MEDICAL MUTUAL®

Drug Policy

Policy:	**Potassium Binders Preferred Step Therapy**	**Annual Review Date:** **10/21/2021**
Impacted Drugs:	Veltassa® (patiromer for oral suspension – Relypsa)	**Last Revised Date:** **10/21/2021**

OVERVIEW

Lokelma and Veltassa are non-absorbed potassium-binders indicated for the treatment of **hyperkalemia** in adults. Lokelma is a nonabsorbed zirconium silicate that preferentially exchanges potassium for hydrogen and sodium in the lumen of the gastrointestinal (GI) tract. Veltassa is a nonabsorbed cation exchange polymer that contains a calcium-sorbitol counterion; it exchanges calcium for potassium in the GI lumen. 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).

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent 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.

Preferred Medication

- Lokelma

Non-Preferred Medication

- Veltassa

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.

Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

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Step Therapy Exception Criteria
Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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.