PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

LOTRONEX
(alosetron)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

FDA-APPROVED INDICATIONS

Lotronex is indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have:

- chronic IBS symptoms (generally lasting six 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 adverse reactions associated with Lotronex, the indication is restricted to those patients 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.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for a biological female or a person that self-identifies as a female with a diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS)

AND

- The patient has experienced chronic irritable bowel syndrome (IBS) symptoms lasting at least 6 months

AND

- Gastrointestinal tract abnormalities have been ruled out

AND

- The patient has had an inadequate response to conventional therapy

REFERENCES

1. Lotronex [package insert]. Roswell, GA: Sebela Pharmaceuticals Inc.; July 2016.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed August 31, 2022.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed August 31, 2022.