RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Lokelma (sodium zirconium cyclosilicate) and Veltassa (patiromer for oral suspension) are used to treat hyperkalemia, a serious condition in which the amount of potassium in the blood is too high. The kidneys remove potassium from the blood to maintain a proper balance of potassium in the body. But when the kidneys are not able to remove enough potassium from the blood, the level of potassium can get too high. Hyperkalemia typically occurs in patients with acute or chronic kidney disease or heart failure, particularly in those who are taking drugs that inhibit the renin-angiotensin-aldosterone system (RAAS), which regulates blood pressure and fluid balance in the body. Lokelma and Veltassa work by binding potassium in the gastrointestinal tract, decreasing its absorption. Lokelma and Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action (1-2).

Regulatory Status
FDA-approved indication: Lokelma and Veltassa are potassium binders indicated for the treatment of hyperkalemia (1-2).

Limitation of Use:
Lokelma and Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of the delayed onset of action (1). Lokelma and Veltassa could decrease the absorption of other medications and reduce their effectiveness. Administer other oral medications at least 3 hours before or 3 hours after Veltassa and 2 hours before or 2 hours after Lokelma (1-2).

The recommended starting dose of Veltassa is 8.4 grams once daily. Monitor serum potassium and adjust the dose of Veltassa based on the serum potassium level and the desired target range. The dose may be increased or decreased, as necessary, to reach the desired serum potassium concentration, up to a maximum dose of 25.2 grams once daily. The dose can be up-titrated based on serum potassium level at 1-week or longer intervals, in increments of 8.4 grams (1).

The recommended starting dose of Lokelma is 10 grams (orally as a suspension in water) administered three times a day for up to 48 hours. For maintenance treatment, recommend dose is
POTASSIUM BINDERS
Lokelma (sodium zirconium cyclosilicate), Veltassa (patiromer)

10 grams once daily. Adjust dose at one-week intervals as needed (by 5 grams daily) to obtain desired serum potassium target. Maximum dosage of Lokelma is 15 grams daily (2).

Avoid use of Lokelma and Veltassa in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders, because Lokelma and Veltassa have not been studied in patients with these conditions and may be ineffective and may worsen gastrointestinal conditions (1-2).

Safety and efficacy of Lokelma and Veltassa in pediatric patients have not been established (1-2).

Summary
Lokelma and Veltassa is used to treat high levels of potassium in blood (hyperkalemia). Monitor serum potassium and adjust the dose of Lokelma and Veltassa based on the serum potassium level and the desired target range. Lokelma and Veltassa should not be used as an emergency treatment for life threatening hyperkalemia because of the delayed onset of action. Lokelma and Veltassa may affect other medicines taken by mouth if they are taken too close together. Safety and efficacy in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Lokelma and Veltassa while maintaining optimal therapeutic outcomes.

References