Effective Date: 07/01/2016
Last P&T Approval/Version: 04/27/2022
Next Review Due By: 04/2023
Policy Number: C8840-A

Veltassa (patriomer)

PRODUCTS AFFECTED

Veltassa (patriomer)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Hyperkalemia

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. HYPERKALEMIA
1. Laboratory documentation of serum potassium levels supporting hyperkalemia
   AND
2. Prescriber attests that serum potassium and magnesium levels will be monitored
   AND
3. Prescriber is NOT using as emergency treatment for life-threatening hyperkalemia
   AND
4. Prescriber attests that 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 if no therapeutic alternative to these medications, therapy is reduced to the lowest effective dose as clinically appropriate
AND

5. Prescriber attests that where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed
AND
6. Member is not on concurrent or dual therapy with another potassium binder
AND
7. Documentation that member has been counseled to follow a low potassium diet (less than or equal to 3 grams per day)

CONTINUATION OF THERAPY:

A. HYPERKALEMIA

1. Prescriber monitors serum potassium and magnesium levels
AND
2. Documented evidence of clinical benefit from treatment with Veltassa (e.g., potassium level returned to normal or significant decrease from baseline) and continues to require treatment for hyperkalemia

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 6 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a nephrologist or cardiologist

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Maximum dose of 25.2 grams once daily

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral

DRUG CLASS:

Antidote, Potassium binder

FDA-APPROVED USES:

Hyperkalemia

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Veltassa are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. History of hypersensitivity to patiromer or any of its components. Avoid use of Veltassa in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders, because Veltassa may be ineffective and may worsen gastrointestinal conditions.

OTHER SPECIAL CONSIDERATIONS:

Administer Veltassa at least 3 hours before or 3 hours after other oral medications

Clinically important interactions with ciprofloxacin, thyroxine, and metformin have been identified; these three drugs need to be administered more than three hours before or after patiromer.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Veltassa PACK 8.4GM, Veltassa PACK 16.8GM, Veltassa PACK 25.2GM, Veltassa PACK 25.2GM

REFERENCES

1. Veltassa (patiromer) [prescribing information]. Redwood City, CA: Relypsa Inc; Dec 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at www.clinicalpharmacology.com. Accessed September 2019. [via subscription]
3. Lesko LJ, Offman E, Brew CT, et al. Evaluation of the Potential for Drug Interactions with Patiromer in Healthy Volunteers. J Cardiovasc Pharmacol Ther 2017; 22:434.
4. Rafique Z, Weir MR, Onuigbo M. et al. Expert Panel Recommendations for the Identification and Management of Hyperkalemia and Role of Patiromer in Patients with Chronic Kidney Disease and Heart Failure. Journal of Managed Care & Specialty Pharmacy 2017 23:4-a Suppl, S10-S19 . Available at: https://www.jmcp.org/doi/10.18553/jmcp.2017.23.4-a.s10

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file