Title: patiromer (Veltassa™)

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department:

1.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, updated and/or revised, or archived.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.
Medical Department Procedure Manual

Section: Chapter 7A Prescription Medications Prior Authorization        Number: 07.214

Title: patiromer (Veltassa™)

Background Information, continued:

Medication Summary

- Patiromer (Veltassa™) is an oral, non-absorbed, cation exchange polymer used for the treatment of hyperkalemia. Patiromer (Veltassa™) works by binding potassium in gastrointestinal track, decreasing its absorption.

- Patiromer (Veltassa™) should not be used as an emergency treatment for life-threatening hyperkalemia.

- Patiromer (Veltassa™) has a boxed warning regarding the potential for binding to other oral medications. Other oral medication should be administered at least 6 hours before and after Patiromer (Veltassa™).

- Patiromer (Veltassa™) is available as an oral suspension and is packaged in single-use packets containing 8.4 grams, 16.8 grams, or 25.2 grams in cartons of four packets or 30 packets.

- Patiromer (Veltassa™) is recommended to start at 8.4 grams once daily, with maximum dose of 25.2 grams once daily.

Exclusion Criteria

- Members < 18 years old
- Member has known hypersensitivity to patiromer (Veltassa™) or any of its components.
- Member has a history of bowel obstruction or major gastrointestinal surgery, severe gastrointestinal disorder, or swallowing disorders.
- Prescriber intended to use for an emergency treatment for life-threatening hyperkalemia.

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.
Procedure:

1.0 Request for *initial therapy* with patiromer (Veltassa™) for the treatment of hyperkalemia requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

1.1 Prescriber must be gastroenterologist, cardiologist, or endocrinologist; AND

1.2 Documentation of hyperkalemia with a baseline serum potassium level of 5.1 mEq/L to < 6.5 mEq/L; AND

1.3 Member previously failed or contraindicated to sodium polystyrene sulfonate product; AND

1.4 If all criteria above are met, patiromer (Veltassa™) may be approved for six (6) months.

2.0 Request for *continuation of therapy* with patiromer (Veltassa™) for the treatment of – hyperkalemia beyond the initial authorization period requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

2.1 Member is deriving clinical benefit from therapy; AND

2.2 Absence of unacceptable toxicity from the drug. AND

2.3 If all criteria above are met, patiromer (Veltassa™) may be approved for twelve (12) months.
Section:  Chapter 7A Prescription Medications Prior Authorization        Number:  07.214

Title:  patiromer (Veltassa™)

References:

1. Veltassa [Prescribing Information]. Redwood City, CA Relypsy, Inc; October 2015.