Lotronex (alosetron)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Lotronex (alosetron) tablets	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Lotronex (alosetron) may be approved based if the following criteria are met:

I. Individual is female age 18 or over; **AND**
II. Individual has a diagnosis of severe diarrhea-predominant Irritable Bowel Syndrome (IBS) defined as including diarrhea and one or more of the following:
   A. Frequent and severe abdominal pain/discomfort; **OR**
   B. Frequent bowel urgency or fecal incontinence; **OR**
   C. Disability or restriction of daily activities due to IBS;

AND
III. Individual has chronic symptoms of IBS that have persisted for 6 months or longer; **AND**
IV. Individual does NOT have an anatomic or biochemical abnormality of the gastrointestinal tract (e.g., intestinal obstruction, stricture, hypercoagulable state); **AND**
V. Individual has had a trial and inadequate response or intolerance to two of the following medications or has a contraindication to all of the following medications
   A. Loperamide; **OR**
   B. Antispasmodics (hyoscyamine, dicyclomine); **OR**
   C. Tricyclic antidepressants (ACG 2021).

Requests for **brand** Lotronex must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Individual has failed an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one chemically equivalent generic alosetron agent;
   AND
   A. Generic alosetron had inadequate response; **OR**
   B. Generic alosetron caused adverse outcome; **OR**
   C. The individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Lotronex (alosetron) may not be approved for any of the following:

I. Individuals with constipation, history of chronic or severe constipation, or complications resulting from constipation; **OR**
II. Individuals with a history of severe bowel disorders (such as but not limited to, intestinal obstruction, ischemic colitis, Crohn's disease, ulcerative colitis, or diverticulitis); **OR**
III. Individual has a diagnosis of severe hepatic impairment (Child-Pugh Class C); **OR**
IV. Concomitant use with fluvoxamine; **OR**
V. Concomitant use with Viberzi (eluxadoline).

Note:
Lotronex (alosetron) has a black box warning for serious gastrointestinal adverse reactions. Infrequent but serious gastrointestinal adverse reactions, including ischemic colitis and serious complications of constipation, have resulted in hospitalization, and rarely, blood transfusion, surgery, and death. The FDA has required the manufacturer to develop a comprehensive risk management program that includes the enrollment of physicians in the Lotronex REMS Program. Additional information and forms for individuals, prescribers, and pharmacists may be found on the manufacturer's website:
http://www.lotronexrems.com.

Key References:

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3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 7, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Ford AC, Moayyedi P, Chey WD; ACG Task Force on Management of Irritable Bowel Syndrome. American College of Gastroenterology Monograph on Management of Irritable Bowel Syndrome. Am J Gastroenterol. 2018. Jun;113(Suppl 2):1-18.
6. Lacy BE, Pimentel M, Brenner DM, et al; ACG Clinical Guideline: Management of Irritable Bowel Syndrome. Am J Gastroenterol. 2021 Jan 1;116:17-44.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
8. Pimentel M, Saad RJ, Long MD, Rao SSC. ACG clinical guideline: small intestinal bacterial overgrowth. *Am J Gastroenterol*. 2020;115(2):165-178.
9. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic Encephalopathy in Chronic Liver Disease: 2014 Practice Guideline by American Association for the Study of Liver Diseases and the European Association for the Study of the Liver. Hepatology. 2014;60(2):715-35.
10. Weinberg DS, Smalley W, Heidelbaugh JJ, et. al. American Gastroenterological Association Institute Guideline on the Pharmacological Management of Irritable Bowel Syndrome. *Gastroenterology*. 2014; 147(5):1146-48.