Nonformulary Criteria for Use: Lubiprostone

VHA Pharmacy Benefits Management-Strategic Healthcare Group and Medical Advisory Panel

The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of individual patient situations.

Refer to the National PBM Drug Monograph for Lubiprostone (Amitiza™) at: http://www.pbm.va.gov/monograph/Lubiprostone.%20Monograph.pdf

Exclusions (if ONE is checked, patient is not eligible)

- ☐ Treatment of constipation- or diarrhea-predominant irritable bowel syndrome (IBS)
- ☐ Chronic constipation induced by medications that can be discontinued
- ☐ History of or current symptoms of bowel obstruction
- ☐ Presence of severe or frequent diarrhea
- ☐ Women of child-bearing potential who have not had a baseline pregnancy test or in whom it has been determined that the potential risk to the fetus outweighs the benefit of therapy

Indications For Therapy (all three criterion MUST be met)

- ☐ Meets criteria for chronic functional constipation (refer to Diagnostic Criteria for Functional Constipation below)
- ☐ Treatment of chronic constipation in patients who have documented lack of response or contraindication to, or inability to tolerate at least three agents on the VA National Formulary from the following drug classes (i.e., bulk-forming laxatives, osmotic laxatives, stimulant laxatives) as well as nonpharmacologic measures (e.g., adequate dietary changes, increased fluid intake, physical activity)
- ☐ Evaluation of chronic functional constipation has been performed by appropriate personnel*

Dosing

- Recommended dose is 24 mcg twice daily orally with food

Monitoring

- Patients should be reevaluated after a 30 day trial. The patient should be encouraged to keep a daily report of stool frequency or other data deemed relevant by the prescriber, to assess the number of spontaneous bowel movements per week. Reassessment for efficacy by documenting symptom and/or quality of life improvement in the patient's medical record is needed for continued use.
- Monitor for severe or frequent diarrhea
- Discuss risk vs. benefit of therapy in patients of child-bearing potential and appropriate methods of contraception

Discontinuation

- No documented constipation relief after 2 to 4 weeks of therapy (i.e., change in frequency, consistency or form of stool, bloating, discomfort or straining)

Provider signature: _____ Date: _____

*Complete and/or refer for an appropriate gastrointestinal assessment if patient has symptoms or signs that suggest colorectal cancer or another serious gastrointestinal condition (refer to http://www.romecriteria.org/PDFs/p1480FBDs.pdf)

Diagnostic Criteria* for Functional Constipation

1. Must include *2 or more* of the following:
   - straining during at least 25% of defecations
   - lumpy or hard stools in at least 25% of defecations
   - sensation of incomplete evacuation for at least 25% of defecations
   - sensation of anorectal obstruction/blockage for at least 25% of defecations
   - manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor)
   - fewer than 3 defecations per week
2. Loose stools rarely present without the use of laxatives
3. There are insufficient criteria for IBS

**Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis*