PREFERRED STEP THERAPY POLICY

POLICY: Potassium Binders Preferred Step Therapy Policy
- Lokelma® (sodium zirconium cyclosilicate for oral suspension – AstraZeneca)
- Veltassa® (patiromer for oral suspension – Relypsa)

REVIEW DATE: 12/16/2020

OVERVIEW

Lokelma and Veltassa are non-absorbed potassium-binders indicated for the treatment of **hyperkalemia** in adults.[1,2] Lokelma is a nonabsorbed zirconium silicate that preferentially exchanges potassium for hydrogen and sodium in the lumen of the gastrointestinal (GI) tract.[1] Veltassa is a nonabsorbed cation exchange polymer that contains a calcium-sorbitol counterion; it exchanges calcium for potassium in the GI lumen.[2] Ultimately, with both agents, the reduction in free potassium in the GI tract increases fecal potassium excretion and lowers serum potassium levels. Lokelma and Veltassa are both supplied as powder for oral suspension and most commonly dosed once daily. Both medications need to be administered separate other medications (by 2 hours with Lokelma and by 3 hours with Veltassa).

Clinical Efficacy

There are no direct comparative data between Lokelma and Veltassa. Both agents demonstrated significant potassium-lowering effects in their pivotal trials.[1-6] Differences in study designs, patient populations, and the endpoints evaluated make indirect efficacy comparisons between Lokelma and Veltassa difficult; however, reductions in potassium levels were similar in magnitude following 4 weeks of therapy with either agent in their respective trials.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Preferred Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Preferred Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: Lokelma

Step 2: Veltassa

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

2. No other exceptions are recommended.

REFERENCES

1. Lokelma™ powder for oral suspension [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2020.
2. Veltassa® powder for oral suspension [prescribing information]. Redwood City, CA: Relypsa Inc.; May 2018.
3. Packham DK, Rasmussen HS, Lavin PT, et al. Sodium zirconium cyclosilicate in hyperkalemia. *N Engl J Med*. 2015;372(3):222-231.
4. Kosiborod M, Rasmussin HS, Lavin P, et al. Effect of sodium zirconium cyclosilicate on potassium lowering for 28 days among outpatients with hyperkalemia: the HARMONIZE randomized clinical trial. *JAMA*. 2014;312(21):2223-2233.
5. 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(3):211-221.
6. Bakris GL, Pitt B, Weir MR, et al. Effect of patiromer on serum potassium level in patients with hyperkalemia and diabetic kidney disease: the AMETHYST-DN randomized clinical trial. *JAMA*. 2015;314(2):151-161.