



Prior Authorization Criteria

LOTRONEX® (*alosetron*) PA Criteria:

FDA Indication: Treatment of severe diarrhea-predominant irritable bowel syndrome (IBS) in women.

Select the diagnosis:

Severe diarrhea-predominant irritable bowel syndrome

ICD-10 code(s): _____

Initial approval: 12 week approval

Yes No Age of patient is within the age range as recommended by the FDA label.

AND

Yes No Female gender at birth

AND

Yes No Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) **and** at least one the following:

Yes No frequent and severe abdominal pain/discomfort

Yes No frequent bowel urgency or fecal incontinence

Yes No disability or restriction of daily activities due to IBS

AND

Yes No Symptoms for at least 6 months

AND

Yes No Anatomical or biochemical abnormalities of the GI tract have been excluded

AND

Has **NOT** responded adequately to **ALL** conventional therapies as follows:

Yes No Bulk forming fiber supplements

Yes No Anti-diarrhea medications

Yes No Antispasmodics: dicyclomine and/or hyoscyamine

Yes No Preferred drugs diarrhea predominant IBS

Reauthorization: 52 weeks approval based on the following criteria:

Yes No Symptoms of IBS continue to persist

AND

Yes No Documentation of positive clinical response

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Dosage and Administration: (0.5-1mg twice daily)

- Starting dose: 0.5 mg twice daily with meals.
 - Patients who become constipated should stop taking Lotronex until the constipation resolves.
 - Restart at one 0.5 mg tablet by mouth once a day. If constipation recurs, discontinue immediately.
- If after 4 weeks the dosage does not adequately control IBS symptoms, increase to one 1 mg tablet by mouth twice a day.
- Discontinue Lotronex in patients who have not had adequate control of IBS symptoms after 4 weeks of treatment with 1 mg twice a day.

Contraindications:

- Chronic or severe constipation or sequelae from constipation, intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation and/or adhesions, ischemic colitis, impaired intestinal circulation, thrombophlebitis, hypercoagulable state, Crohn's disease, ulcerative colitis, diverticulitis, severe hepatic impairment
- Concomitant use of fluvoxamine

Other Important information to Consider:

Lotronex also carries the following black box warnings:

- 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.
- Lotronex is indicated only for women with severe diarrhea predominant irritable bowel syndrome (IBS) who have not responded adequately to conventional therapy.
- Discontinue Lotronex immediately in patients who develop constipation or symptoms of ischemic colitis. Do not resume Lotronex in patients who develop ischemic colitis. Patients who have constipation should immediately contact their prescriber if the constipation does not resolve after LOTRONEX is discontinued. Patients with resolved constipation should resume LOTRONEX only on the advice of their treating prescriber