Clinical Policy: Sodium Zirconium Cyclosilicate (Lokelma)
Reference Number: ERX.NPA.102
Effective Date: 07.24.18
Last Review Date: 11.18

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Sodium zirconium cyclosilicate (Lokelma®) is a non-absorbed potassium-binding polymer.

FDA Approved Indication(s)
Lokelma is indicated for the treatment of hyperkalemia in adults.

Limitation(s) of use: Lokelma should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Lokelma is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Hyperkalemia (must meet all):
      1. Diagnosis of hyperkalemia;
      2. Age ≥ 18 years;
      3. Failure of sodium polystyrene sulfonate at up to maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced;
      4. Dose does not exceed the following:
         a. Initial dose: 30 g per day for up to 48 hours;
         b. Maintenance dose: 15 g per day.

   Approval duration: Length of Benefit

   B. Other diagnoses/indications
      1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. Hyperkalemia (must meet all):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
      3. If request is for a dose increase, new dose does not exceed 15 g per day.

   Approval duration: Length of Benefit

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

   Approval duration: Duration of request or 12 months (whichever is less); or
      2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).
III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient
documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or
evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   FDA: Food and Drug Administration

   Appendix B: Therapeutic Alternatives
   This table provides a listing of preferred alternative therapy recommended in the approval criteria.
The drugs listed here may not be a formulary agent and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>sodium polystyrene sulfonate</td>
<td>15 g PO QD to QID, or 30-50 g PR Q6H</td>
<td>Individualize dosage and duration of therapy according to assessment of potassium levels</td>
</tr>
<tr>
<td>(Kayexalate®, Kionex®, SPS®)</td>
<td></td>
<td></td>
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</tbody>
</table>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

   Appendix C: Contraindications/Boxed Warnings
   Not applicable

V. Dosage and Administration
   Indication | Dosing Regimen | Maximum Dose |
   Hyperkalemia | Initial: 10 g PO TID for up to 48 hrs
               | Maintenance: 10 g PO QD (adjust dose by 5 g as needed at weekly intervals) | 15 g/day |

VI. Product Availability
   Packet for oral suspension: 5 g, 10 g

VII. References
   Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/207078s000lbl.pdf.

Reviews, Revisions, and Approvals
   Policy created: 07.24.18, P&T Approval Date: 11.18

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care
professionals based on a review and consideration of currently available generally accepted standards of
medical practice; peer-reviewed medical literature; government agency/program approval status;
evidence-based guidelines and positions of leading national health professional organizations; views of
physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical
information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute
a contract or guarantee regarding payment or results. Providers are expected to exercise professional

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medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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