

**Linzess (linaclotide) capsules
 Lubiprostone capsules
 Prucalopride tablets
 Trulance (plecanatide) tablets
 Effective 10/01/2026**

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange		Program Type	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit			
Specialty Limitations	N/A			
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029	
Exceptions	N/A			

Overview

Lubiprostone is a chloride channel activator indicated for the treatment of:

- Chronic idiopathic constipation (CIC) in adults
- Opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
 - Limitation: Effectiveness of lubiprostone in the treatment of OIC in patients taking diphenylheptane opioids (e.g., methadone) has not been established.
- Irritable bowel syndrome with constipation (IBS-C) in women 18 years of age or older

Linzess (linaclotide) is a guanylate cyclase-C agonist indicated for the treatment of:

- Irritable bowel syndrome with constipation (IBS-C) in adults and pediatric patients 7 years of age and older
- Chronic idiopathic constipation (CIC) in adults
- Functional constipation (FC) in pediatric patients 2 years of age and older

Prucalopride is a 5-HT₄ receptor agonist indicated for the treatment of chronic idiopathic constipation in adults.

Trulance (plecanatide) is a guanylate cyclase-C agonist indicated in adults for treatment of:

Chronic idiopathic constipation (CIC)
 Irritable bowel syndrome with constipation (IBS-C)

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when all of the following criteria are met:

1. ONE of the following:
 - a. Member is 18 years or older with one for the following indications:
 - i. Chronic idiopathic constipation (CIC)
 - ii. Irritable bowel syndrome with constipation (IBS-C) (**lubiprostone, Linzess, and Trulance only**)
 - iii. 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 (**lubiprostone only**)
 - iv. 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.)
 - b. Member is 2 to 17 years of age with a diagnosis of functional constipation (FC) (**Linzess only**)
 - c. Member is 7 to 17 years of age with a diagnosis of IBS-C (**Linzess only**)
2. Member has failed dietary and lifestyle modifications
3. 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.)
4. **Prucalopride only:** Diagnosis of chronic idiopathic constipation and previous treatment with either lubiprostone or Linzess

Continuation of Therapy

Requests for reauthorization will be approved when all of the following criteria are met:

1. Member demonstrates a positive clinical response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months
2. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limit
Linzess capsule	1 capsule per day
Lubiprostone capsule	2 capsules per day
Prucalopride tablet	1 tablet per day
Trulance tablet	1 tablet per day

References

1. Amitiza (lubiprostone) [prescribing information]. Bridgewater, NJ: Sucampo Pharma Americas LLC; January 2024.
2. Linzess (linaclotide) [prescribing information]. North Chicago, IL: Abbvie, Inc; Allergan USA, Inc; May 2026.
3. Motegrity (prucalopride) [prescribing information]. Lexington, MA: Shire US Inc; July 2025.
4. 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.



5. 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.
6. Trulance (plecanatide) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals, a division of Bausch Health US, LLC; March 2024.

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

02/11/2026 – Reviewed and updated at February P&T. Added supplemental indication for Linzess for IBS-C in children 7-17 years of age. Updated policy to reflect generic availability of Amitiza and Motegrity. Updated reauthorization criteria to require attestation. Updated initial criteria to indicate that only lubiprostone, Linzess and Trulance will be approved for irritable bowel syndrome with constipation (IBS-C). Effective 05/01/2026.

07/15/2026 – Reviewed and updated at July P&T. Lowered approvable age for Linzess for functional constipation from 6 years to 2 years to reflect expanded age indication. Effective 10/01/2026.

