

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2025 P 3193-1
Program	Step Therapy
Medication	Constipation agents - Ibsrela® (tenapanor)*, Motegrity® [(prucalopride) brand only]*, Movantik® (naloxegol), Relistor® (methylnaltrexone) tablets*, Trulance® (plecanatide)*
P&T Approval Date	7/2025
Effective Date	10/1/2025

1. Background:

Amitiza (lubiprostone)* is indicated for the treatment of chronic idiopathic constipation, for opioid induced constipation 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, and for irritable bowel syndrome with constipation in women aged 18 years and older. Ibsrela (tenapanor)* is indicated for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults. Linzess (linaclotide) is indicated in adults for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation and for the treatment of functional constipation (FC) in pediatric patients 6 to 17 years of age. Trulance (plecanatide)* is indicated in adults for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation. Motegrity (prucalopride)* is indicated for the treatment of chronic idiopathic constipation (CIC) in adults. Movantik (naloxegol)*, Relistor (methylnaltrexone) tablets* and Symproic (naldemedine) are opioid antagonists indicated for the treatment of opioid-induced constipation 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. Physicians and patients should periodically assess the need for continued treatment with these agents.

2. Coverage Criteria^a:

A. Chronic Idiopathic Constipation

- a. **Motegrity*brand only or Trulance*** will be approved based on the following criterion:
 - 1. History of failure, contraindication or intolerance to <u>two</u> of the following (document drug and date tried):
 - a) lubiprostone (generic Amitiza)
 - b) prucalopride (generic Motegrity)
 - c) Linzess

Authorization will be issued for 12 months.

B. Irritable Bowel Syndrome with Constipation

a. **Ibsrela*** or **Trulance*** will be approved based on the following criterion:



- 1. History of failure, contraindication or intolerance to **both** of the following (document date tried):
 - a. lubiprostone (generic Amitiza)
 - b. Linzess

Authorization will be issued for 12 months.

C. Opioid-induced constipation

- a. Movantik* or Relistor tablets* will be approved based on the following criterion:
 - 1. History of failure, contraindication or intolerance to **both** of the following (document date tried):
 - a. lubiprostone (generic Amitiza)
 - b. Symproic

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic.
 Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- Notification/Prior Authorization may be in place

4. References:

- 1. Amitiza [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020.
- 2. Ibsrela [package insert]. Waltham, MA: Ardelyx; January 2025.
- 3. Linzess [package insert]. North Chicago, IL: AbbVie, Inc; June 2023.
- 4. Motegrity [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020
- 5. Movantik [package insert]. Chicago, IL: Valinor Pharma, LLC; March 2023.
- 6. Relistor [package insert]. Bridgewater, NJ: Bausch Health US, LLC.; May 2024.
- 7. Symproic [package insert]. Raleigh, NC: BioDelivery Services International, Inc.; July 2021.
- 8. Trulance [package insert]. Bridgewater, NJ: Bausch Health US, LLC; March 2024.

^{*}Ibsrela, Movantik, Relistor tablets, Trulance, Brand Amitiza and Brand Motegrity are typically excluded from coverage



Program	Step Therapy – Constipation agents	
Change Control		
Date	Change	
7/2025	New program.	