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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	February 26, 2016
Subject:	Potassium Binders	**Page:**	1 of 6

Last Review Date: March 7, 2025

Potassium Binders

Description

Lokelma (sodium zirconium cyclosilicate), Veltassa (patiromer)

Background
Lokelma (sodium zirconium cyclosilicate) and Veltassa (patiromer) are potassium binders used to treat hyperkalemia, a serious condition in which the amount of potassium in the blood is too high. The level of serum potassium is affected by several body systems, but the kidneys are the primary organ regulating blood potassium levels. When the kidneys are not able to remove enough potassium from the blood, the level of potassium can get too high. Hyperkalemia typically occurs in patients with acute or chronic kidney disease or heart failure, particularly in those who are taking drugs that inhibit the renin-angiotensin-aldosterone system (RAAS), which regulates blood pressure and fluid balance in the body. Strategies to control chronic hyperkalemia include dietary potassium restriction; discontinuation of potassium supplements, certain salt substitutes, and hyperkalemic drugs; adding potassium-wasting diuretics, and oral potassium binders. The 2021 Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practical Guideline for the Management of Blood Pressure in Chronic Kidney Disease advises that hyperkalemia in chronic kidney disease patients receiving RAAS blockade agents can be controlled with potassium binders rather than decreasing the dose or stopping RAAS therapy (1-3).

Lokelma and Veltassa work by binding potassium in the gastrointestinal tract, decreasing its absorption. Lokelma and Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action (1-2).

Regulatory Status
FDA-approved indications: Lokelma and Veltassa are potassium binders indicated for the treatment of hyperkalemia (1-2).

Limitations of Use:
Lokelma and Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of the delayed onset of action (1-2).

Lokelma and Veltassa could decrease the absorption of other medications and reduce their effectiveness. Administer other oral medications at least 3 hours before or 3 hours after Veltassa and 2 hours before or 2 hours after Lokelma (1-2).

The recommended starting dose of Veltassa is 8.4 grams once daily for adults and 4 grams once daily for pediatric patients 12 to 17 years of age. Monitor serum potassium and adjust the dose of Veltassa based on the serum potassium level and the desired target range. The dose may be increased or decreased, as necessary, to reach the desired serum potassium concentration, up to a maximum dose of 25.2 grams once daily. The dose can be up-titrated based on serum potassium level at 1-week or longer intervals, in increments of 8.4 grams for adults and 4 grams for pediatric patients 12 to 17 years of age (2).

The recommended starting dose of Lokelma is 10 grams (orally as a suspension in water) administered three times a day for up to 48 hours. For maintenance treatment, recommended dose is 10 grams once daily. Adjust dose at one-week intervals as needed (by 5 grams daily) to obtain desired serum potassium target. Maximum dosage of Lokelma is 15 grams daily (1).

Avoid use of Lokelma and Veltassa in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders, because Lokelma and Veltassa have not been studied in patients with these conditions and may be ineffective and may worsen gastrointestinal conditions (1-2).

Safety and efficacy of Lokelma in pediatric patients have not been established. Safety and efficacy of Veltassa in patients under 12 years of age have not been established (1-2).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lokelma and Veltassa may be considered **medically necessary** if the conditions indicated below are met.

Lokelma and Veltassa may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age Lokelma **only**: 18 years of age or older
Veltassa **only**: 12 years of age or older

Diagnosis

Patient must have the following:

Hyperkalemia

AND ALL of the following:

1. Prescriber agrees to adjust the dose based on the serum potassium level
2. Prescriber agrees **NOT** to use this medication as emergency treatment for life-threatening hyperkalemia
3. Patients **WITHOUT** chronic kidney disease (CKD) **only**:
    a. Patient has **ONE** of the following:
        i. Patient is not taking a drug that can cause hyperkalemia (such as ACE inhibitor, ARB, aldosterone antagonist, or potassium-sparing diuretic)
        ii. Patient is using the lowest effective dose of the drug(s) that can cause hyperkalemia **AND** there is no therapeutic alternative to the medication(s)
4. Inadequate treatment response, intolerance, or contraindication to a loop or thiazide diuretic
5. Patient is on a low potassium diet (2-3 grams per day)
6. **NO** dual therapy with another potassium binder

Prior – Approval *Renewal* Requirements

Age Lokelma **only**: 18 years of age or older

Veltassa **only**: 12 years of age or older

Diagnosis

Patient must have the following:

Hyperkalemia

AND ALL of the following:

1. Prescriber agrees to adjust the dose based on the serum potassium level
2. Prescriber agrees **NOT** to use this medication as emergency treatment for life-threatening hyperkalemia
3. Patients **WITHOUT** chronic kidney disease (CKD) **only**:
    a. Patient has **ONE** of the following:
        i. Patient is not taking a drug that can cause hyperkalemia (such as ACE inhibitor, ARB, aldosterone antagonist, or potassium-sparing diuretic)
        ii. Patient is using the lowest effective dose of the drug(s) that can cause hyperkalemia **AND** there is no therapeutic alternative to the medication(s)
4. Patient is on a low potassium diet (2-3 grams per day)
5. **NO** dual therapy with another potassium binder

Policy Guidelines

Pre - PA Allowance

None

Prior – Approval Limit

Quantity

Lokelma

Strength	Quantity Limit
5 gram packet	270 packets per 90 days
10 gram packet	

Veltassa

Strength	Quantity Limit
1 gram packet	360 packets per 90 days **OR**
8.4 gram packet	270 packets per 90 days **OR**
16.8 gram packet	90 packets per 90 days **OR**
25.2 gram packet	90 packets per 90 days

***Maximum daily limit of any combination of Veltassa: 25.2 grams**

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Lokelma and Veltassa are indicated for the treatment of hyperkalemia. Monitor serum potassium and adjust the dose of Lokelma and Veltassa based on the serum potassium level and the desired target range. Lokelma and Veltassa should not be used as an emergency treatment for life threatening hyperkalemia because of the delayed onset of action. Lokelma and Veltassa may affect other medicines taken by mouth if they are taken too close together. Safety and efficacy of Lokelma in pediatric patients and Veltassa in patients under 12 years of age have not been established (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Lokelma and Veltassa while maintaining optimal therapeutic outcomes.

References

1. Lokelma [package insert]. Wilmington, DE: AstraZeneca, Inc.; February 2024.
2. Veltassa [package insert]. Redwood City, CA: Vifor Pharma, Inc.; October 2023.
3. *Kidney supplement to - KDIGO*. (n.d.). Retrieved October 12, 2021, from https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2021-BP-GL.pdf.

Policy History

Date	Action
February 2016	Addition to PA
September 2016	Annual review and reference update

December 2017	Annual editorial review and reference update
June 2018	Change in policy name from “Veltassa” to “Potassium Binders” and initiation duration from 6 months to 12 months Addition of Lokelma to PA Addition of no dual therapy to initiation and renewal criteria
September 2018	Annual review
November 2018	Annual review and reference update. Addition of requirements per SME: patient is not taking a drug that can cause hyperkalemia; inadequate response, intolerance, or contraindication to a loop or thiazide diuretic; patient is on a low potassium diet; and removal of Kayexalate trial requirement
December 2019	Annual review
December 2020	Annual review and reference update
May 2021	Revised the emergency use requirement
June 2021	Annual review
October 2021	Revised requirements per FEP: patients not taking drugs that can cause hyperkalemia now only applies to patients without chronic kidney disease
December 2021	Annual review and reference update
September 2022	Annual review and reference update
March 2023	Annual review and reference update
November 2023	Per PI update, lowered age requirement for Veltassa to 12 and older and added 1 gram packets to quantity chart
December 2023	Annual review
March 2024	Annual review. Per SME, revised regulatory status section for Veltassa pediatric dosing
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2024.