MEDICATION POLICY:
Lotronex®

Generic Name: Alosetron

Therapeutic Class or Brand Name: Lotronex®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 5255401510

Preferred: Alosetron tablets (generic)

Non-preferred: Lotronex® tablets

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 2/5/2019

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; 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/Lotronexalosetron.pdf.ashx .
2. Medi-Span®.
3. https://www.lotronex.com/hcp/_docs/PI%20v.Sebela_Final.pdf .

Historical Tracking of Changes Made to Policy

Date	Notes/Changes
2/5/2019	1. Policy reviewed: no changes.
1/4/2018	1. **Removed** "https://www.optumrx.com/rxsol/live/PAGDocs/Guideline_3587.pdf" **from References** (link no longer valid).
10/9/2016	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	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	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.

to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.