AMITIZA® (lubiprostone)

LENGTH OF AUTHORIZATION: Up to 6 months

REVIEW CRITERIA:

Chronic Idiopathic Constipation:
- Patient must be ≥ 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 ≥ 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

DOSSING & 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