Sodium Zirconium Cyclosilicate (Lokelma®)
EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO059

Description
Sodium zirconium cyclosilicate (Lokelma) is an orally administered suspension that eliminates potassium through fecal excretion by binding potassium in the gastrointestinal tract in exchange for sodium and hydrogen.

Length of Authorization
- Initial: One month
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit	DDID
sodium zirconium cyclosilicate (Lokelma)	5 g packets	Hyperkalemia	30 packets/30 days	203578, 202886
	10 g packets		Initial: 36 packets/30 days Renewal: 30 packets/30 days	203579, 202887

Initial Evaluation

I. Sodium zirconium cyclosilicate (Lokelma®) may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; **AND**
   B. A diagnosis of **hyperkalemia** (as noted by a baseline potassium level >5 mEq/L) when the following are met:
      1. Provider attestation secondary causes have been ruled out (e.g., hypoaldosteronism, hyperglycemia/hyperosmolality, metabolic acidosis); **AND**
      2. Treatment with one of the following has been ineffective, not tolerated, or all are contraindicated: loop diuretics (i.e., furosemide, toresemide), thiazide diuretics (i.e., hydrochlorothiazide, chlorthalidone), and/or dialysis; **AND**
      3. Provider indication that starting dose will be 10 g daily

Renewal Evaluation

I. Member has demonstrated a reduction of serum potassium and is now within normal limits (3.5-5 mEq/L)

Normal potassium level	3.5-5mEq/L
Mild hyperkalemia	5.1-6mEq/L
Moderate hyperkalemia	6.1-7mEq/L
Severe hyperkalemia	Greater than 7mEq/L

Supporting Evidence

I. The safety and efficacy of loop diuretics, thiazide diuretics, and dialysis for lowering serum potassium levels has been established. Use of these conventional agents with established therapeutic efficacy and a known safety profile will be considered as they are cost-effective therapies.

II. Hyperkalemia may often be precipitated by other conditions such as hypoaldosteronism, hyperglycemia/hyperosmolarity and metabolic acidosis which should be ruled out to treat the root cause.

III. Data from the HARMONIZE trial which was a randomized, double-blind, placebo-controlled trial supports the use of sodium zirconium cyclosilicate for up to 28 days. The study evaluated mean serum potassium levels during days 8-29 and found that sodium zirconium cyclosilicate reduced serum potassium to within the normal range across three different doses and was significantly superior to placebo (P<0.001). The study also demonstrated during the open-label phase that sodium zirconium cyclosilicate dropped the serum potassium levels from 5.6 mEq/L at baseline to 4.5 mEq/L at 48 hours.

IV. An additional multicenter, two-stage, double-blind, randomized, placebo-controlled trial was used to demonstrate the efficacy and safety of sodium zirconium cyclosilicate for hyperkalemia at 48 hours. The results demonstrated that patients receiving 2.5 g, 5 g, and 10 g all reduced their serum potassium levels to within a normal range.

References

1. Sodium Zirconium Cyclosilicate (Lokelma®) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals. July 2018.
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3. Inker, Lesley A. et al. KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guideline for the Evaluation and Management of CKD. *American Journal of Kidney Diseases*. 2012; Volume 63, Issue 5, 713 – 735.
4. Anker SD, Kosiborod M, Zannad F, et al. Maintenance of serum potassium with sodium zirconium cyclosilicate (ZS-9) in heart failure patients: results from a phase 3 randomized, double-blind, placebo-controlled trial. *European Journal of Heart Failure*. 2015; 17, 1050–1056.
5. Kosiborod M, Rasmussen HS, Lavin P, et al. Effect of Sodium Zirconium Cyclosilicate on Potassium Lowering for 28 Days Among Outpatients With Hyperkalemia: The HARMONIZE Randomized Clinical Trial. *JAMA*. 2014;312(21):2223-2233.
6. Packham DK, Rasmussen HS, Lavin PT, et al. Sodium Zirconium Cyclosilicate in Hyperkalemia. *N Engl J Med.* 2015;372:222-31.
7. Reardon LC, Macpherson DS. Hyperkalemia in Outpatients Using Angiotensin-Converting Enzyme Inhibitors: How Much Should WE Worry? *Arch Intern Med*. 1998;158(1):26-32.
8. National Kidney Foundation: Clinical update on Hyperkalemia at: https://www.kidney.org/sites/default/files/02-10-6785_HBE_Hyperkalemia_Bulletin.pdf.

Policy Implementation/Update:

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Date Created	October 2018
Date Effective	November 2018
Last Updated	August 2019
Last Reviewed	10/2018, 08/2019

Action and Summary of Changes	**Date**
Updated criteria to policy: Included provider attestation that secondary causes of hyperkalemia have been ruled out. Adjusted language regarding try and fail at least one alternative or show CI to use/intolerance: loop diuretics (i.e. furosemide, toresemide), thiazide diuretics (i.e. hydrochlorothiazide, chlorthalidone), and/or dialysis. Removed requirement members not be diagnosed with CKD.	08/2019