



## Prior Authorization Approval Criteria

### *Amitiza (lubiprostone)*

<b>Generic name:</b>	Lubiprostone
<b>Brand name:</b>	Amitiza
<b>Medication class:</b>	Selective chloride channel activator
<b>FDA-approved uses:</b>	Chronic idiopathic constipation (CIC) Irritable bowel syndrome (IBS) with constipation in women 18 years and older
<b>Available dosage forms:</b>	8 mcg and 24 mcg capsules
<b>Usual dose range:</b>	CIC: 24 mcg twice daily IBS: 8 mcg twice daily
<b>Duration of therapy:</b>	Indefinite

#### **Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- Must have one of the following diagnoses:
    - Clinically diagnosed irritable bowel syndrome, defined as abdominal pain or discomfort occurring over at least 6 months with two or more of the following:
      - Relieved with defecation
      - Onset associated with a change in stool frequency
      - Onset associated with a change in stool form
  - OR**
  - Clinically diagnosed chronic idiopathic constipation, defined as less than 3 SBMs (spontaneous bowel movements) per week, on average, with one or more of the following symptoms of constipation for at least 6 months:
    - Very hard stools for at least a quarter of all bowel movements
  - OR**
  - Sensation of incomplete evacuation following at least a quarter of all bowel movements
  - OR**
  - Straining with defecation at least a quarter of the time.
- Must have a GI consult.
  - Over the age of 18 years.
  - Failed/intolerant to an increase in dietary fiber.
  - Failed/intolerant to at least one saline laxative, such as milk of magnesia, magnesium citrate or Fleet phospho-soda.
  - Failed/intolerant to at least one stimulant laxative, such as sennosides (Ex-lax, Senokot), bisacodyl (Dulcolax) or cascara sagrada.
  - Failed/intolerant to at least one other laxative, such as lactulose or polyethylene glycol (Miralax).

#### **Contraindications:**

- History of mechanical gastrointestinal obstruction.
- Known hypersensitivity to lubiprostone.

**Not approved if:**

- Does not meet the above-stated criteria.
- Has any contraindication to the use of lubiprostone

**Special considerations:**

One study reported that following 4 weeks of therapy, withdrawal of lubiprostone did not result in a rebound effect. There are no clinical trials comparing lubiprostone with other agents.

The most frequent adverse effects reported in a study are: nausea (30.9%), diarrhea (13.2%) and headache (13.0%).

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 9/13/06

Revised: 6/18/08