



**Amitiza® (lubiprostone) capsules
Linzess® (linaclotide) capsules
Trulance® (plecanatide) tablets
Effective January 1, 2020**

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Lubiprostone is a chloride channel activator that acts locally on the gastrointestinal membrane to increase intestinal fluid secretion and improve fecal transit.

Linaclotide and plecanatide bind and agonize an intestinal enzyme (guanylate cyclase-C) resulting in increase in intestinal fluid and GI transit.

FDA Approved Indications

1. Treatment of Chronic idiopathic constipation (CIC) in adults
2. Treatment of irritable bowel syndrome (IBS) with constipation in adults
3. Treatment of opioid-induced constipation in adults with chronic noncancer pain, including patient with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation (**Amitiza only**)
4. Chronic constipation (not otherwise specified) and all other causes of constipation have been ruled out (medication-induced constipation, gastrointestinal [GI] motility issues, GI obstruction, etc.)

Coverage Guidelines

1. Authorization may be granted for members, 18 years of age and older, who are currently receiving treatment for an approved indication, excluding when the product is obtained as samples or via manufacturer’s patient assistance program.

OR



2. Authorization may be granted for members, 18 years of age and older, when all the following criteria are met:
 - a. The member requires treatment for an approved indication
 - b. The member has failed dietary and lifestyle modifications
 - c. The member has experienced an allergy or side effect with or has had at least a 1-week trial resulting in treatment failure or inadequate response with one (1) laxative agent such as saline, stimulant, bulk, or osmotic laxatives (e.g., milk of magnesia, lactulose, polyethylene glycol [PEG], psyllium, methylcellulose, magnesium citrate, senna, bisacodyl, etc.)

Continuation of Therapy

Reauthorizations may be approved when a physician assessment of improvement in the member's condition has been submitted.

Limitations

1. Authorizations will be granted for 12 months

References

1. Amitiza (lubiprostone) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America; June 2018
2. Linzess (linaclotide) [prescribing information]. Madison, NJ: Allergan USA, Inc; October 2018.
3. Trulance (plecanatide) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals, a division of Bausch Health US, LLC; May 2019
4. FDA approves New Prescription Drug for Adults for Treatment of Chronic “Idiopathic” Constipation. January 31, 2006. Available at: <http://www.fda.gov/bbs/topics/news/2006/NEW01305.html>.
5. Krause R, Foehl H, Koltun W, et al. Sa1444 effect of plecanatide on stool consistency in the treatment of chronic idiopathic constipation (CIC): results from two phase III studies. *Gastroenterology* 2016; 150:S317.
6. Schoenfeld P, Lacy BE, Chey WD, et al. Low-Dose Linaclotide (72 µg) for Chronic Idiopathic Constipation: A 12-Week, Randomized, Double-Blind, Placebo-Controlled Trial. *Am J Gastroenterol* 2018; 113:105.
7. Nualart M, Morgan W, Berenguer R, et al. Sa1443 effect of plecanatide on patient assessments in chronic idiopathic constipation (CIC): results from two phases III studies. *Gastroenterology* 2016; 150:S317.
8. Ueno R. Multiple, escalating, oral-dose study to assess the safety, tolerance and pharmacodynamic profile of lubiprostone in normal healthy volunteers (Abstract). *Neurogastroenterology and Motility* 2005;17:625.
9. Weinberg DS, Smalley W, Heidelbaugh JJ, Sultan S; American Gastroenterological Association. American Gastroenterological Association Institute Guideline on the pharmacological management of irritable bowel syndrome. *Gastroenterology*. 2014;147(5):1146-8. World Gastroenterology Organisation Global Guideline. Constipation: a global perspective. Available at: http://www.worldgastroenterology.org/assets/export/userfiles/05_constipation.pdf. Accessed May 27, 2015.

Review History

Trulance Program:

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Implemented: 01/01/18
Reviewed: 09/18/17 P&T Mtg

Linzess Program:

06/24/13 – Reviewed
08/12/13 – Implemented
04/07/14 – Reviewed
06/23/14 – Reviewed

Amitiza Program:

04/23/07 – Reviewed
06/01/07 – Implemented
06/16/08 – Added IBS-C indication
06/15/09 – Updated warnings
06/21/10 – Reviewed
06/27/11 – Updated hepatic dosing
06/25/12 – Updated dosing
06/24/13 – Updated
04/07/14 – Reviewed
06/23/14 – Reviewed

Criteria Programs combined:

06/22/15 – Reviewed
06/27/16 – Reviewed
06/26/17 – Reviewed
02/26/18 – Reviewed
02/20/19 – Reviewed
11/20/19 – Changed laxative trials from two to one required

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