Clinical Policy: Patiromer (Veltassa)

Reference Number: CP.PMN.205
Effective Date: 09.01.19
Last Review Date: 08.19
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Patiromer (Veltassa®) is a non-absorbed potassium-binding polymer.

FDA Approved Indication(s)

Veltassa is indicated for the treatment of hyperkalemia.

Limitation(s) of use: Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Veltassa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hyperkalemia (must meet all)**:**

1. Diagnosis of hyperkalemia;
2. Age ≥ 18 years;
3. Failure of preferred sodium polystyrene sulfonate at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 25.2 gm per day.

Approval duration:
Medicaid – 6 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Hyperkalemia (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed 25.2 gm per day.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid, or evidence of coverage documents;

B. Emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CKD: chronic kidney disease
FDA: Food and Drug Administration
RAAS: renin-angiotensin-aldosterone system

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sodium polystyrene sulfonate (Kayexalate)	15 gm PO QD to QID or 30-50 gm PR Q6H	Individualize dosage and duration of therapy according to assessment of potassium levels

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): known hypersensitivity to Veltassa or any of its components
- Boxed warning(s): none reported

Appendix D: General Information

- Veltassa binds to many orally administered medications, which could decrease their absorption and reduce their effectiveness. Administer Veltassa at least 3 hours before or 3 hours after other oral medications.
- Hyperkalemia can occur from impaired urinary potassium excretion due to kidney disease and/or drugs that inhibit the renin-angiotensin-aldosterone system (RAAS).
- A two-part, single-blind phase 3 study evaluated the efficacy and safety of Veltassa in 243 patients with chronic kidney disease (CKD) receiving RAAS inhibitors. Results demonstrated a mean change in serum potassium of -1.01 ± 0.03 mEq/L (95% CI: -1.07, -0.95; P<0.001) following an onset of action of 7 hours; 76% (95% CI: 70, 81) of patients reached the target potassium level (3.8 mEq/L to <5.1 mEq/L) by week 4 of treatment.
- The efficacy and safety of Veltassa administered for up to 52 weeks was evaluated in a study of 306 patients (AMETHYST-DN). The treatment effect on serum potassium was maintained with daily use of Veltassa.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Hyperkalemia	Initial dose is 8.4 gm PO QD Adjust dose by 8.4 gm as needed at weekly intervals	25.2 gm/day

VI. Product Availability

Packets, powder for oral suspension: 8.4 gm, 16.8 gm, and 25.2 gm

VII. References

1. Veltassa Prescribing Information. Redwood City, CA: Relypsa, Inc; May 2018. Available at: www.veltassa.com. Accessed June 4, 2019.
2. Bakris GL, Pitt B, Weir MR, et al. Effect of patiromer on serum potassium levels in patients with hyperkalemia and diabetic kidney disease: The AMETHYST-DN randomized clinical trial. JAMA. 2015; 314(2):151-161.
3. Weir MR, Bakris GL, Bushinsky DA, et al; for the OPAL-HK Investigators. Patiromer in patients with kidney disease and hyperkalemia receiving RAAS inhibitors. N Engl J Med. 2015; 372(3):211-221.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 7, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adopted from CP.CPA.117 by adding Medicaid line of business.	06.04.19	08.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program

approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.