



## Prior Authorization Approval Criteria

### *Lotronex (alosetron)*

<b>Generic name:</b>	Alosetron
<b>Brand name:</b>	Lotronex
<b>Medication class:</b>	Selective 5-HT <sub>3</sub> receptor antagonist
<b>FDA-approved uses:</b>	Diarrhea-prominent irritable bowel syndrome in women
<b>Usual dose:</b>	1 mg once daily for 4 weeks, after 4 weeks may increase to 1 mg twice daily (if tolerated and once daily not sufficient to control symptoms). Lotronex should be discontinued in patients who have not had adequate control of IBS symptoms after 4 weeks of treatment with 1 mg twice daily.
<b>Duration of therapy:</b>	Indefinite

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

- Clinically diagnosed severe diarrhea-predominant irritable bowel syndrome (IBS)
- Adult female
- Only physicians who have enrolled in the Prometheus Prescribing Program for Lotronex should prescribe Lotronex.
- Must have diarrhea and one or more of the following:
  - Frequent and severe abdominal pain/discomfort
  - Frequent bowel urgency or fecal incontinence
  - Disability or restriction of daily activities due to IBS
- IBS symptoms are chronic (generally lasting 6 months or longer)
- Other GI medical conditions that could explain the symptoms have been ruled out
- Failed conventional therapy including:
  - Dietary changes (including fiber), or stress reduction, or behavioral changes
  - Antidiarrheals (ie, loperamide, diphenoxylate and atropine)
  - Antidepressants (ie, desipramine, imipramine)
  - Antispasmodics (ie, dicyclomine, hyoscyamine)

**Cautions:** Infrequent but serious gastrointestinal adverse reactions have been reported with the use of Lotronex. These events, including ischemic colitis and serious complications of constipation, have resulted in hospitalization and, rarely, blood transfusion, surgery, and death.

**Contraindications:** Patient has any of the following:

- Constipation
- History of chronic or severe constipation or with a history of sequelae from constipation
- History of intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions
- History of ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state
- Current or history of Crohn's disease or ulcerative colitis
- Active diverticulitis or a history of diverticulitis
- Unable to understand or comply with the Patient-Physician Agreement
- Known hypersensitivity to any component of the product

**Not approved if:**

- Patient has any contraindications to the use of alosetron.
- Patient does not meet the above-stated criteria.

**Special considerations:**

The Prescribing Program for Lotronex was implemented to help reduce risks of serious gastrointestinal adverse reactions. Only physicians who have enrolled in the Prometheus Prescribing Program for Lotronex, based on their understanding of the benefits and risks, should prescribe Lotronex.

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

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

Adopted: 11/12/04