Pharmacy Policy Bulletin: J-0474 Veltassa (patiromer) and Lokelma (sodium zirconium cyclosilicate) – Commercial and Healthcare Reform	
Number: J-0474	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial (1.):** 1. Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0474-015	**Original Date:** 06/01/2016
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Veltassa (patiromer) • Lokelma (sodium zirconium cyclosilicate)

FDA-Approved Indication(s):	• Veltassa (patiromer)
	  ○ Treatment of hyperkalemia in adults and pediatric patients ages 12 years and older
	• Lokelma (sodium zirconium cyclosilicate)
	  ○ Treatment of hyperkalemia in adults.

Background:	• Veltassa is a cation-exchange resin that binds potassium in the lumen of the gastrointestinal tract ultimately reducing serum potassium by increasing fecal excretion of potassium. • Lokelma is highly selective for potassium ions, even in the presence of other cations such as calcium and magnesium, which results in increase of fecal potassium excretion and reduction of the free potassium concentration in the gastrointestinal lumen. • Hyperkalemia is multifactorial with medication use, especially in patients with baseline renal dysfunction or hypoaldosteronism. Medication-induced hyperkalemia is most often a result of the medication interfering with potassium excretion. Examples of medications that contribute to hyperkalemia include angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), and aldosterone antagonists. • Risk factors that lead to hyperkalemia include chronic kidney disease and use of medications for heart failure, such as renin-angiotensin-aldosterone system inhibitors (RAASi), which can increase the potassium levels in the blood. Per the 2016 National Kidney Foundation, RAASi discontinuation is helpful in controlling and preventing hyperkalemia in these patients; however, it increases the risk for kidney disease progression and cardiovascular events. • In clinical studies for Veltassa, patients had a serum potassium level greater than or equal to 5.1 mmol/L to less than 6.4 mmol/L. • In clinical studies for Lokelma, patients had a serum potassium level greater than or equal to 5.1 mmol/L to less than or equal to 7.4 mmol/L.

	• Veltassa and Lokelma are not to be used for emergency treatment for life-threatening hyperkalemia due to its delayed onset of action.
	• Hyperkalemia is generally an acute condition. For continued treatment, monitor serum potassium and adjust the dose of Lokelma or Veltassa based on the serum potassium level and desired target range. Once potassium levels are resolved or below the desired target range Lokelma or Veltassa are discontinued.
	• Prescribing considerations:
	  ○ Patients taking potassium binder agents (i.e., Veltassa and Lokelma) must be following a low potassium diet (less than or equal to 3 grams per day).
	  ○ Veltassa and Lokelma should be avoided in patients with severe constipation, bowel obstruction, abnormal post-operative bowel mobility disorder, or any other gastrointestinal disorder.
	  ○ Sodium polystyrene sulfonate should be used with caution in patients who cannot tolerate even a small increase in sodium loads (i.e., severe congestive heart failure, severe hypertension, or marked edema). In such instances compensatory restriction of sodium intake from other sources may be indicated.
	  ○ Lokelma has a high sodium content which increases the risk of edema in patients with heart failure and/or renal disorders. Monitor for signs of edema and counsel patients on following a sodium restricted diet.
	  ○ Veltassa is an appropriate treatment option for patients who cannot tolerate sodium polystyrene sulfonate due to inability to tolerate increase in sodium load.
	  ○ Veltassa may cause hypomagnesemia. Monitor serum magnesium and consider magnesium in patients with low magnesium concentration baseline levels.
	  ○ Members that have chronic kidney disease and medications known to cause hyperkalemia (e.g., ACE inhibitors, ARBs, etc.) should be discontinued or reduced to the lowest effective dose.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Veltassa or Lokelma may be approved when all of the following criteria are met **(A. through D.)**:

A. The member meets one (1) of the following criteria **(1. or 2.)**:
  1. If the request is for Veltassa, the member is 12 years of age or older.
  2. If the request is for Lokelma, the member is 18 years of age or older.

B. The member has a diagnosis of chronic hyperkalemia. (ICD-10: E87.5)

C. The member has a serum potassium level between 5.1 and 7.4 mmol/L on at least two (2) screenings (lab results must be provided).

D. The prescriber submits documentation that modification of medications (i.e., ACE inhibitors, ARBs, aldosterone antagonist, etc.) to reduce potassium levels, if appropriate, were not successful.

II. Reauthorization

When a benefit, reauthorization of Veltassa or Lokelma may be approved when all of the following criteria are met **(A. and B.)**:

A. The prescriber submits documentation of a reduction in serum potassium levels following Veltassa or Lokelma administration.

B. The member continues to require treatment for hyperkalemia.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of its FDA-approved indications should be denied based on the lack of clinical data to support its effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial and HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.
    - *For Delaware Commercial fully-insured and ACA members, a 12 month authorization must be granted pursuant to 18 Del. C. §§3376(a) and 3586(a) and market conduct examination docket #5467 (Exam Authority #53287-22-701)..*

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Lokelma [package insert]. Wilmington, DE. AstraZeneca Pharmaceuticals. February 2024.
2. Veltassa [package insert]. Redwood City, CA: Vifor Pharma, Inc.; October 2023.
3. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2023.
4. Clinical Pharmacology. Tampa, FL: Gold Standard Multimedia; 2018. Accessed June 25, 2025.
5. Weir, MR, Bakris GL, Bushinsky DA, et al. Patiromer in Patients with Kidney Disease and Hyperkalemia Receiving RAAS Inhibitors. *NEJM.* 2015; 372:211-221.
6. National Kidney Foundation. Best practices in Managing Hyperkalemia in Chronic Kidney Disease. Accessed June 25, 2025.