PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

LOTRONEX
(alosetron)

Status: CVS Caremark Criteria ***MDC-2***
Type: Initial Prior Authorization ***Ref # 690-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated*

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 events 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 all of the following apply: A) Chronic IBS symptoms lasting at least six months, B) Gastrointestinal tract abnormalities have been ruled out, C) Inadequate response to conventional therapy

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. 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.

REFERENCES

1. Lotronex [package insert]. San Diego, CA: Prometheus Laboratories Inc.; July 2016.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed September 2018.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed September 2018.

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, 08/2013, (JH) 08/2014, 08/2015, (SE) 06/2016 (created separate Med D); 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)
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 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, 11/2017, 12/2018

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) AND do all of the following apply: A) Chronic IBS symptoms lasting at least 6 months, B) Gastrointestinal tract abnormalities have been ruled out, C) Inadequate response to conventional therapy?	Yes	No

Guidelines for Approval	
Duration of Approval	**12 Months**
Set 1	
Yes to questions	**No to questions**
1	None

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are a biological female or you self-identify as female with severe diarrhea-predominant irritable bowel syndrome (IBS) and all of the following: – You have had IBS symptoms for at least 6 months – Gastrointestinal tract abnormalities have been ruled out – Other therapies did not work for you Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]