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UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2100-10
Program	Prior Authorization/Medical Necessity
Medication	Lokelma® (sodium zirconium cyclosilicate), Veltassa® (patiromer)
P&T Approval Date	6/2016, 6/2017, 8/2018, 12/2018, 3/2020, 6/2021, 6/2022, 6/2023 6/2024, 7/2024
Effective Date	10/1/2024

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[a]:**

A.   Initial Authorization

1. **Lokelma** and **Veltassa** will be approved based on **all** of the following criteria:

   a. Diagnosis of non-life threatening hyperkalemia

   b. Where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed
   c. Patient follows a low potassium diet (less than or equal to 3 grams per day)

   Authorization will be issued for 12 months

B.   Reauthorization

1. **Lokelma** or **Veltassa** will be approved based on **both** of the following criteria:

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

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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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; Vifor Pharma, Inc.: October 2023.
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: February 2024.
6. Mount D. Treatment and prevention of hyperkalemia in adults. Sterns, R (Ed). UpToDate. Waltham, MA: UpToDate Inc. February 2024. Accessed May, 1 2024.
7. De Nicola L, Ferraro PM, Montagnani A, Pontremoli R, Dentali F, Sesti G. Recommendations for the management of hyperkalemia in patients receiving renin-angiotensin-aldosterone system inhibitors. Intern Emerg Med. 2024 Mar;19(2):295-306. doi: 10.1007/s11739-023-03427-0. Epub 2023 Sep 29. PMID: 37775712; PMCID: PMC10954964.
8. KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney Int. 2024;105(4S): S117–S314. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group.

Program	Prior Authorization/Medical Necessity – Veltassa, Lokelma
Change Control	
Date	Change
6/2016	New program
6/2017	Annual review. Updated reference.
8/2018	Annual review. Updated references.
12/2018	Added Lokelma. Updated references.
3/2020	Updated references.
6/2021	Updated references.
6/2022	Updated references.
6/2023	Annual review. Updated references.
6/2024	Annual review. Updated references.
7/2024	Removed requirement to adjust medications.