

Clinical Pharmacy Program Guidelines for Veltassa

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| Program | Prior Authorization - Veltassa |
| Medication | Veltassa (patiomer) |
| Issue Date | 6/2016 |
| Pharmacy and Therapeutics Approval Date | 6/2017 |
| Effective Date | 8/2017 |

1. Background:

Veltassa is indicated for the treatment of hyperkalemia. Veltassa should not be used as an emergency treatment for life threatening hyperkalemia because of its delayed onset of action. Non-emergent hyperkalemia is generally treated by addressing the reversible causes, such as removing drugs that may be causing impaired renal function, removing or adjusting medications that directly cause hyperkalemia, and initiating therapies for potassium removal.

2. Coverage Criteria:

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| A. | <p><u>Initial Authorization</u></p> <p>1. Veltassa will be approved based on <u>all</u> of the following criteria:</p> <ul style="list-style-type: none"> a. Diagnosis of non-life threatening hyperkalemia b. Where clinically appropriate, medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, NSAIDs) have been discontinued or reduced to the lowest effective dose c. Where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed d. Patient follows a low potassium diet (less than or equal to 3 grams per day) <p style="text-align: center;">Authorization will be issued for 12 months.</p> |
| B. | <p><u>Reauthorization</u></p> <p>1. Veltassa will be approved based on <u>all</u> of the following criteria:</p> <ul style="list-style-type: none"> a. Patient has a positive clinical response to Veltassa therapy and continues to require treatment for hyperkalemia |

- b. Where clinically appropriate, medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, NSAIDs) have been discontinued or reduced to the lowest effective dose
- c. Patient follows a low potassium diet (less than or equal to 3 grams per day)

Authorization will be issued for 12 months.

3. References:

1. Veltassa prescribing information. Relypsa, Inc. Redwood City, CA. November 2016.
2. Weir MR, Bakris GL, Bushinsky DA, et al. Patiromer in patients with kidney disease and hyperkalemia receiving RAAS inhibitors. N Engl J Med 2015; 372:211.
3. Palmer BF. Managing hyperkalemia caused by inhibitors of the renin-angiotensin-aldosterone system. N Engl J Med 2004; 351:585.
4. Khanna A, White WB. The management of hyperkalemia in patients with cardiovascular disease. Am J Med. 2009 Mar. 122(3):215-21

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| Program | Prior Authorization - Veltassa |
| Change Control | |
| Date | Change |
| 6/2016 | New program |
| 6/2017 | Annual review. Updated references. |