Clinical Policy: Patiromer (Veltassa)
Reference Number: CP.CPA.117
Effective Date: 11.16.16
Last Review Date: 08.18
Line of Business: Commercial

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 sodium polystyrene sulfonate powder at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
      4. Dose does not exceed 25.2 gm/day.

      Approval duration: 12 months

   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.

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/day.

      Approval duration: 12 months
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.

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 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.

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

   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
   Not applicable

   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 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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperkalemia</td>
<td>Initial dose is 8.4 gm PO QD</td>
<td>25.2 gm/day</td>
</tr>
<tr>
<td></td>
<td>Adjust dose by 8.4 gm as needed at weekly intervals</td>
<td></td>
</tr>
</tbody>
</table>

VI. Product Availability

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

VII. References


Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
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<tbody>
<tr>
<td>01.11.17</td>
<td>11.17</td>
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<tr>
<td>05.07.18</td>
<td>08.18</td>
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</tbody>
</table>

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
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