

Reference number(s)
129-A, 690-A

Initial Prior Authorization

Lotronex

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lotronex	alosetron

Indications

FDA-approved Indications

Lotronex 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, 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.

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Coverage Criteria

Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS)

Authorization may be granted when 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) when ALL of the following criteria are met:

- The patient has experienced chronic IBS symptoms lasting at least 6 months.
- Gastrointestinal tract abnormalities have been ruled out.
- The patient has had an inadequate response to conventional therapy.

Duration of Approval (DOA)

- 129-A: DOA: 36 months
- 690-A: DOA: 12 months

References

1. Lotronex [package insert]. Roswell, GA: Sebelo Pharmaceuticals Inc.; July 2016.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed September 15, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/15/2025).