

Louisiana Medicaid
Sodium Zirconium Cyclosilicate (Lokelma™) — Potassium Binders

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- ~~pPrior clinical authorization for sodium zirconium cyclosilicate (Lokelma™), non-preferred potassium binders;~~
- Clinical authorization for patiomer (Veltassa®) and sodium zirconium cyclosilicate (Lokelma®)

Additional Point-of-Sale edits may apply.

These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.

Approval Criteria for Non-Preferred Potassium Binder Agents (except Lokelma® and Veltassa®)

Approval Criteria

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
 - The recipient has had *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
 - The recipient is established on the medication with *positive clinical outcomes*; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any *Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements*; **AND**

- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of ~~a~~Authorization ~~a~~Approval: 12 months

Patiromer (Veltassa®)

Approval Criteria

- The recipient is at least 18 years of age on the date of the request; **AND**
- The recipient has a diagnosis of non-life-threatening hyperkalemia; **AND**
- The dose does not exceed 25.2 grams once a day; **AND**
- The quantity does not exceed 1 packet per day; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
 - The recipient has had a *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - Patiromer will **NOT** be used as an emergency treatment for life threatening hyperkalemia because of its delayed onset of action; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

Sodium Zirconium Cyclosilicate (Lokelma®)

Approval ~~Criteria~~criteria for requests to initiate treatment

- The recipient is at least 18 years of age on the date of the request; **AND**
- The recipient has a diagnosis of non-life-threatening hyperkalemia; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
 - The recipient has had a *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
 - *There is no preferred product that is appropriate to use for the condition being treated; AND*
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - Sodium zirconium cyclosilicate will **NOT** be used as an emergency treatment for life threatening hyperkalemia because of its delayed onset of action; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.
 - ~~The recipient has no concomitant drug therapies or disease states that limit the use of sodium zirconium cyclosilicate.~~

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **OR**

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

- ~~The prescriber states on the request that the recipient is established on sodium zirconium cyclosilicate therapy and that there has been a positive clinical response.~~

Duration of ~~authorization approval, both initial and reauthorization~~ approval: 12 months

Reference

Lokelma (sodium zirconium cyclosilicate) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; ~~October 2020~~2018. Retrieved from <https://www.azpicentral.com/lokelma/lokelma.pdf#page=1>

Veltassa (patiromer) [package insert]. Redwood City, CA: Relypsa, Inc.; May 2018. <https://www.veltassa.com/pi.pdf>

<u>Revision / Date</u>	<u>Implementation Date</u>
<u>Combined Lokelma® and Veltassa® criteria, added previous use wording, formatting changes, removed POS criteria wording from document, updated references / April 2021</u>	<u>JulyApril 2021</u>