BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 3/17/16**
SECTION: DRUGS	**LAST REVIEW DATE: 2/21/19**
	LAST CRITERIA REVISION DATE: 2/21/19
	ARCHIVE DATE:

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.**

LOKELMA™ (sodium zirconium cyclosilicate) oral suspension
VELTASSA™ (patiromer) oral suspension (cont.)

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 hyperkalemia
  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:
     - Potassium level
  5. There are **NO** contraindications.
     - Contraindications include:
       - Known hypersensitivity to any of its components of the product

  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
     - Response is defined as:
       - Has benefited from therapy but remains at high risk for recurrence of hyperkalemia
       - Serum potassium levels are within the normal range
  2. Individual has been adherent with the medication
  3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Contraindications as listed in the criteria for initial therapy section
     - Significant adverse effect such as:
       - Severe constipation
       - Bowel obstruction or impaction
       - Severe edema form Lokelma
  4. There are no significant interacting drugs

  Renewal duration: 6 months

LOKELMA™ (sodium zirconium cyclosilicate) oral suspension
VELTASSA™ (patiromer) oral suspension (cont.)

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 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. 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).

LOKELMA™ (sodium zirconium cyclosilicate) oral suspension
VELTASSA™ (patiromer) oral suspension (cont.)

Resources:

Veltassa (patiromer) product information accessed 01-18-19 at DailyMed:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bf002984-d6c9-46df-aecb-a07733f763c1

Lokelma (sodium zirconium cyclosilicate) product information accessed 01-18-19 at DailyMed:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=90bf8e28-748d-4e4b-a19f-9cf483370eff

Kionex(sodium polystyrene sulfonate) product information accessed 01-18-19 at DailyMed:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b916f972-10be-4e14-8603-087955fa9ad7

Lokelma. Package Insert. Revised by manufacturer 5/2018. Accessed 8/23/18.

Veltassa. Package Insert. Revised by manufacturer 10/2015. Accessed 01-26-2016.

Veltassa. Package Insert. Revised by manufacturer 11/2016. Accessed 02-09-2017, 02-14-18

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

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Office notes, labs, and medical testing relevant to the request that show medical justification are required.