

Clinical Pharmacy Program Guidelines for Lokelma, Veltassa

Program	Prior Authorization - Lokelma, Veltassa
Medication	Lokelma (sodium zirconium cyclosilicate), Veltassa (patiromer)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	6/2016
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

1. Background:

Lokelma and Veltassa are indicated for the treatment of hyperkalemia. Lokelma and Veltassa should not be used as an emergency treatment for life threatening hyperkalemia because of its delayed onset of action. Non-emergent hyperkalemia is generally treated by addressing the reversible causes, such as removing drugs that may be causing impaired renal function, removing or adjusting medications that directly cause hyperkalemia, and initiating therapies for potassium removal.

2. Coverage Criteria:

<p>A. <u>Initial Authorization</u></p> <p>1. Lokelma and Veltassa will be approved based on <u>all</u> of the following criteria:</p> <ul style="list-style-type: none"> a. Diagnosis of non-life threatening hyperkalemia b. 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 c. Where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed d. Patient follows a low potassium diet (less than or equal to 3 grams per day) <p>Authorization will be issued for 12 months.</p> <p>B. <u>Reauthorization</u></p>
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1. **Lokelma** or **Veltassa** will be approved based on **all** of the following criteria:

- a. Patient has a positive clinical response to Lokelma or Veltassa therapy and continues to require treatment for hyperkalemia
- b. 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
- c. Patient follows a low potassium diet (less than or equal to 3 grams per day)

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Veltassa [package insert]. Redwood City, CA: Relypsa, Inc.; May 2018.
2. Weir MR, Bakris GL, Bushinsky DA, et al. Patiromer in patients with kidney disease and hyperkalemia receiving RAAS inhibitors. *N Engl J Med* 2015; 372:211.
3. Palmer BF. Managing hyperkalemia caused by inhibitors of the renin-angiotensin-aldosterone system. *N Engl J Med* 2004; 351:585.
4. Khanna A, White WB. The management of hyperkalemia in patients with cardiovascular disease. *Am J Med.* 2009 Mar. 122(3):215-21.
5. Lokelma [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2020.
6. Mount D. Treatment and prevention of hyperkalemia in adults. Sterns, R (Ed). UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on December 4, 2020.)

Program	Prior Authorization – Veltassa, Lokelma
Change Control	
Date	Change
6/2016	New program
6/2017	Annual review. Updated references.
8/2018	Annual review. Updated references.
12/2018	Added Lokelma and renamed policy. Updated references.

1/2019	Annual review. Updated references.
1/2020	Annual review. Updated references.
1/2021	Annual review. Added low potassium diet to reauthorization criteria for consistency with the initial authorization. Updated references.