Oscar Clinical Guideline: Lokelma (sodium zirconium cyclosilicate) (PG143, Ver. 3)

Lokelma (sodium zirconium cyclosilicate)

Summary

Hyperkalemia is a medical condition characterized by an abnormally high concentration of potassium (K+) in the blood. Normal serum potassium levels typically range between 3.5 and 5.0 millimoles per liter (mmol/L). Hyperkalemia is generally defined as a serum potassium level above 5.5 mmol/L. Elevated potassium levels can cause serious complications, including disturbances in cardiac conduction, muscle weakness, and, in severe cases, paralysis or fatal cardiac arrhythmias.

Hyperkalemia can result from various factors, including:

- Increased potassium intake: excessive consumption of potassium-rich foods or supplements.
- Decreased potassium excretion: reduced kidney function, certain medications (e.g., angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, potassium-sparing diuretics), and hormonal imbalances (e.g., adrenal insufficiency).
- Shifts in potassium distribution: movement of potassium from intracellular to extracellular space due to metabolic acidosis, tissue injury, or certain medications (e.g., beta-blockers, digoxin).

Hyperkalemia is typically diagnosed through laboratory tests, including blood tests to measure serum potassium levels and electrocardiogram (ECG) to assess for cardiac conduction abnormalities. The severity of hyperkalemia is commonly classified as follows:

1. Mild: Serum potassium levels of 5 (or upper limit of normal range) to 6 mEq/L without electrocardiogram (ECG) changes.
2. Moderate:
    a. Serum potassium levels of 5 (or upper limit of normal range) to 6 mEq/L with ECG changes.
    b. Serum potassium levels of 6.1 to 6.5 mEq/L without ECG changes.
3. Severe:
    a. Serum potassium levels of 6.1 to 6.5 mEq/L with ECG changes.
    b. Serum potassium levels of 6.5 mEq/L or higher regardless of ECG changes

Symptoms of hyperkalemia can be nonspecific and vary based on the severity and rate of onset. They may include:

- Weakness or fatigue
- Muscle cramps or pain
- Numbness or tingling sensations
- Nausea or vomiting
- Palpitations or irregular heartbeats
- Shortness of breath
- Chest pain

Treatment of hyperkalemia depends on the severity, underlying cause, and presence of any associated symptoms. Management strategies include:

- Discontinuing or adjusting medications that contribute to hyperkalemia.
- Dietary modifications to reduce potassium intake.
- Medical treatments aimed at promoting potassium excretion, such as diuretics, sodium polystyrene sulfonate (SPS), or patiromer.
- Intravenous calcium gluconate for acute stabilization of the cardiac membrane.
- Insulin and glucose administration to facilitate the movement of potassium into cells.
- Albuterol inhalation for mild cases, as it can help drive potassium back into cells.
- Dialysis in severe or refractory cases, particularly when kidney function is compromised.

Lokelma (sodium zirconium cyclosilicate) is a potassium binder indicated for the treatment of hyperkalemia in adults. It can be used for acute episodes of hyperkalemia, as well as for the chronic maintenance therapy to prevent the recurrence of hyperkalemia in patients at risk. Lokelma (sodium zirconium cyclosilicate) works by selectively binding to potassium ions in the gastrointestinal (GI) tract, particularly in the colon. This binding helps to increase the excretion of potassium from the body through feces, thereby reducing the serum potassium levels. Lokelma (sodium zirconium cyclosilicate) is not recommended for use in emergency treatment of life-threatening hyperkalemia due to its delayed onset of action. The recommended starting dose of Lokelma (sodium zirconium cyclosilicate) is 10 grams (g) three times daily for 48 hours, followed by a maintenance dose of a minimum of 5g every other day to 15g daily based on serum potassium goal directed by one's healthcare provider. Lokelma (sodium zirconium cyclosilicate) is available as an oral suspension in a 5g or 10g packet. Contents of the packet are mixed in approximately 3 tablespoons or more of water for self-administration.

Definitions

"Chronic kidney disease (CKD)" refers to a persistent anomaly in the structure or function of the kidneys, which lasts for a period of at least 3 months. It's identified by consistently unusual readings of real or approximated GFR (i.e., estimated GFR less than 60 mL/min/1.73 m^2) over a period of at least three months, or by instances where the GFR is within the normal range but irregularities are present in albuminuria levels, kidney biopsy results, or kidney imaging findings.

"Dialysis" is a medical procedure that removes waste products and excess fluid from the body when the kidneys are unable to do so effectively. There are two main types of dialysis: hemodialysis, which uses a machine to filter the blood externally, and peritoneal dialysis, which uses the lining of the abdomen to filter the blood internally.

"Diuretics," are medications that promote the excretion of excess water and salt from the body through the kidneys, thereby increasing urine output. Diuretics are commonly used to treat conditions such as high blood pressure, heart failure, and edema. Diuretics can be classified into several categories based on their mechanism of action, such as loop diuretics, thiazide diuretics, potassium-sparing diuretics, and osmotic diuretics.

"ECG (Electrocardiogram)" is a diagnostic test that records the electrical activity of the heart. It can detect abnormalities in heart rate, rhythm, and conduction, as well as indicate the presence of heart disease, heart attack, or electrolyte imbalances, such as hyperkalemia.

"Hyperkalemia" is a medical condition characterized by abnormally high levels of potassium (K+) in the blood. In adults, it is typically defined as a serum potassium concentration greater than 5.0-5.5 milliequivalents per liter (mEq/L), while the range in infants and children is age-dependent. Elevated potassium levels can lead to significant hemodynamic and neurologic consequences, with levels higher than 7 mEq/L considered life-threatening. Levels exceeding 8.5 mEq/L can cause respiratory paralysis or cardiac arrest and can quickly be fatal.

Medical Necessity Criteria for Initial Authorization

The Plan considers Lokelma (sodium zirconium cyclosilicate) medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with a nephrologist IF there is documentation of ANY of the following:
    a. Hyperkalemia and chronic kidney disease; *or*
    b. Unexplained hyperkalemia; *AND*
2. The member is 18 years of age or older; *AND*
3. The member has a diagnosis of hyperkalemia and documentation of ONE of the following:
    a. Acute hyperkalemia, if severe (or if moderate with ECG changes); *or*

b. The member's condition is characterized as ONE of the following and has tried and failed or is unable to use loop or thiazide diuretics due to contraindications, intolerability, or inadequate response:
    i. Acute hyperkalemia, if mild to moderate (and with no ECG changes); *or*
    ii. Chronic hyperkalemia, and correctable causes have been identified and treated, but additional management of potassium levels is still required; *or*
c. Lokelma (sodium zirconium cyclosilicate) is being used as an adjunct therapy in combination with other treatments, such as diuretics, for acute or chronic hyperkalemia when the member's condition warrants a multimodal approach to potassium management; *AND*

4. The information reviewed does NOT indicate evidence of ANY of the following:
    a. the drug is being used as an emergency treatment for life-threatening hyperkalemia (i.e., potassium levels of 7 to 8 mEq/L or higher); *or*
    b. the member has severe constipation, bowel obstruction, or fecal impaction, including abnormal postoperative bowel motility disorders, unless corrected; *or*
    c. Lokelma will be used in conjunction with another potassium binder (i.e., Patiromer, Sodium Polystyrene Sulfonate).

<u>If the above prior authorization criteria is met, Lokelma (sodium zirconium cyclosilicate) will be approved for up to 6 months.</u>

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12 months will be approved if BOTH of the following are met:

1. Correctable causes of hyperkalemia have been identified and treated (e.g., dietary potassium restriction and/or discontinuation (or dose reduction) of medications contributing to hyperkalemia)*; AND*
2. Recent medical records (within the past three months) provide documented evidence of BOTH of the following:
    a. The member continues to require treatment for hyperkalemia to maintain safe potassium levels OR there is a high likelihood that serum potassium concentrations will increase without maintenance treatment*; and*
    b. The member has had a positive clinical response to therapy as evidenced by ONE of the following:
        i. Reductions in elevated serum potassium concentrations from baseline*; or*
        ii. Achievement of normokalemia (serum potassium concentration of 3.5–5 mEq/L).

Experimental or Investigational / Not Medically Necessary

Lokelma (sodium zirconium cyclosilicate) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to:

- emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.
- treating lithium toxicity.

Applicable Billing Codes

ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E87.5	Hyperkalemia

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