Effective Date: 06/01/2019
Last P&T Approval/Version: 04/27/2022
Next Review Due By: 04/2022
Policy Number: C17652-A

Lokelma (sodium zirconium cyclosilicate)

PRODUCTS AFFECTED

Lokelma (sodium zirconium cyclosilicate)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Mild to moderate hyperkalemia

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. HYPERKALEMIA:
1. Documented diagnosis of hyperkalemia (Serum potassium 5.0 – 6.5 mEq/L)
   AND
2. Prescriber is NOT using as emergency treatment for life-threatening hyperkalemia
   AND
3. Prescriber attests that where clinically appropriate, medications known to cause

hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, NSAIDs) have been discontinued or reduced to the lowest effective dose
AND

4. Prescriber attests that where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed
AND
5. Documentation that member has been counseled to follow a low potassium diet (less than or equal to 3 grams per day)
AND
6. Lokelma (sodium zirconium cyclosilicate) will not be used concurrently with another potassium binder

CONTINUATION OF THERAPY:

A. HYPERKALEMIA:

1. Chart note documentation that member has had a positive clinical response to Lokelma (sodium zirconium cyclosilicate) and continues to require treatment for hyperkalemia
AND
2. Prescriber attests that member has not experienced any intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial approval: 3 months, Continuation: 6 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a nephrologist or cardiologist

AGE RESTRICTIONS:

18 years of age or older

QUANTITY:

Dose does not exceed the following: Initial dose: 30 g per day for up to 48 hours; Maintenance dose:15g per day.

Maximum Quantity Limits – << based on FDA label>>

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral

DRUG CLASS:

Potassium Removing Agents

FDA-APPROVED USES:

Indicated for the treatment of hyperkalemia in adults

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Hyperkalemia is an electrolyte imbalance in which serum potassium concentrations are greater than5 mEq/L. Three different categories can be defined as mild hyperkalemia (5.1 to 5.9 Eq/L), moderate hyperkalemia (6– 7 mEq/L), and severe hyperkalemia (> 7 mEq/L).3
Hyperkalemia can be caused by several different factors such as impaired potassium excretion due to CKD, drugs or disorders that inhibit the RAAS (renin angiotensin aldosterone system) or increased dietary potassium consumption.
Treatment of hyperkalemia will be based on whether the patient is in severe hyperkalemia or mild to moderate hyperkalemia.
Lokelma has been shown to be effective in treating mild to moderate hyperkalemia and maintenance of normokalemia once it is achieved.4,6 Trials have shown the efficacy is best when members achieve normokalemia within 48 hours of Lokelma use (loading dose).4

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Lokelma (sodium zirconium cyclosilicate) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. There are no FDA labeled contraindications to Lokelma (sodium zirconium cyclosilicate).

OTHER SPECIAL CONSIDERATIONS:
Lokelma is a cation exchange polymer that functions in the GI tract and may interact with other medications whose absorption is pH dependent. Therefore, its dosing should be separated from other medications by 2 hours before and after.

EDEMA
Every 5g dose of Lokelma contains 400mg of sodium, which can cause edema in patients. Patients who are prone to fluid overload (heart failure, renal disease) may have to be counseled to adjust dietary sodium, increase the dose of diuretics, or use a lower dose of Lokelma as deemed appropriate.

Lokelma has radio-opaque properties and may give the appearance typical of an imaging agent during abdominal X-ray procedures

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Lokelma PACK 5GM (box of 1, 11 or 30 packets for oral suspension), Lokelma PACK 10GM (box of 1, 11 or 30 packets for oral suspension)

REFERENCES

1. Packham, David et al. Sodium Zirconium cyclosilicate in hyperkalemia. The New EnglandJournal of Medicine. 372:222-231. 2015.
2. Lokelma (sodium zirconium cyclosilicate) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2021.
3. Flurie RW, Brophy DF. Disorders of Potassium and Magnesium Homeostasis. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill. Available at: http://accesspharmacy.mhmedical.com.proxy.lib.wayne.edu/content.aspx?bookid=1861&sectionid=134127639. Accessed May 21, 2019
4. 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.doi:10.1001/jama.2014.15688
5. Packham, David et al. Sodium Zirconium cyclosilicate in hyperkalemia. The New England Journal of Medicine. 372:222-231. 2015.
6. Ng K and Lee C. Updated Treatment Options in the Management of Hyperkalemia. US Pharm. 2017;42(2):HS15-HS18.
7. Betts K, Woolley J, Mu F, et al. The prevalence of hyperkalemia in the United States. Current Medical Research and Opinion. 2018; 34 (6): 971-978.
8. Mount D. Treatment and prevention of hyperkalemia in adults. Sterns, R (Ed). UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com [via subscription only] Accessed on April 2020.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Other Special Considerations References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file