Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Lotronex (alosetron)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***September 2013 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Lotronex (alosetron).

Lotronex (alosetron) is indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have:
- Chronic IBS symptoms (generally lasting 6 months or longer)
- Had anatomic or biochemical abnormalities of the gastrointestinal tract excluded
- Not responded adequately to conventional therapy

Severe IBS includes diarrhea and 1 or more of the following:
- Frequent and severe abdominal pain/discomfort
- Frequent bowel urgency or fecal incontinence
- Disability or restriction of daily activities due to IBS

DEFINITIONS

N/A

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POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Lotronex (alosetron), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a gastroenterologist
- Must be a female member
- Must be age 18 years or older
- Must have a diagnosis of severe diarrhea-predominant IBS with chronic IBS symptoms (generally lasting 6 months or longer). Chart documentation describing how diagnosis was confirmed (e.g. duration of symptoms, types of symptoms, exclusion of other diagnoses and causes of diarrhea, etc.) is required.
- Must have an adequate trial and failure of loperamide or antispasmodics (such as dicyclomine or hyoscyamine) with inadequate response or significant side effect/toxicity or have a contraindication to these therapies
- Must NOT have any of the following:
    - Constipation
    - Anatomic or biochemical abnormalities of the gastrointestinal tract
    - 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 impairement
    - Concomitant use of fluvoxamine (Luvox®, Luvox® CR)

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon the following:

- Documentation from the provider that the member's condition has improved as a result of treatment
- Documentation that there is no evidence of constipation or ischemic colitis

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year
Quantity Level Limit	
Lotronex	60 tablets per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Lotronex [prescribing information]. San Diego, CA: Prometheus Therapeutics and Diagnostics; September 2010.
2. Bardhan K, Bodemar G, Geldof H, et. al. A double-blind, randomized, placebo-controlled dose-ranging study to evaluate the efficacy of alosetron in the treatment of irritable bowel syndrome. *Aliment Pharmacol Ther* 2000;14:23-34.
3. Irritable Bowel Syndrome in Adults: Diagnosis and Management of Irritable Bowel Syndrome in Primary Care. *National Institute for Health and Clinical Excellence*. February 2008.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*