



Preferred Step Therapy Potassium Binders

Table of Contents

National Formulary Medical Necessity	1
Conditions Not Covered.....	2
Background.....	2
References	2
Revision History	2

Product Identifier(s)

65220

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

- Lokelma™ (sodium zirconium cyclosilicate for oral suspension)
- Veltassa® (patiromer for oral suspension)

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.

Step 1: Lokelma

Step 2: Veltassa

Cigna covers Step 2 agents as medically necessary when the following criteria are met:

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

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

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 counter ion; 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.

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, Rasmussen 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

Revision History

Type of Revision	Summary of Changes	Review Date
Annual Revision	No changes.	12/16/2020

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., QualCare, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2021 Cigna