UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1060-14
Program	Prior Authorization/Notification
Medication	Lotronex®* (alosetron)
P&T Approval Date	5/2013, 5/2014, 5/2015, 4/2016, 10/2016, 10/2017, 10/2018, 10/2019, 11/2020, 11/2021, 1/2023, 1/2024, 1/2025
Effective Date	4/1/2025

1. Background:

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

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Lotronex** will be approved based on **all** of the following criteria:

   a. Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) with symptoms for at least six months

   -AND-

   b. Patient was female at birth

   -AND-

   c. Has not responded adequately to conventional therapy (e.g., loperamide, antispasmodics)

   -AND-

   d. Anatomic or biochemical abnormalities of the GI tract have been excluded

Authorization will be issued for 12 months

B. Reauthorization

1. **Lotronex** will be approved based on documentation of positive clinical response to Lotronex therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

***** **Brand Lotronex** is typically excluded from coverage. Tried/failed criteria may be in place. Please refer to plan specifics to determine coverage status

3. Additional Clinical Programs:

- 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 [package insert]. Roswell, Georgia: Sebela Pharmaceuticals; April 2019.

Program	Prior Authorization/Notification- Lotronex
Change Control	
Date	Change
5/2013	New Program
5/2014	Clarified reauthorization criteria and increased reauthorization approval period. Removed age edit. Added requirement for exclusion of anatomic or biochemical abnormalities of GI tract.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
5/2015	Annual Review. No changes.
4/2016	Annual Review. Added requirements for symptoms associated with IBS.
10/2016	Added HCR gender dysphoria language.
10/2017	Revised initial authorization criteria. Increased authorization to 6 months. Revised reauthorization criteria.
10/2018	Annual review. No changes.
10/2019	Annual review. No changes.
11/2020	Annual review. Updated references.
11/2021	Annual review. Added requirements for exclusion of anatomic or biochemical abnormalities of GI tract. Updated references.
1/2023	Annual review. Added state mandate language.
1/2024	Annual review. No changes.
1/2025	Annual review. Updated initial authorization to 12 months.