 2009 Jul 1;27(19):3154-60.
16. Hensley ML, Sill MW, Scribner DR Jr, Brown J, Debernardo RL, Hartenbach EM, McCourt CK, Bosscher JR, Gehrig PA. Sunitinib malate in the treatment of recurrent or persistent uterine leiomyosarcoma: a Gynecologic Oncology Group phase II study. Gynecol Oncol. 2009 Dec;115(3):460-5.
17. 26. Mackay HJ, Tinker A, Winquist E, Thomas G, Swenerton K, Oza A, Sederias J, Ivy P, Eisenhauer EA. A phase II study of sunitinib in patients with locally advanced or metastatic cervical carcinoma: NCIC CTG Trial IND.184. Gynecol Oncol. 2010 Feb;116(2):163-7.
18. Kao J, Packer S, Vu HL, Schwartz ME, Sung MW, Stock RG, Lo YC, Huang D, Chen SH, Cesaretti JA. Phase 1 study of concurrent sunitinib and image-guided radiotherapy followed by maintenance sunitinib for patients with oligometastasis: acute toxicity and preliminary response. Cancer. 2009 Aug 1;115(15):3571-80.
19. 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.
20. Kulke MH, Lenz HJ, Meropol NJ, et. al. Activity of sunitinib in patients with advanced neuroendocrine tumors. J Clin Oncol. 2008 Jul 10;26(20):3403-10.
21. Machiels JP, Henry S, Zanetta S, Kaminsky MC, Michoux N, Rommel D, Schmitz S, Bompas E, Dillies AF, Faivre S, Moxhon A, Duprez T, Guigay J. Phase II study of sunitinib in recurrent or metastatic squamous cell carcinoma of the head and neck: GORTEC 2006-01. J Clin Oncol. 2010 Jan 1;28(1):21-8.
22. Mannavola D, Coco P, Vannucchi G, et al. A novel tyrosine-kinase selective inhibitor, sunitinib, induces transient hypothyroidism by blocking iodine uptake. J Clin Endocrinol Metab. 2007 Sep;92(9):3531-4.
23. Motzer RJ, et al. "Activity of SU11248, a multitargeted inhibitor of vascular endothelial growth factor receptor and platelet-derived growth factor receptor, in patients with metastatic renal cell carcinoma." J Clin Oncol. 2006;24:16-24.
24. Motzer RJ, Hutson TE, Tomczak P, Michaelson MD, Bukowski RM, Rixe O, et al. Sunitinib versus interferon alfa in metastatic renal-cell carcinoma. N Engl J Med. 2007 Jan 11;356(2):115-24.
25. Motzer RJ, Rini BI, Bukowski RM, Curti BD, George DJ, Hudes GR, et al. Sunitinib in patients with metastatic renal cell carcinoma. JAMA. 2006 Jun 7;295(21):2516-24.
26. Motzer RJ, Michaelson MD, Rosenberg J, et. al. Sunitinib efficacy against advanced renal cell carcinoma. J Urol. 2007 Nov;178(5):1883-7.
27. Novello S, Scagliotti GV, Rosell R, Socinski MA, Brahmer J, Atkins J, Pallares C, Burgess R, Tye L, Selaru P, Wang E, Chao R, Govindan R. Phase II study of continuous daily sunitinib dosing in patients with previously treated advanced non-small cell lung cancer. Br J Cancer. 2009 Nov 3;101(9):1543-8.
28. Raymond E, Dahan L, Raoul JL, et. al. Sunitinib malate for the treatment of pancreatic neuroendocrine tumors. N Engl J Med. 2011 Feb 10;364(6):501-13.
29. Rini BI, Garcia JA, Cooney MM, Elson P, Tyler A, Beatty K, Bokar J, Mekhail T, Bukowski RM, Budd GT, Triozzi P, Borden E, Ivy P, Chen HX, Dolwati A, Dreicer R. A phase I study of sunitinib plus bevacizumab in advanced solid tumors. Clin Cancer Res. 2009 Oct 1;15(19):6277-83.

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

30. Saltz LB, Rosen LS, Marshall JL et. al. Phase II trial of sunitinib in patients with metastatic colorectal cancer after failure of standard therapy. J Clin Oncol. 2007 Oct 20;25(30):4793-9.
31. 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.
32. Socinski MA, Novello S, Brahmer JR, et. al. Multicenter, phase II trial of sunitinib in previously treated, advanced non-small-cell lung cancer. J Clin Oncol. 2008 Feb 1;26(4):650-6.
33. Socinski MA, Scappaticci FA, Samant M, Kolb MM, Kozloff MF. Safety and efficacy of combining sunitinib with bevacizumab + paclitaxel/carboplatin in non-small cell lung cancer. J Thorac Oncol. 2010 Mar;5(3):354-60.
34. Sunitinib. 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.
35. Sutent. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
36. Thyroid 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.
37. Wildiers H, Fontaine C, Vuylsteke P, et. al. Multicenter phase II randomized trial evaluating antiangiogenic therapy with sunitinib as consolidation after objective response to taxane chemotherapy in women with HER2-negative metastatic breast cancer. Breast Cancer Res Treat. 2010 Sep;123(2):463-9.

SYMDEKO (TEZACAFTOR/IVACAFTO)

Initial:

- Diagnosis of Cystic Fibrosis (CF); AND
- **ONE** of the following:
  - Documentation confirming patient is homozygous for the F508del mutation in the CFTR gene
    - **OR –**
  - 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

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

SYMLIN/SYMLIN PEN (PRAMLINTIDE ACETATE)

Exclude Members from targeting if they have a history of antidibetic drugs (GPI 27);

- 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 Hbg A1C greater than 6.5% (chart notes providing Hgb A1C required)

References

1. Buse J, Weyer C, Maggs D, et al. Amylin Replacement with Pramlintide in Type 1 and Type 2 Diabetes: A Physiological Approach to Overcome Barriers With Insulin Therapy. Clinical Diabetes. 20(3):137-144.
2. Hollander PA, Levy P, Fineman MS, et al. Pramlintide as an adjunct to insulin therapy Improves long-term glycemic and weight control in patients with type 2 diabetes: a 1-year randomized controlled trial. Diabetes Care. 2003 Mar;26(3):784-790.
3. Monnier L, Lapinski H, Colette C. Contributions of fasting and postprandial plasma glucose increments to the overall diurnal hyperglycemia of type 2 diabetic patients: variations with increasing levels of HbA(1c). Diabetes Care. 2003 Mar;26(3):881-885.
4. Pramlitide. 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. Ratner RE, Dickey R, Fineman M, et al. Amylin replacement with pramlintide as an adjunct to insulin therapy improves long-term glycaemic and weight control in Type 1 diabetes mellitus: a 1-year, randomized controlled trial. Diabet Med. 2004 Nov;21(11):1204-1212.
6. Ratner RE, Want LL, Fineman MS et al. Adjunctive therapy with the amylin analogue pramlintide leads to a combined improvement in glycemic and weight control in insulin-treated subjects with type 2 diabetes. Diabetes Technol Ther. 2002;4:51-61.
7. Standards of medical care for patients with diabetes mellitus. Diabetes Care. 2008 ; 31(Suppl 1:S12-S54.
8. Symlin. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
9. The American Association of Clinical Endocrinologists (AACE) medical guidelines for clinical practice for the management of diabetes mellitus. Endocrine Practice. 2007(suppl 1):S3-S34.
10. Whitehouse F, Kruger DF, Fineman M, et al. A randomized study and open-label extension evaluating the long-term efficacy of pramlintide as an adjunct to insulin therapy in type 1 diabetes. Diabetes Care. 2002;25:724-730.

SYNAGIS (PALIVIZUMAB)

Synagis therapy starting prior to November 1st will be approved only if local virology data supplied from the National Respiratory & Enteric Virus Surveillance System (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.

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

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

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 dyslplasia (BPD) defined as:
            - BPD - Oxygen requirement at 36 weeks gestational age or at 28 days of age regardless of birth gestational age
            - CLD – Infant who has developed an oxygen requirement or other pulmonary condition requiring treatment or close medical observation
            - Infants with CLD/BPD who are less than 24 months of age at start of RSV season who have required intervention or maintenance therapy for their BPD/CLD within 6 months of the start of RSV season (the administration of Synagis in a previous month is sufficient to qualify for administration in a qualified month)
        - Infants and children between 12 and 24 months of age who have CLD of prematurity and continue to require supplemental oxygen, diuretic therapy or chronic corticosteroid therapy within six months before the anticipated RSV season.
    - **Heart Disease**
        - Infants who are 12 months of age or younger with hemodynamically significant Congenital Heart Disease (CHD). Those children with CHD

who are most likely to benefit from immunoprophylaxis include those with:
    - acyanotic heart disease who are receiving medication to control congestive heart failure (documentation required) and will require cardiac surgical procedures ; or
    - moderate to severe pulmonary hypertension; or
    - cyanotic heart disease (if recommended by a pediatric cardiologist).
    - Additionally, children younger than 24 months who undergo cardiac transplantation during the RSV season may be considered for prophylaxis.
- Immune prophylaxis for RSV **is considered not medically necessary** for
    - Infants and children with hemodynamically insignificant heart disease including but not limited to:
        - secundum atrial septal defect,
        - small ventricular septal defect,
        - pulmonic stenosis,
        - uncomplicated aortic stenosis,
        - mild coarctation of the aorta, and
        - patent ductus arteriosus.
        - Lesions adequately corrected by surgery unless they continue to require medication for congestive heart failure.
        - Infants with mild cardiomyopathy who are not receiving medical therapy for the condition.

    - **Note**: Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that involve cardiopulmonary bypass, for children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a post-operative dose of palivizumab (15mg/kg) should be considered after cardiac bypass or at the conclusion of extra-coporeal membrane oxygenation for infants and children younger than 24 months.
- **Neuromuscular disease, congenital airway anomaly or pulmonary abnormality**
    - Infants under 12 months of age with neuromuscular disease, congenital anomalies of the airway or pulmonary abnormalities that impair the ability to clear secretions from the upper airway because of ineffective cough.
- **Immunocompromised**
    - Infants and children, who are 24 months of age or younger, who are profoundly immunocompromised because of chemotherapy or other conditions during the RSV season.
- **Cystic Fibrosis (CF)***
    - Infants with CF who are younger than 12 months of age with clinical evidence of CLD and/or nutritional compromise.

- **Genetic Disease**
  - Infants who are less than 12 months of age or younger at the start of RSV season, who are clinically diagnosed with Down's Syndrome
- Children 12-24 months of age with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile.
- **Dosage and Administration**
  - The recommended dose of Synagis is 15mg/kg body weight administered intramuscularly. Because 5 monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months (>24 weeks) of serum palivizumab concentrations above the desired level for most children, administration of more than 5 monthly doses is not recommended within the continental United States. For qualifying infants who require 5 doses, a dose beginning in November and continuation for a total of 5 monthly doses will provide protection for most infants through April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered in February, which will provide protection for most infants through March. Qualifying infants born during the RSV season may require fewer doses.
- **Discontinuation of Synagis**
  - If any infant or young child receiving monthly Synagis prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season (<0.5%).
- ***Miscellaneous Information**
  - The clinical reviewer, in his or her professional judgment, will override criteria when the requested item is medically necessary. In addition, because there is no definite evidence for the treatment of patients undergoing stem cell transplant or infants and children with Cystic Fibrosis, the approval of Synagis for these patients will be done on a case by case basis by the clinical reviewer.

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

References

1. National Perinatal Association 2018 Respiratory Syncytial Virus (RSV) Prevention Clinical Practice Guideline: An Evidenced-Based Interdisciplinary Collaboration. NEONATOLOGY TODAY. 2017; 12(10):1-14.
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
3. Palivizumab. 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. Subcommittee on Diagnosis and Management of Bronchiolitis. Diagnosis and management of bronchiolitis clinical practice guideline. Pediatrics. 2006;118(4):1174-1793, Available from http://aappolicy.aappublications.org/cgi/reprint/pediatrics;118/4/1774.pdf.
5. Synagis. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.
6. The Viriginia 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

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; A**ND**
- 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:

Requests for continuing 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 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
- 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.
4. Corrado EM, Peluso GF, Gigliotti S. The effects of intra-articular administration of hyaluronic acid on osteoarthritis of the knee: A clinical study with immunological and biochemical evaluations. Eur J Rheumatol Inflamm. 1995;15:47-56.
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.

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

10. Lohmander LS, Dalen N, Englund G, H, et al. Intra-articular hyaluronan injections in the treatment of osteoarthritis of the knee: A randomised, double blind, placebo controlled multicentre trial. Hyaluronan Multicentre Trial Group. Ann Rheum Dis. 1996;55(7):424-431.
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
- Tried and failed calcipotriene cream or solution and betamethasone (as separate products) simultaneously
  Or
- Inability (other than convenience or non-compliance) to use two separate medications

Cautions:

- Should not be applied to the face, axillae, or groin
- Should not be used in the presence pre-existing skin atrophy at treatment site
- Treatment of more than 30% body surface area is not recommended
- Maximum weekly dose should not exceed 100gm
- Hypercalcemia has been observed. Discontinue Taclonex if serum calcium exceeds normal range until normal calcium levels are restored. The effects of Taclonex on calcium metabolism beyond 4 weeks is not known.
- May produce reversible HPA axis suppression
- Limit exposure to natural or artificial sunlight

Monitoring:

- Serum calcium
- HPA axis suppression
- Skin infections

References

1. Virginia Premier

TAFINLAR (DABRAFENIB; BRAF-INHIBITOR)

- Patient must be >= 18 years old; AND
- 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 bu 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 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

Requests for continuing 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 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
- 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 of 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.

Requests for continuing 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: 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
- Chardoma

Contraindications:

- None stated

Not Approved if:

- The patient does not meet the above stated criteria.

References

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)

Requests for continuing 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 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.
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 Philidelphia chromosome positive chronic myelogenous leukemia, AND
    - Must be 18 years of age or older, AND
    - Failed or intolerant to therapy with imatinib (Gleevac), 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

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

Criteria for Continuation of Therapy:

- Patient responding to treatment 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)
- 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

Requests for continuing 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. Stop Tasigna, and monitor blood counts
2. Resume within 2 weeks at prior dose if ANC >1.0 x 109/L and platelets >50 x 109/L
3. If blood counts remain low for > 2 weeks, reduce the dose to 400 mg once daily

- **Contraindications**:
  - Do not use in patients with hypokalemia, hypomagnesemia, or long QT syndrome.

Not Approved if:

- Does not meet the above stated criteria, OR
- Have any contraindications to the use of nilotinib, OR.
- Patients with the BCR-ABL mutation T315I, as data suggests that Tasigna is not effective against this mutation, OR
- Patients with galactose intolerance, severe lactase deficiency, or glucose-galactose malabsorption syndromes

Special Considerations:

- FDA's approval of Tasigna includes a black box warning for possible life-threatening heart problems that may lead to an irregular heartbeat and possible sudden death.
- The effectiveness of Tasigna is based on hematological and cytogenetic (chromosome related) response rates. So far, no controlled trials have shown a clinical benefit, such as improvement in disease related symptoms or increased survival.
- Imatinib Resistance/failure
- Failure to achieve a complete hematologic response (CHR) after 3 months or loss of CHR, or a failure to achieve a cytogenetic response (CyR) after 6 months or loss of CyR, or a failure to achieve a major cytogenetic response (MCyR) after 12 months of treatment or loss of MCyR
- Imatinib Intolerance
  - 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/.

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

TAVALISSE (FOSTAMATINIB DISODIUM HEXAHYDRATE)

I. **Length of Authorization**
   a. Coverage is provided for six months and may be renewed.

II. **Dosing Limits**
   a. Quantity Limit (max daily dose) [Pharmacy Benefit]: – 100 mg tablets – 2 tablets per day – 150 mg tablets – 2 tablets per day
   b. Max Units (per dose and over time):
      - 300 mg daily

III. **Initial Approval Criteria** - Coverage is provided in the following conditions:
   a. Chronic immune (idiopathic) thrombocytopenia (ITP)
      - Patient aged 18 years or older; AND
      - Patient has previously failed any of the following treatments for ITP:
         1. Patient has failed previous therapy with corticosteroids; OR
         2. Patient has failed previous therapy with immunoglobulins; OR
         3. Patient has had a splenectomy; OR
         4. Patient has failed previous therapy with a thrombopoietin receptor agonist (e.g., eltrombopag, romiplostim, etc.); AND
      - The patient is at increased risk for bleeding as indicated by platelet count (within the previous 28 days) of less than 30 × 109 /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:
   a. 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 × 109 /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

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

TAVNEOS (AVACOPAN)

Initial therapy:

1. Member must have a clinical diagnosis of severe active antineutrophil cytoplasmic autoantibody-associated vasculitis (granulomatosis with polyagniitis (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 mL/min/1.73m^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**
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.

Requests for continuing 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. 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
   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 clicnial documentation (chart notes, prescriber statement, 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

- 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)

• 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

Requests for continuing 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

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)

- 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.

Requests for continuing 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

5. Patient is 12 years of age or older, AND
6. Diagnosis of moderate to severe asthma, AND
7. Prescribed by, or in consultation with an allergist or pulmonologist, AND
8. 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;
6. Will not be used in combination with Dupixent, Xolair, Nucala, Cinqair or Fasenra

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

-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

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

- Documented 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

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.TE.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.
- 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.

Requests for continuing 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 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 capusle 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.

* **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 (athelete'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
    - 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:

Requests for continuing 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 ≥ 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 ≥ 1systemic 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
- 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 (ELEXACAFTOR, TEZACAFTOR, IVACAFTOR)

Initial:

- Diagnosis of Cystic Fibrosis (CF); AND
- 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)

Requests for continuing 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.
- Must be 18 years of age or older
- Clinically diagnosed major depressive disorder.
- Failed or intolerant to at least one generic SSRI. (Citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine HCl immediate-release, sertraline).
  AND
- Failed or intolerant to at least one SNRI. (duloxetine, venlafaxine,desvenlafaxine, Fetzima)
  AND
- Viibryd

Criteria for continuation of therapy:

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication. Renew yearly.

Contraindication:

- Hypersensitivity to vortioxetine or any components of the Brintellix formulation.
- Must not be used concomitantly with an MAOI or within 14 days of stopping an MAOI. Do not use MAOI's within 21 days of stopping treatment with Brintellix.
- Do not start Brintellix in a patient who is being treated with linezolid or IV methylene blue.

Not approved if:

- Patient has any contraindications to the use of Brintellix.
- Patient does not meet the above stated criteria.
- **Description:** Brintellix (vortioxetine) inhibits reuptake of serotonin (5-HT). It also has agonist activity at the 5-HT1A receptor and antagonist activity at the 5-HT3 receptor. The mechanism of the antidepressant effect of vortioxetine is not fully understood, but is thought to be related to its enhancement of serotonergic activity in the CNS through inhibition of the reuptake of serotonin (5-HT). It also has several other activities including 5-HT3 receptor antagonism and 5-HT1A receptor agonism. The contribution of these activities to vortioxetine's antidepressant effect has not been established.
- **FDA-approved uses:** treatment of major depressive disorder
- **Available dosage forms:** 5, 10, 15, and 20mg tablets
- **Usual dose:** Starting dose is 10mg once daily up to a maintenance dose of 20mg once daily.
- **Duration of therapy:** Renew yearly, If the below criteria are met authorization will be given for 1 year.
- Quantities will be limited to 1 tablet per day (30 tablets per month)

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

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**
- 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

TROKENDI XR (TOPIRAMATE)

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

TRUDHESA (DIHYDROERGOTAMINE MESYLATE)

Initial Approval:

- Confirm member has a diagnosis of migraine with or without aura; AND
- Member is 18 years of age or older; AND
- Member has had an adequate trial and failure of at least 2 triptans (e.g. sumatriptan, rizatriptan); AND
- Member has had an adequate trial and failure of generic dihydroergotamine; AND
- Prescriber provides clinical documentation for medical necessity of this formulation over gendihydroergotamine nasal spray

Renewal Approval:

- Documentation of response to therapy and tolerating therapy

Authorization Duration:

Initial approval: 6 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: 1/1/22

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

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-Positve; 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
- 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.

Requests for continuing 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. 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 EnglJ 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).
        - 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:

Requests for continuing 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.) 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

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 initation of treatment, or history of thromboembolism, pulmonary hypertension, renal insufficiency, or other end organ complications from PNH, or atypical hemolytic uremic syndrome without serious unresolved Neisseria meningitides infection **AND**
- Patient has tried/failed or intolerant to Soliris

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

Requests for continuing 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 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**
- 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:

- 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 (Pediculosis humanus capitis), crab lice (Pthirus pubis), and their ova only in patients who have failed or cannot tolerate other approved therapies. **The CDC recommends this agent not be used in infants and children less than 2 years old.**
- **Xeglyze** Indicated for the topical treatment of head lice in those 6 months of age or older
- **Ovide (lotion):** Indicated for patients infested with Pediculus humanus capitus (head lice and their ova) of the scalp hair in **patients ≥ 6 years old.**
- **Ulesfia (lotion):** Indicated for the topical treatment of head lice infestation in patients **6 months of age and older.** Ulesfia does not have ovicidal activity.

Quantity Limits

- **LINDANE** Shampoo: 1% (Quantity Limit 60ml)
- **OVIDE® (malathion)** Lotion: 0.5% (Quantity Limit 60ml)
- **ULESFIA™ (benzyl alcohol*)*** Lotion: 5% (Quantity Limit 48oz)

PA CRITERIA FOR APPROVAL:

- Diagnosis of pediculus capitus (head lice and its eggs).
  - **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.

Requests for continuing 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 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.

VALTOCO NASAL (DIAZEPAM)

1. Criteria for use (bullet points below are all inclusive unless otherwise noted):Patient is at least 6 years of age or older; AND
2. Diagnosis of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures) that are distinct from a pateint's usual seizure pattern in patients with epilepsy

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 formualry 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):

- 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

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

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

    - 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
- 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.

Not approved if:

• The patient has any contraindications to the use of voriconazole.

• The patient does not meet the above stated guidelines for approval.

References

1. Virginia Premier

VIAGRA (SILDENAFIL CITRATE)

• Prescribed by a pulmonologist

• Pulmonary Arterial Hypertension (PAH) diagnosis only. (Only this diagnosis will be approved).

References

1. Virginia Premier

VIBERZI (ELUXADOLINE)

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

- Must have diagnosis of diarrhea predominant Irritable Bowel Syndrome ***AND***
- Must be 18 years old or over ***AND***
- Must have failed conventional therapies including: Dietary changes (including fiber), or stress reduction, or behavioral changes **AND** any ONE of the following medications:
  a. Anti-diarrheals (i.e. Loperamide, diphenoxylate/atropine); **OR**
  b. Antispasmodics (hyoscyamine, dicyclomine); **OR**
  c. Tricyclic antidepressants (despiramine, imipramine)
  AND
- The member does not have severe (Child-Pugh C) hepatic impairment; **AND**
- Must be prescribed by a gastroenterologist; AND
- Other gastrointestinal medical conditions that could explain the symptoms have been ruled out; **AND**
- Must have tried and failed Xifaxan

For Continuation of therapy

- Patient must be responding to treatment and tolerating treatment; **AND**
- Patient must continue to follow dietary and physical activity recommendations

Approval Duration:

- 6 months

Caution:

- Sphincter of Oddi Spasm and Pancreatitis

Contraindications:

- Biliary Duct Obstruction
- 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)

• 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.

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

• Failed 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

LAST REVISION: 10/1/22

References:

1. Vijoice (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

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

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)

*****Partially approve the EOC and submit to the PA Hub Client Sign-off queue. Send an e-mail to COPTeam@elixirsolutions.com and the "CC" the CDPharmacist e-mail distribution box, noting the EOC # and requested indication for use.**

• Diagnosed with rheumatoid arthritis or osteoarthritis, or other chronic diseases associated with pain, **AND**
• Predisposition to gastric ulcer, **AND**
• Failed/intolerant to Celecoxib***, AND**
• Failed/intolerant to preferred formulary proton pump inhibitors and any formulary Naproxen, **AND**
• Intolerance to naproxen delayed-release and **Nexium 24Hr OTC used simultaneously for 90 days**. (both are formulary)
Or
• Inability to use two separate medications-Specifically documented.

***Celecoxib requires a prior authorization. Please place a PA for Celecoxib for patient in lieu of Vimovo.**

Not approved if:

- Does not meet the above stated criteria

References

1. Virginia Premier

VIVITROL (NALTREXONE) INJ

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

- Patient must be 18 years old or over
- Patient must have already abstained form drinking alcohol.
- Must be part of a comprehensive treatment program for alcohol dependence that should include a psychosocial support system.
- Failed/intolerant to oral naltrexone
- Failed/intolerant to Campral*
    - Campral requires a prior authorization and the criteria that must be met for approval.

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

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

- Patient must be 18 years old or over
- Patient must be opioid free for a minimum of 7-10 days
- Patient must not have a current need for opioid analgesics
- Must be part of a comprehensive treatment program for opioid dependence that should include a psychosocial support system.
- Failed/intolerant to oral naltrexone
- Failed/intolerant to Suboxone and Subutex

Contraindications:

- Should not be administered to patients in opioid withdrawal.
- Acute hepatitis or liver failure.
- Patients allergic to naltrexone, or any inactive ingredient of Vivitrol powder or diluent.
- **Not approved if:**
    - Does not meet the above stated criteria.
    - Have any contraindications to the use of Vivitrol.

Special considerations:

- Alternative to daily doses of oral naltrexone.
- Expected to work the same as oral naltrexone.
- No head to head trials with other medications for alcohol dependence.
- No head to head trials with other medications for opioid dependence.
- High incidence of nausea that may decrease with subsequent doses.
- Patients at risk of opioid overdose after stopping therapy and restarting prior opioid dose.
  Patients are advised to wear a medical alert bracelet so they get proper pain management in case of an emergency. If an opioid must be used in the ER or hospital, the dose must be carefully titrated to give enough to overcome the naltrexone, but not too much to cause respiratory depression."• The patient does not meet the above stated guidelines for approval.

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

Please note Quantity Limits Apply: 18 capsules per 365 days

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

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 x 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.
- Must have failed or is intolerant to oral fluconazole.

Contraindications:

• Hypersensitivity to voriconazole or its excipients.

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

• 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)

- 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

WEIGHT LOSS

Prior Authorization – (Duration of Approval – 6 months per authorization, 3 months interval for Qsymia)

A prior authorization request will be required for all prescriptions for the anti-obesity medications listed below. These requests will be approved when the following criteria are met:

Xenical, Qsymia, Belviq, Alli, phentermine, diethylpropion, phendimetrazine, benzphetamine

Initial Therapy

Documentation of the following:

1. Body Mass index (BMI) ≥ 30 kg/m^2***; OR*** Body Mass Index ≥ 27 kg/m^2 and at least one of the following high risk factors:
    - Obstructive Sleep Apnea
    - Coronary Heart Disease
    - Type 2 Diabetes
    - Atherosclerotic disease; ***AND***
2. Inability to meet target weight loss goal despite lifestyle modifications including dietary changes and participating in a structured exercise program for at least 2 months; ***AND***

Continuation of Therapy

Xenical, Belviq, Alli, phentermine, diethylpropion, phendimetrazine, benzphetamine

Documentation of the following:

Requests for continuing 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. Continued coverage (up to 12 months) may be authorized for members who provide documentation of weight loss of at least 5% during the first 12 weeks of treatment; ***AND***

2. The member continues to practice lifestyle modifications including dietary changes and participates in a structured exercise program.

Note: The Plan will not approve use of any of the above anti-obesity medications for more than a total of 24 months.

Limitations Virginia Premier will *not* approve coverage for anti-obesity agents in the following instances:

- When the above criteria are not met.
- Member under 18 years of age
- Member has contraindications to the use of agent.
- When the total duration of use the medication is > 24 months.

References

1. National Institutes of Health (NIH); National Heart, Lung, and Blood Institute and National Institute of Diabetes and Digestive and Kidney Diseases. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: The evidence report. Bethesda, MD: NIH; 1998. http://www.nhlbi.nih.gov/guidelines/obesity/ob gdlns.pdf. Accessed July 2012.
2. Product Information. Adipex –P UpToDate® accessed July 2012
3. Product Information Xenical® UpToDate® accessed July 2012
4. Weight and Obesity. Treatment and Prevention Guidelines. http://fnic.nal.usda.gov/weight-and-obesity/treatment-and-prevention-guidelines. Accessed July 2012.
5. Bray GA. Drug therapy of obesity. UpToDate® available at https://www.uptodate.com, accessed August 2013

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

WEGOVY (SEMAGLUTIDE)

Initial Approval:

- Member is 18 years of age or older: AND
- Member meets ONE of the following:
    - Member currently has a BMI > 30 kg/m^2; OR
    - Member has a BMI ≥ 27 kg/m^2 in the presence of at least one weight-related comorbid conditions (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia); AND
- Member is currently engaged in behavioral modification and on a reduced calorie diet; AND
- Member has had a trial and failure, intolerance, or contraindication to at least one (1) of the following if indicated in members age: AND
    - Adipex-P (Phentermine)
    - Xenical
    - Contrave
    - Qsymia
- Baseline weight and BMI are provided; AND
- Member is not using other semaglutide-containing products or any other GLP-1 receptor agonist.

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

- Member has lost at least 5% of baseline body weight; OR
    - Maintenance of at least a 5% reduction in body weight over the renewal period for subsequent renewals; AND
- Member tolerates the 2.4mg dose (maintenance dose)

Authorization Duration:
Initial approval: 4 months
Renewal approval: 12 months

LAST REVISION: 11/1/21

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

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

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

Requests for continuing 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 tried and failed Humira and Enbrel.

Treatment of Polycarticular 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 303/30 require a quantity limit review.
- Xeljanze XR 11 mg tablets: 1 tablet per day, quanitites 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.
- 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/.

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, opthamologist, 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;
- **No contraindications:**
    - Pregnancy, OR
    - Sensitivity or allergic reaction to other botulinum toxins, OR
    - Contraindications to the use of dapsone, 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)
    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

Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults

- Must have diagnosis of diarrhea predominant Irritable Bowel Syndrome ***AND***
- Must be 18 years old or over ***AND***
- Must have failed conventional therapies including: Dietary changes (including fiber), or stress reduction, or behavioral changes **AND** any ONE of the following medications:
    a. Anti-diarrheals (i.e. Loperamide, diphenoxylate/atropine); **OR**
    b. Antispasmodics (hyoscyamine, dicyclomine); **OR**
    c. Tricyclic antidepressants (despiramine, imipramine)

  AND
- One 550 mg tablet 3 times a day for 14 days. Patients who experience recurrence can be retreated up to two times with the same regimen.

Criteria for continuation of therapy:

Travelers Diarrhea: Discontinue therapy if patient has persistent or worsening symptoms after 24-48 hours

Duration of therapy: TD: 3 days

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.
- 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,
    - 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

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

- 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
    - 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.

Requests for continuing 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. 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:**

- 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

Requests for continuing 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 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.

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

Requests for continuing 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

- 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 inotophoretic device and a drug reservoir card. Patient is required to assemble and activate the device
- Patients with migraine who also have nausea, vomiting, or gastroparesis may not be able to take or absorb an oral triptan. Nasal sprays have a more rapid onset of action than oral (10-15 vs 30-60 minutes) but they can have unpleasant taste and they also depend on GI absorption of the significant portion of the dose that is swallowed. SubQ administered sumatriptan is fastest acting (~10 minutes) and most effective.

References

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

ZEGALOGUE (DASIGLUCAGON)

- Confirm member has a diagnosis of severe hypoglycemia with diabetes; **AND**
- Member is 6 years of age or older; **AND**
- Documentation provided that supports member has trial and failure of glucagon

Authorization Duration: 12 months

LAST UPDATED: 7/1/21

ZELBORAF (vemurafenib; BRAF-inhibitor)

- Patient must be >= 18 years old; AND

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

- Prescribed by an Oncologist or Hematologist; AND
- A diagnosis of unresectable or metastatic melanoma; AND
- BRAF mutation V600E; AND
- Confirmation of mutation by FDA-approved test, AND
- No Wild-BRAF mutation; AND
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0 – 1; AND
    - Fully active, able to carry on all pre-disease performance without restriction
    - Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (e.g., light house work, office work)
    - Ambulatory and capable of all self care but unable to carry out any work activities; up and about more than 50% of waking hours
    - Capable of only limited self care, confined to bed or chair more than 50% of waking hours
    - Completely disabled: cannot carry on any self care; totally confined to be or chair
- Baseline ECG, electrolytes, & bilirubin assessed prior to initiation of therapy and within acceptable limits; AND
- Performed dermatologic evaluation; AND
- No concomitant BRAF-inhibitor, MEK inhibitor, or ipilimumab therapy.

References

1. Virginia Premier

ZEMPLAR (PARICALCITOL)

- Secondary hyperparathyroidism, AND
- Intact Parathyroid Hormone (iPTH) > 240 pg/mL, AND
- Corrected serum calcium <10.5 mg/dL, AND
- Corrected Serum Ca x(times) Serum Phosphorus <70, AND
- Trail/failure/intolerance to calcitriol/Hectorol oral or injection therapy by demonstrating iPTH level Greater than180 pg/mL, AND
- Development of hypercalcemia (serum Calcium >11.5 mg/dL) despite adequate therapy and discontinuance of calcium based phosphate binders.

Reauthorization/Continuing treatment:

- iPTH >120 pg/mL (or 2 times the upper limit of normal), AND
- Corrected Serum calcium <11.5 mg/dL, AND
- Corrected Serum Ca x (times) Serum Phosphorus < 75

References

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.

Requests for continuing 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. Paricalcitriol. 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 treatement; **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 evalution 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
    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

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

12) 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)

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,
    - 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

1. Fung MA, Murphy MJ, Hoss DM, et al. Practical evaluation and management of cutaneous lymphoma. J Am Acad Dermatol. 2002;46:325-357.

Requests for continuing 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. Mycosis Fungoides and the Sezary Syndrome Treatment. National Cancer Institute. http://www.cancer.gov/cancertopics/pdq/treatment/mycosisfungoides/HealthProfessional.
3. Non-Hodgkins 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.
4. Siegel R, Pandolfino T, Guitart J, et al. Primary cutaneous t-cell lymphoma: review and current concepts. J Clin Oncol. 2000;15:2908-2925.
5. Vorinostat. 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. Zometa. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. [Prescribing information] Whitehouse Station, NJ:Merck & CO. November 2011.

ZOMETA (ZOLEDRONIC ACID)

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

- Paget's disease of bone with elevations in serum alkaline phosphatase (ALP) of ≥2 x ULN of the age-specific normal reference range with:
    - Symptomatic disease (bone pain, hearing loss, bone deformities, fractures, arthritis), AND
    - At risk of complications from Paget's disease (e.g., osteoarthritis, heart failure, kidney stones, broken bones), AND
    - Concomitant treatment with calcium and vitamin D, AND

Requests for continuing 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 alendronate and pamidronate, and generic zolendronic acid, OR
- Hypercalcemia of malignancy
    - Tried/failed/intolerance to generic zolendronic 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, Colsn-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.
6. Reid DM, Devogelaer J, Saag K, et al. Zoledronic acid and resedronate in the prevention and treatment of glucocorticoid-induced osteoporosis (HORIZON): a multicenter, double-blind, double-dummy, randomized controlled trial. The Lancet. 2009; 373:1253-1263.
7. Siris ES, Lyles KW, et al. Medical management of Paget's disease of bone: indications for treatment and review of current therapies. J Bone Miner Res. 2006 Dec;21 Suppl 2:P94-8.
8. 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.
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/.

ZOVIRAX (ACYCLOVIR) TOPICAL

Zovirax Cream Criteria for Use:

- Must have documented diagnosis of herpes labialis (cold sores).
- Must have documented trial and failure or intolerance to Abreva

References

1. Zovirax Cream. Prescribing Information. GlaxoSmithKline. July 2009.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.

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**

Requests for continuing 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 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

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 t member and is qualified to prescribe this therapy according the DATA 2000 and SAMHSA. Physician must be listed on the Buprenorphine Physician Locator maintained by the Substance Abuse and Mental Health Services Administration **(SAMSHA).**
- The member has been referred or is participating in a substance abuse or behavioral health treatment program, behavioral health counseling, or an addictions recovery program. (During the initial course of treatment, referral and enrollment must be with a licensed Drug and Alcohol or behavioral health provider)
- The prescriber must sign and agree to the Suboxone/Buprenorphine Attestation Form

Requests for continuing 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 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 mgbuprenorphine/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.
- 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.

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

<u>Coverage renewal</u>, 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 sumbit 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 Opiods, Opiod-derivates, illicit Opiod-derivatives, carisoprodol, or meprobamate** during the reauthorization request, the prescribing physician must acknowledge the positive drug screen and provide the steps being taken to address member's non-compliance with program. A 1x, 30 day supply will be allowed for failure of (positive) drug screens/UDS medical records/chart notes **for the drugs listed above.** Another prior authorization request would be needed for the next authorization and must include a new clean drug screen/UDS medical record/chart note (from the last request), otherwise will result in denial of request for continued therapy.

Renewal authorizations will be for a 180 day period.

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.
3. Mah FS. New antibiotics for bacterial infections. Ophthalmol Clin North Am. 2003;16(1):11-27
4. Zymar. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: http://www.micromedex.com/.

ZYVOX (LINEZOLID)

- Therapy is NOT being used for prophylaxis therapy, AND
- Infection is NOT a decubitus ulcer, AND

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- Chart notes, lab values and susceptibility results that document that the pathogen is susceptible to Zyvox, other meds that the organism is susceptible to have been tried, the infection is a covered indication listed below, and the organism is a covered pathogen also listed below:
    - Infection caused by Vanco-Resistant Enterococcus faecium, nosocomial pneumonia infection caused by Staph aureus (MTH-susceptible and MTH-resistant strains) or S. pneumoniae (including multi-drug resistant strains [MDRSP]), AND
    - Susceptibility report shows that the pathogen is not susceptible to any other antibiotics, OR
    - Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis, caused by Staph aureus (MTH-susceptible and MTH-resistant strains) OR S. pyogenes OR S. agalactiae, AND
    - Susceptibility report shows that the pathogen is not susceptible to any other antibiotics, AND
    - Patient does NOT have osteomyelitis, OR
    - Uncomplicated skin and skin structure infections caused by MTH-susceptible only –Staph aureus AND the pathogen is MTH-susceptible only, AND
        - Susceptibility report shows that the pathogen is not susceptible to any other antibiotics, OR
    - Bacteremia associated with intravascular line, AND
        - Confirmed ampicillin- and vancomycin-resistant Enterococcus faecalis/faecium, OR
    - Febrile neutropenia
    - Bone infection, AND
        - Susceptibility report shows that the pathogen is not susceptible to any other antibiotics, OR
    - Infective endocarditis, AND
        - Susceptibility report shows that the pathogen is not susceptible to any other antibiotics, AND
- Documented documented trial and failure or intolerance to the susceptible antibiotics, OR
- A first time Zyvox request to treat uncomplicated skin and skin structure infections caused by S. pyogenes, OR
- A first time Zyvox request to treat community-acquired pneumonia caused by S. pneumoniae (including multi-drug resistant strains [MDRS]), including cases with concurrent bacteremia, AND
    - Susceptibility report shows that the pathogen is not susceptible to any other antibiotics, OR
- A first time Zyvox request to treat community-acquired pneumonia caused by Staph aureus (MTH-susceptible strains only), AND the pathogen is MTH-susceptible, AND
- Susceptibility report shows that the pathogen is NOT susceptible to any other antibiotics.

References

Requests for continuing 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. Asad E et al. Cost-effectiveness of linezolid and vancomycin in the treatment of surgical site infections. Current Medical Research and Opinion. 2007;23(1):185-93.
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.
4. Clinical experience with recently approved antibiotics. Curr Opin Pharmacol. 2006 Aug 8.
5. Falagas ME. Manta KG. Ntziora F. Vardakas KZ. Linezolid for the treatment of patients with endocarditis: a systematic review of the published evidence. Journal of Antimicrobial Chemotherapy. 2006;58(2):273-80.
6. Green SL, Maddox JC, Huttenbach ED. Linezolid and reversible myelosuppression. JAMA 2001:285(10):1291.
7. Lewis et al. Approaches to serious methicillin-resistant Staphylococcus aureus infections with decreased susceptibility to vancomycin: clinical significance and options for management. Current Opinion in Infectious Diseases. 2007;20(6):568-73.
8. Linezolid. 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.
9. Lipsky BA. Itani K. Norden C. Linezolid Diabetic Foot Infections Study Group. Treating foot infections in diabetic patients: a randomized, multicenter, open-label trial of linezolid versus ampicillin-sulbactam/amoxicillin-clavulanate. Clinical Infectious Diseases. 2004;38(1):17-24
10. McKinley SH. Foroozan R. Optic neuropathy associated with linezolid treatment. Journal of Neuro-Ophthalmology. 2005;25(1):18-21.
11. Razonable RR. Osmon DR. Steckelberg JM. Linezolid therapy for orthopedic infections. Mayo Clinic Proceedings. 2004;79(9):1137-44.
12. Role of linezolid in the treatment of complicated skin and soft tissue infections. Expert Rev Anti Infect Ther. 2006 Jun;4(3):357-66.
13. Trevino et al. Endemic linezolid-resistant Staphylococcus epidermidis in a critical care unit. European Journal of Clinical Microbiology and Infectious Disease. 2009;28(5):527-33.
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