PHARMACY COVERAGE GUIDELINE

VELTASSA™ (patiromer) oral suspension
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Veltassa (patiromer), and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual's is 12 years of age or older

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

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

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4. Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for Lokelma or member is between the age of 12 and 18 years old

5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Veltassa (patiromer), and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual's condition has responded while on therapy with response defined as serum potassium levels are within the normal range and the medication is needed to maintain normal levels

2. Individual has been adherent with the medication

3. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

4. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
    a. Severe constipation
    b. Bowel obstruction or impaction
    c. Bowel motility disorders
    d. Severe edema form Lokelma
    e. Severe hypomagnesemia from Veltassa
    f. Severe clinically significant hypokalemia

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

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**

BlueCross BlueShield Arizona

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Generic Equivalent (if available)

Description:

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. 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.

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).

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Resources:

Veltassa (patiromer) powder for oral suspension product information, revised by Vifor Pharma, Inc. 10-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 18, 2024.

Mount DB. Treatment and prevention of hyperkalemia in adults. In: UpToDate, Sterns RH, Forman JP (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Literature current through December 2023. Topic last updated August 17, 2022. Accessed January 18, 2024.

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