UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Irritable Bowel Syndrome-Diarrhea

Program	Prior Authorization
Medication	Lotronex (alosetron), Viberzi (eluxadoline)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

1. Background:

Lotronex (alosetron) is indicated only for use in women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have: chronic IBS, had anatomical or biochemical abnormalities of the gastrointestinal tract excluded, and not responded adequately to conventional therapy.

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. Lotronex

1. Initial Authorization

a. **Lotronex** will be approved based on **all** 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 (e.g. dicyclomine)
(b) antidiarrheal agents (e.g. loperamide)
(c) tricyclic antidepressant (e.g. amitriptyline)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Lotronex** will be approved based on the following criterion:

(1) 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 (e.g. dicyclomine)
(b) antidiarrheal agents (e.g. loperamide)
(c) tricyclic antidepressant (e.g. amitriptyline)

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Viberzi therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Lotronex Prescribing Information. San Diego, CA: Prometheus Laboratories Inc.; January 2016.
2. Hadley SK, Gaarder SM. Treatment of irritable bowel syndrome. Am Fam Physician. 2005 Dec 15;72(12):2501-6.
3. Spruill WJ, Wade WE. Diarrhea, Constipation, and Irritable Bowel Syndrome. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey M. eds. *Pharmacotherapy: A Pathophysiologic Approach*. 8th ed. NY: Mc-Graw-Hill, 2011.
4. Viberzi Prescribing Information. Madison, NJ: Allergan USA, Inc.; June 2018.
5. American College of Gastroenterology Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. Am J Gastroenterol. 2014; 109: S2-S26.
6. Pietrzak, A., Skrzydło-Radomańska, S., Mulak, A., et. al. Guidelines on the management of irritable bowel syndrome. *Gastroenterology*. 2018; 13(4):259-288.

Program	Prior Authorization- Irritable Bowel Syndrome- Diarrhea
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.
3/2019	Renamed policy- Irritable Bowel Syndrome- Diarrhea. Removed multisource brand language for brand Lotronex to be consistent with format of other policies that contain multisource brand drugs. Updated background and references.
3/2020	Annual review. Updated references.