UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 3096-9
Program	Step Therapy
Medication	Ibsrela® (tenapanor)*, Trulance® (plecanatide)*
P&T Approval Date	6/2017, 3/2018, 3/2019, 12/2019, 12/2020, 11/2021, 12/2021, 4/2022, 11/2022, 11/2023
Effective Date	2/1/2024

1. Background:

Ibsrela (tenapanor)* is indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults. Amitiza® (lubiprostone)* is indicated for the treatment of IBS-C in women 18 years of age and older, chronic idiopathic constipation (CIC) in adults, and 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. Linzess® (linaclotide) and Trulance (plecanatide)* are indicated for the treatment of CIC and IBS-C; while, Motegrity® is indicated for the treatment of CIC in adults.

Step therapy programs are intended to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try lower cost alternatives before providing coverage for Ibsrela*, and Trulance*

2. Coverage Criteria[a]:

A. Chronic Idiopathic Constipation

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

1. History of failure, contraindication or intolerance to **two** of the following:

a) lubiprostone (generic Amitiza)
b) Linzess
c) Motegrity

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:

a. lubiprostone (generic Amitiza)
b. Linzess

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.

***Ibsrela,Trulance and Brand Amitiza are typically excluded from coverage**

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
  Prior Authorization/Medical Necessity 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; April 2022.
3. Linzess [package insert]. North Chicago, IL: AbbVie, Inc; June 2023.
4. Motegrity [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020
5. Trulance [package insert]. Bridgewater, NJ: Bausch Health US, LLC; April 2021.

Program	Step Therapy –Ibsrela, Trulance
Change Control	
Date	Change
6/2017	New program
3/2018	Annual review. Updated background section and references.
3/2019	Annual review. Updated background section, added statement regarding use of automated process and references.
12/2019	Added Ibsrela and Zelnorm to criteria.
12/2020	Removed Ibsrela from criteria. Noted as discontinued on FDA website. Updated references.
12/2021	Annual review. Removed auto-lookback for Trulance and Zelnorm. Added a step through Motegrity for Trulance. Added that Trulance is typically excluded from coverage.
4/2022	Added criteria for Ibsrela. Updated references.
11/2022	Zelnorm was removed because discontinued from the market. Updated references.
11/2023	Annual review. Updated references. Condensed Ibsrela and Trulance criteria in section B without change to intent. Added lubiprostone as a step 1 option.