UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for IBS-Diarrhea

Program	Prior Authorization
Medication	IBS-Diarrhea
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

1. Background:

Lotronex (alosetron hydrochloride) is indicated for severe diarrhea-predominant irritable bowel syndrome (IBS) in women. It is indicated only for women with severe diarrhea-predominant IBS who have: • chronic IBS symptoms (generally lasting 6 months or longer) • had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and • not responded adequately to conventional therapy. Diarrhea-predominant IBS is severe if it includes diarrhea and one 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. Because of infrequent but serious gastrointestinal events associated with Lotronex, the indication is restricted to those for whom the benefit-to-risk balance is most favorable. Clinical studies have not been performed to adequately confirm the benefits of Lotronex in men.

Viberzi (eluxadoline) is a mu-opioid receptor agonist, indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults. Viberzi stimulates mu-opioid receptors in the GI tract, leading to decreased muscle contractility, inhibition of water and electrolyte secretion, and increased rectal sphincter tone. It also acts as an antagonist at delta-opioid receptors in the gut, which may reduce the risk of iatrogenic constipation and abdominal pain.

2. Coverage Criteria:

A. <u>Brand Lotronex, Generic alosetron</u>

1. <u>Initial Authorization</u>

a. **Brand Lotronex, generic alosetron** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS)

-AND-

(2) Symptoms for at least 6 months

-AND-

(3) Patient was female at birth

-AND-

(4) Age greater than or equal to 18 years

-AND-

(5) History of failure, contraindication, or intolerance to **two** of the following:
- (a) antispasmodic agent [eg, Bentyl (dicyclomine)]
- (b) antidiarrheal agents [eg, loperamide]
- (c) tricyclic antidepressant [eg, amitriptyline]

-AND-

(6) If the request is BRAND Lotronex, **one** of the following:
- (a) The multi-source brand is being requested because of an adverse reaction, allergy or sensitivity to a generic equivalent
- (b) The multi-source brand is being requested due to a therapeutic failure with the generic equivalent
- (c) The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient
- (d) Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient

Authorization will be issued for 12 months.

2. Initial Authorization

a. **Brand Lotronex, generic alosetron** will be approved based on **all** of the following criteria:

(1) Symptoms of IBS continue to persist

-AND-

(2) Documentation of positive clinical response to Lotronex therapy

Authorization will be issued for 12 months.

B. Viberzi

1. Initial Authorization

a. **Viberzi** will be approved based on **all** of the following criteria:

(1) Diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

-AND-

(2) History of failure, contraindication, or intolerance to **two** of the following:

(a) antispasmodic agent [eg, Bentyl (dicyclomine)]
(b) antidiarrheal agents (eg, loperamide)
(c) tricyclic antidepressant (eg, amitriptyline)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Viberzi** will be approved based on the following criteria:

(1) Documentation of positive clinical response to Viberzi therapy

Authorization will be issued for 12 months.

3. References:

1. Lotronex Prescribing Information. Prometheus Laboratories Inc., March 2014.
2. American Gastroenterological Association medical position statement: Irritable Bowel Syndrome. Gastroenterol 2002;123:2105-7.
3. Wilkins T, Pepitone C, Alex B, Schade RR. Diagnosis and management of IBS in adults. Am Fam Physician. 2012;86(5):419-26.
4. Camiller M, Mayer EA, Drossman DA, et al. Improvement in the pain and bowel function in female irritable bowel patients with alosetron, a 5-HT3 antagonist. Aliment Pharmacol Ther 1999;13(9):1149-5.

5. Chey WD, Chey WY, Health AT, et al. Long-term Safety and Efficacy of Alosetron in Women with Severe Diarrhea-Predominant Irritable Bowel Syndrome. Am J of Gastroenterol 2004;99:2195-2203.
6. American College of Gastroenterology IBS Task Force. Evidence-based position statement on the management of irritable bowel syndrome in North America. Am J Gastroenterol. 2009;104(suppl 1):S1-S35.
7. Viberzi Prescribing Information. Allergan USA, Inc., Irvine, CA. November 2017.
8. American College of Gastroenterology Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. Am J Gastroenterol. 2014; 109: S2-S26.
9. American Gastroenterological Association Institute Guideline on the Pharmacological Management of Irritable Bowel Syndrome. Gastroenterology 2014; 147:1146–1148.

Program	Program Type- Prior Authorization
Change Control	
Date	Change
3/21/2013	New program
3/31/2016	Annual Review- Added Viberzi to this policy; Updated policy template; Added TCA as an alternative step option for Lotronex and Viberzi.
10/2016	Updated female patient language.
3/2017	Updated all authorization durations to 12 months. Updated references.
10/2017	Added multisource brand language for brand Lotronex. Deleted endnote references throughout.
3/2018	Updated background and references. Added abbreviation IBS-D in clinical criteria.