

**Amitiza® (lubiprostone) capsules
 Linzess® (linaclotide) capsules
 Motegrity® (prucalopride) tablets
 Trulance® (plecanatide) tablets
 Effective 5/1/2024**

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
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 an increase in intestinal fluid and GI transit.

Prucalopride is a 5-HT₄ receptor agonist whose action at the receptor site promotes cholinergic and noradrenergic, noncholinergic neurotransmission by enteric neurons leading to stimulation of the peristaltic reflex, intestinal secretions, and gastrointestinal motility.

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 when all the following criteria are met:

- a. ONE of the following:
 - i. Member is 18 years or older with one for the following indications:
 - A. Treatment of Chronic idiopathic constipation (CIC) in adults
 - B. Treatment of irritable bowel syndrome (IBS) with constipation in adults
 - C. 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**)
 - D. 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.)
 - ii. Member is 6 to 17 years of age with a diagnosis of functional constipation (FC) [**Linzess only**]
- 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.)
- d. **Motegrity only:** The member has a diagnosis of chronic idiopathic constipation and previous treatment with either Amitiza or Linzess

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 approved for 12 months
- 2. The following quantity limits apply:

Amitiza	60 capsules per 30 days
Trulance	30 tablets per 30 days
Linzess	30 capsules per 30 days
Motegrity	30 tablets per 30 days

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.
10. Motegrity (prucalopride) [prescribing information]. Lexington, MA Shire US Inc: December 2018.

Review History

Trulance Program:

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

01/22/20 – Added Motegrity, added QL for Amitiza, Linzess, and Trulance.

4/10/2024 – Reviewed and updated for April P&T; added pediatric indication for Linzess for functional constipation. Effective 5/1/2024

