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.

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

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: Sebela Pharmaceuticals Inc.; July 2016.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed August 13, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 08/13/2024).

Document History

Written by: UM Development (LS)

Date Written: 09/2003

Revised: (JG) 11/2002; (MG) 08/2003; (CM) 09/2004; (JG) 10/2005; (CT) 06/2006, 05/2007, 06/2008, 06/2009, 06/2010, 07/2011, 07/2012, 10/2012 (extended duration), 08/2013; (JH) 08/2014, 08/2015; (KM) 08/2016 (removed safety question, removed female from question 1), 09/2016 (updated wording of criteria for approval to not discriminate for TGC patients); (DS) 08/2017 (no clinical changes); (JG) 09/2018 (no clinical changes); (DS) 09/2019 (no clinical changes; combined criteria; removed MDC); (PM) 08/2020 (no clinical changes); (DS) 09/2021 (no clinical changes); (VLS) 09/2022 (no clinical changes); (SS) 09/2023 (no clinical changes); (ANB) 09/2024 (no clinical changes)

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

Reviewed: Medical Affairs 02/11/2000, 08/2000, 11/2002, 08/2003; (MM) 10/2004, 10/2005, 06/2006; (WF) 05/2007, 06/2008, 06/2009; (KP) 06/2010, 07/2011; (LB) 07/2012; (KP) 08/2013; (KC) 08/2014; (MC) 08/2015: (ME) 08/2016; (CHART) 09/26/2019, 09/24/2020/ 09/30/2021, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 02/2003, 10/2003, 11/2004, 12/2006, 12/2007, 12/2008, 12/2009, 02/2011, 02/2012, 04/2013, 12/2013, 12/2014, 12/2015, 12/2016, 12/2017, 12/2018, 12/2019, 12/2020, 12/2021, 12/2022, 12/2023, 12/2024

CRITERIA FOR APPROVAL

1	Is the requested drug 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)? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Has the patient experienced chronic irritable bowel syndrome (IBS) symptoms lasting at least 6 months? [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Have gastrointestinal tract abnormalities been ruled out? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Has the patient had an inadequate response to conventional therapy? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for irritable bowel syndrome (IBS) with diarrhea as the main symptom in a biological female or a person that self-identifies as a female. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.

			[Short Description: Diagnosis.]
2.	Go to 3	Deny	Your plan only covers this drug if you have experienced chronic irritable bowel syndrome (IBS) symptoms for at least 6 months. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Disease severity]
3.	Go to 4	Deny	Your plan only covers this drug if gastrointestinal tract abnormalities have been ruled out. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Other, GI abnormalities not ruled out]
4.	Approve, 12 Months	Deny	Your plan only covers this drug if you have tried conventional therapy and it did not work well for you. We have denied your request because you have not tried conventional therapy. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Conventional therapy]