



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 13, 2012 May 13, 2013, January 6, 2015

## AMITIZA® (lubiprostone)

**LENGTH OF AUTHORIZATION:** Up to 6 months

### **REVIEW CRITERIA:**

#### *Chronic Idiopathic Constipation:*

- Patient must be  $\geq 18$  years old.
- Diagnosis of chronic **idiopathic (from an unknown cause)** constipation as evidenced in the medical records by:
  - less than three spontaneous bowel movements per week **-along with at least one of the following-**
  - at least a recent (within past year) six month history of very hard stools, sensation of incomplete evacuation or straining with defecation (constipation).
  - the provider must attempt to treat constipation related to a known cause by correcting the known cause (i.e. reducing or discontinuing opioid medication).
- The patient must have a history of trial and failure of over the counter laxatives (including Miralax [polyethylene glycol 3350]) and lactulose (a prescription medication) within the past month.
- Submission must contain medical documentation from a digestive disease specialist

#### *Irritable Bowel Syndrome (IBS) with constipation:*

- Patient must be a woman  $\geq 18$  years old.
- Diagnosis of IBS **with constipation** as evidenced in medical records by:
  - abdominal pain or discomfort occurring over at least 6 months **with**
  - two or more of the following: 1) relieved with defecation; 2) onset associated with a change in stool frequency ( $<3$  spontaneous bowel movements per week); and 3) onset associated with a change in stool form (associated with straining).
- Submission must contain medical documentation from a digestive disease specialist

### **DOSING & ADMINISTRATION:**

#### *Chronic idiopathic constipation:*

- 24 mcg taken twice daily orally with food and water
- Reduce the dosage in patients with moderate and severe hepatic impairment

#### *Irritable bowel syndrome with constipation:*

- 8 mcg taken twice daily orally with food and water
- Reduce the dosage in patients with severe hepatic impairment

*Dosage form:* 8 mcg and 24 mcg gelatin capsules