

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

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| Program Number    | 2023 P 2100-8   |
| 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 |
| Effective Date    | 9/1/2023;<br>Oxford only: 9/1/2023                              |

**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<sup>a</sup>:**

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

**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.: March 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: September 2022.
6. Mount D. Treatment and prevention of hyperkalemia in adults. Sterns, R (Ed). UpToDate. Waltham, MA: UpToDate Inc. August 2022.

| Program               | Prior Authorization/Medical Necessity – Veltassa, Lokelma |
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| <b>Change Control</b> |   |
| 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.                        |