



PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 3/17/16  
LAST REVIEW DATE: 3/15/18  
LAST CRITERIA REVISION DATE: 3/15/18  
ARCHIVE DATE:

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## VELTASSA™ (patiomer) oral suspension

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**

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## **VELTASSA™ (patiomer) oral suspension (cont.)**

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### **Description:**

Veltassa (patiomer) is an oral potassium binder indicated for the treatment of hyperkalemia. It should not be used as emergency treatment for life-threatening hyperkalemia because of its delayed onset of action. Veltassa is a non-absorbed, cation exchange polymer that contains a calcium-sorbitol counter-ion. It increases fecal potassium excretion through binding of potassium in the lumen of the gastrointestinal tract. Binding of potassium reduces the concentration of free potassium in the gastrointestinal lumen, resulting in a reduction of serum potassium levels.

Other pharmacological options for the treatment of hyperkalemia include generic sodium polystyrene sulfonate (SPS), available as an oral (powder or suspension) or rectal suspension; and loop or thiazide diuretics. SPS has been available in the United States since 1958.

The efficacy of patiomer was evaluated in a two-part, single-blind withdrawal study of hyperkalemic patients with Chronic kidney disease (CKD) on stable doses of at least one renin-angiotensin-aldosterone system (RAAS) inhibitor (such as Angiotensin Converting Enzyme (ACE) inhibitor or Angiotensin Receptor Blocker (ARB)). In the second part of the study, patients were randomized to continue receiving patiomer or placebo to evaluate the effect of withdrawing Veltassa on serum potassium. Veltassa was given twice daily throughout this study. The results showed that Veltassa reduces serum potassium levels and that upon withdrawal of the drug, potassium levels increase. There is also data on a one year study of Veltassa in hyperkalemic patients with CKD and type 2 diabetes mellitus on RAAS inhibitor therapy. Veltassa in this study was given as divided dosing. The results showed that Veltassa was able to maintain serum potassium levels. The FDA-approved dose frequency for Veltassa is once daily.

Any advantages over current standard-of-care treatment SPS (Kayexalate, Kionex) for the long-term management of hyperkalemia have not been substantiated by any head-to-head clinical studies that directly compare patiomer to SPS. Use of SPS in the treatment of hyperkalemia is considered the current standard of care with almost 60 years of clinical experience.

Measures to prevent hyperkalemia include restricting dietary intake of potassium, close monitoring of serum potassium levels, and avoiding drugs that increase serum potassium or impair potassium excretion (such as aldosterone antagonists, ACE inhibitors, ARB, potassium supplements).

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## **Veltassa (patiomer)**

### **Medication class:**

Antidote, Potassium Binder

### **FDA-approved indication(s):**

- A potassium binder indicated for the treatment of hyperkalemia

### **Limitations of use:**

- Patiomer should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action

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## VELTASSA™ (patiomer) oral suspension (cont.)

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### Recommended Dose:

- 8.4 g once daily, adjust dose at 1 week intervals or longer in increments of 8.4 g
- **Maximum dosage**
- 25.2 g once daily

### Available Dosage Forms:

- 8.4 g, 16.8 g, & 25.2 g oral powder for suspension packets in a box of 30 packets
- Veltassa should be stored in the refrigerator, if stored at room temperature it must be used within 3 months of being taken out of the refrigerator

### Warnings, Precautions, and other Clinical Information:

- Administer at least 3 hours before or 3 hours after other oral medications
- Veltassa decreased the systemic exposure of co-administered ciprofloxacin, levothyroxine and metformin. However, there was no interaction when Veltassa and these drugs were taken 3 hours apart
- Avoid use severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders
- Individuals with a history of bowel obstruction or major gastrointestinal surgery, severe gastrointestinal disorders or swallowing disorders were not included in the clinical studies
- Veltassa may cause hypomagnesemia, magnesium supplementation may be needed
- Veltassa is not absorbed systemically following oral administration

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### Criteria:

- **Criteria for initial therapy:** Veltassa (patiomer) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
  1. Individual is 18 years of age or older
  2. A confirmed diagnosis of hyperkalemia
  3. Individual has failure, contraindication or intolerance to **TWO** different formulations of oral sodium polystyrene sulfonate
  4. **ALL** of the following baseline tests have been completed before initiation of treatment:
    - Potassium level
  5. There are **NO** contraindications.
    - Contraindications include:
      - Known hypersensitivity to Veltassa or any of its components

**Initial approval duration:** Up to 25.2mg/day x 6 months

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## VELTASSA™ (patiomer) oral suspension (cont.)

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➤ **Criteria for continuation of coverage (renewal request):** Veltassa (patiomer) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:

1. Individual's condition responded while on therapy
  - Response is defined as:
    - Has benefited from therapy but remains at high risk for recurrence of hyperkalemia
    - Serum potassium levels are within the normal range
2. Individual has not developed any contraindications
  - Contraindications as listed in the criteria for initial therapy section
3. Individual has been adherent with the medication
4. There are no significant interacting drugs

**Renewal duration:** Up to 25.2mg/day x 6 months

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### **Resources:**

Veltassa. Package Insert. Revised by manufacturer 10/2015. Accessed 01-26-2016.

Veltassa. Package Insert. Revised by manufacturer 11/2016. Accessed 02-09-2017, 02-14-18

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# Pharmacy Prior Authorization Request Form

**6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.**  
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

**Signature affirms that information given on this form is true and accurate and reflects office notes**

Prescribing Provider's Signature:

Date:

**Please note:** Some medications may require completion of a drug-specific request form.

**Incomplete forms or forms without the chart notes will be returned.**

Office notes, labs, and medical testing relevant to the request that show medical justification are required.