BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**3/17/2016**
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LOKELMA™ (sodium zirconium cyclosilicate) oral suspension
VELTASSA™ (patiromer) oral suspension

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Lokelma (sodium zirconium cyclosilicate) and Veltassa (patiromer) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 18 years of age or older

  2. A confirmed diagnosis of non-life-threatening persistent or recurrent hyperkalemia (serum potassium greater than or equal to 5.5 mEq/L)

  3. Individual has failure, contraindication or intolerance to oral sodium polystyrene sulfonate

  4. **ALL** of the following baseline tests have been completed before initiation of treatment:
     a. Potassium level

  5. Individual does not have **ANY** of the following:
     a. Severe constipation
     b. Bowel obstruction or impaction
     c. Abnormal post-operative motility disorder

  6. There are no significant interacting drugs

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Lokelma (sodium zirconium cyclosilicate) and Veltassa (patiromer) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition responded while on therapy
     a. Response is defined as:
        i. Serum potassium levels are within the normal range
        ii. Documented evidence of efficacy, disease stability and/or improvement
        iii. No evidence individual has developed any significant unacceptable adverse drug

  2. Individual has been adherent with the medication

  3. Individual has not developed any significant adverse drug effects that may exclude continued use
     a. Significant adverse effect such as:
        i. Severe constipation
        ii. Bowel obstruction or impaction
        iii. Severe edema form Lokelma
        iv. Severe hypomagnesemia from Veltassa

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4. Individual does not have **ANY** of the following:
    a. Severe constipation
    b. Bowel obstruction or impaction
    c. Abnormal post-operative motility disorder

5. There are no significant interacting drugs

Renewal duration: 6 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Lokelma (sodium zirconium cyclosilicate) is a non-absorbed zirconium silicate that preferentially captures potassium in exchange for hydrogen and sodium. Lokelma increases fecal potassium excretion through binding of potassium in the lumen of the gastrointestinal tract. Binding of potassium reduces the concentration of free potassium in the gastrointestinal lumen, thereby lowering serum potassium levels. Lokelma is indicated for the treatment of hyperkalemia in adults. It should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action; reduction in serum potassium is seen within 1 hour of administration, potassium levels continue to decline over the 48 hours of treatment period. Each 5 g dose of Lokelma contains about 400 mg of sodium. The safety and efficacy of Lokelma were based on data from two double-blind, placebo-controlled studies and two open-label studies in adult patients with hyperkalemia.

Veltassa (patiromer) is an oral potassium binder indicated for the treatment of hyperkalemia. It should not be used as emergency treatment for life-threatening hyperkalemia because of its delayed onset of action. Veltassa is a non-absorbed, cation exchange polymer that contains a calcium-sorbitol counter-ion. It increases fecal potassium excretion through binding of potassium in the lumen of the gastrointestinal tract. Binding of potassium reduces the concentration of free potassium in the gastrointestinal lumen, resulting in a reduction of serum potassium levels.

The efficacy of Veltassa (patiromer) was evaluated in a two-part, single-blind withdrawal study of hyperkalemic patients with chronic kidney disease (CKD) on stable doses of at least one renin-angiotensin-aldosterone system (RAAS) inhibitor (such as Angiotensin Converting Enzyme (ACE) inhibitor or Angiotensin Receptor Blocker (ARB)). In the second part of the study, patients were randomized to continue receiving patiromer or placebo to evaluate the effect of withdrawing Veltassa on serum potassium. Veltassa was given twice daily throughout this study. The FDA-approved dose frequency for Veltassa is once daily. The results showed that Veltassa reduces serum potassium levels and that upon withdrawal of the drug, potassium levels increase. There is also data on a one year study of Veltassa in hyperkalemic patients with CKD and type 2 diabetes mellitus on RAAS inhibitor therapy.

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Veltassa in this study was given as divided dosing. The results showed that Veltassa was able to maintain serum potassium levels.

Other pharmacological options for the treatment of hyperkalemia include generic sodium polystyrene sulfonate (SPS), available as an oral (powder or suspension) or rectal suspension; and loop or thiazide diuretics. SPS has been available in the United States since 1958.

Any advantages over current standard-of-care treatment SPS (Kayexalate, Kionex) for the long-term management of hyperkalemia have not been substantiated by any head-to-head clinical studies that directly compare patiromer or sodium zirconium cyclosilicate to SPS. Use of SPS in the treatment of hyperkalemia is considered the current standard of care with almost 60 years of clinical experience.

Patients with an increased risk of hyperkalemia include those with chronic kidney disease, heart failure, diabetes, and those taking renin-angiotensin-aldosterone system inhibitors.

Measures to prevent hyperkalemia include restricting dietary intake of potassium, close monitoring of serum potassium levels, and avoiding drugs that increase serum potassium or impair potassium excretion (such as aldosterone antagonists, ACE inhibitors, ARB, potassium supplements).

Resources:

Lokelma (sodium zirconium cyclosilicate) product information, revised by AstraZenica Pharmaceuticals, LP. 10-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 20, 2021.

Veltassa (patiromer) product information, revised by Vifir Pharma, Inc. 05-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 20, 2021.

Sodium polystyrene sulfonate product information, revised by CMP Pharma, Inc. 08-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 20, 2021.

Mount DB. Treatment and prevention of hyperkalemia in adults. In: UpToDate, Sterns RH, Forman JP (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Topic last updated October 29, 2021. Accessed December 20, 2021.