



MEDICATION POLICY

Generic Name: Alosetron

Therapeutic Class or Brand Name: Lotronex®

Applicable Drugs (if Therapeutic Class):

Preferred: Alosetron tablets (generic)

Non-Preferred: Lotronex® tablets

Date of Origin: 2/1/13

Date Last Reviewed/Revised: 10/9/16

GPI Code: 5255401510

Prior Authorization Criteria (may be considered medically necessary when criteria I through V are met):

- I. Documented diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) AND documentation that criteria A and B are met:
 - A. Patient has had chronic IBS symptoms for a minimum of 6 months.
 - B. Anatomic or biochemical abnormalities of the gastrointestinal tract have been excluded.
- II. Patient is female.
- III. Patient has had a documented trial and failure of, intolerance to, or contraindication to ALL of the following conventional therapies listed in A through C:
 - A. Dietary changes (including fiber).
 - B. At least one antispasmodic agent (i.e. dicyclomine, hyoscyamine).
 - C. At least one anti-diarrheal agent (i.e. loperamide, diphenoxylate/atropine).
- IV. Minimum age requirement: 18 years old.
- V. Non-preferred products (i.e. Lotronex® tablets) require a documented clinical reason containing details as to why generic alosetron is not appropriate or is contraindicated.

Exclusion Criteria:

- Patients with constipation.
- Patients with a history of chronic or severe constipation or sequelae from constipation; intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions; ischemic colitis;

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impaired intestinal circulation, thrombophlebitis, or hypercoagulable state; Crohn's disease or ulcerative colitis; diverticulitis; severe hepatic impairment.

- Patients with a concomitant use of fluvoxamine.

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- 60 tablets per 30 days.

Approval Length:

- **Authorization:** 3 months.
- **Re-Authorization:** 6 months. An updated letter of medical necessity or progress notes showing positive clinical response on medication. Alosetron should be discontinued in patients who have not had adequate control of IBS symptoms after 4 weeks of treatment with 1 mg twice a day.

Appendix:

N/A

References:

1. <http://www.fchp.org/~media/Files/FCHP/Imported/Lotronexalose tron.pdf.ashx>.
2. https://www.optumrx.com/rxsol/live/PAGDocs/Guideline_3587.pdf.
3. [Medi-Span](#).
4. https://www.lotronex.com/hcp/_docs/PI%20v.20v.SeBELa_Final.pdf.

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Historical Tracking Of Changes Made To Policy	
10/9/2016	<ol style="list-style-type: none"> 1. Changed “N/A” to “Preferred: Alosetron tablets (generic); Non-Preferred: Lotronex® tablets” following Applicable Drugs. 2. Removed “V. Prescriber is enrolled in the Prometheus Prescribing Program for Lotronex®” from Prior Authorization Criteria. 3. Added “V. Non-preferred products (i.e. Lotronex® tablets) require a documented clinical reason containing details as to why generic alosetron is not appropriate or is contraindicated” to Prior Authorization Criteria. 4. Changed “Lotronex®” to “Alosetron” following Re-Authorization under Approval Length. 5. Updated “https://www.lotronex.com/hcp/_docs/Lotronex_PI.pdf” to “https://www.lotronex.com/hcp/_docs/PI%20v.SeBELA_Final.pdf” under References. 6. Removed “http://www.connecticare.com/provider/PDFs/Pharmacy/Lotronex.pdf” from References (link no longer valid).
8/21/2015	<ol style="list-style-type: none"> 1. Changed Prior Authorization Criteria from: “Prior Authorization Criteria (may be considered medically necessary when criteria I through VII are met): I. Documented diagnosis of Irritable Bowel Syndrome (IBS) with diarrhea predominant symptoms for at least 6 months; II. Adult female; III. Documented trial and failure of, or intolerance to, dietary changes (including fiber); IV. Documented trial and failure of, or contraindication to, at least one antispasmodic agent (i.e. dicyclomine, hyoscyamine); V. Documented trial and failure of, or contraindication to, at least one anti-diarrheal agent (i.e. loperamide, diphenoxylate/atropine); VI. Minimum age requirement: 18 years old; VII. Only physicians who have enrolled in the Prometheus Prescribing Program for Lotronex® should prescribe Lotronex®” to: “Prior Authorization Criteria (may be considered medically necessary when criteria I through V are met): I. Documented diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) AND documentation that criteria A and B are met: A. Patient has had chronic IBS symptoms for a minimum of 6 months; B. Anatomic or biochemical abnormalities of the gastrointestinal tract have been excluded; II. Patient is female. III. Patient has had a documented trial and failure of, intolerance to, or contraindication to ALL of the following conventional therapies listed in A through C: A. Dietary changes (including fiber); B. At least one antispasmodic agent (i.e. dicyclomine, hyoscyamine); C. At least one anti-diarrheal agent (i.e. loperamide, diphenoxylate/atropine); IV. Minimum age requirement: 18 years old; Prescriber is enrolled in the Prometheus Prescribing Program for Lotronex®”.
2/14/2014	<ol style="list-style-type: none"> 1. Adapted policy to new format. 2. Added GPI code. 3. Changed Exclusion Criteria from: “Patient has a documented contraindication to Lotronex® (i.e. patient has or has a history of: (1) chronic or severe constipation or with sequelae from constipation; (2) intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions; (3) ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state; (4) Crohn’s disease or ulcerative colitis; or (5) diverticulitis.)” to: “Patients with constipation; Patients with a history of chronic or severe constipation or sequelae from constipation; intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions; ischemic colitis; impaired intestinal circulation, thrombophlebitis, or hypercoagulable state; Crohn’s disease or ulcerative colitis; diverticulitis; severe hepatic impairment; Patients with a concomitant use of fluvoxamine”. 4. Updated references to include Medi-Span and an updated website address for package insert.

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