

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

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 2018).

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).

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

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>.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Chang L, Lembo A, Sultan S. American Gastroenterological Association Institute Technical Review on the Pharmacological Management of Irritable Bowel Syndrome. *Gastroenterology*. 2014; 147(5):1149–1172. Available from: [http://www.gastrojournal.org/article/S0016-5085\(14\)01090-7/pdf](http://www.gastrojournal.org/article/S0016-5085(14)01090-7/pdf). Accessed on: June 6, 2019.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 6, 2019.
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. Available at: https://journals.lww.com/ajg/Fulltext/2018/06002/American_College_of_Gastroenterology_Monograph_on.1.aspx Accessed on June 9, 2019.
6. Lauritano EC, Gabrielli M, Scarpellini E, et. al. Antibiotic therapy in small intestinal bacterial overgrowth: rifaximin versus metronidazole. *Eur Rev Med Pharmacol Sci*. 2009; 13(2): 111-6.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

8. 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.
9. 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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.