



PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/20/18  
LAST REVIEW DATE: 9/20/18  
LAST CRITERIA REVISION DATE:  
ARCHIVE DATE:

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## LOKELMA™ (sodium zirconium cyclosilicate) oral suspension

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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.

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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](http://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](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**

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## LOKELMA™ (sodium zirconium cyclosilicate) oral suspension (cont.)

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### Criteria:

- **Criteria for initial therapy:** Lokelma (sodium zirconium cyclosilicate) 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 **ALL** the following preferred step therapy agents:
    - sodium polystyrene sulfonate oral suspension (Kionex)
  4. **ALL** of the following baseline tests have been completed before initiation of treatment:
    - Potassium level

**Initial approval duration:** 6 months

- **Criteria for continuation of coverage (renewal request):** Lokelma (sodium zirconium cyclosilicate) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual's condition has 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 significant level 4 adverse drug effects that may exclude continued use
    - Significant adverse effect such as:
      - Severe constipation
      - Bowel obstruction or impaction
      - Severe edema
  4. There are no significant interacting drugs

**Renewal duration:** 12 months

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### 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. It is indicated for the treatment

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## **LOKELMA™ (sodium zirconium cyclosilicate) oral suspension (cont.)**

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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 hour 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.

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 diuretics (loop or thiazide). SPS has been available in the United States since 1958.

Any advantages of sodium zirconium cyclosilicate over treatment with SPS (Kayexalate, Kionex) for the long-term management of hyperkalemia have not been substantiated by any head-to-head clinical studies that directly compare 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, and potassium supplements).

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### **Resources:**

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

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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	
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____	<input type="checkbox"/> Exigent (requires prescriber to include a written statement)

Clinical Information	
1. What is the diagnosis? Please specify below. ICD-10 Code: _____ Diagnosis Description: _____	
2. <input type="checkbox"/> Yes <input type="checkbox"/> No    Was this medication started on a recent hospital discharge or emergency room visit?	
3. <input type="checkbox"/> Yes <input type="checkbox"/> 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

# 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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