| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | NA |

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# Lotronex (alosetron)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization<br>Quantity Limit | 1 year |

| Medications | Quantity Limit |
|---|---|
| Lotronex (alosetron) 0.5mg, 1mg tablets | May be subject to quantity limit |

## APPROVAL CRITERIA

Requests for Lotronex (alosetron) may be approved based on the following criteria:

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 (AGA 2014).

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).

| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | NA |

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**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<br>N/A | Date effective<br>N/A | Mandate details (including specific bill if applicable)<br>N/A |

**Key References**:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.