UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2128-10
Program	Prior Authorization/Medical Necessity
Medication	Ibsrela® (tenapanor)*, Trulance® (plecanatide)*
P&T Approval Date	6/2017, 3/2018, 3/2019, 12/2019, 12/2020, 12/2021, 4/2022, 11/2022, 11/2023, 7/2024
Effective Date	10/1/2024

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 for the treatment of adults with IBS-C; while, Motegrity® is indicated for the treatment of CIC in adults. Physicians and patients should periodically assess the need for continued treatment with Ibsrela*,Linzess, Motegrity or Trulance*.

This prior authorization program is intended to encourage the use of lower cost alternatives before providing coverage for Ibsrela*and Trulance*.

2. Coverage Criteria[a]:

A. Chronic Idiopathic Constipation

1. Initial Authorization

   a. **Trulance*** will be approved based on **both** of the following criteria:

      1) Diagnosis of chronic idiopathic constipation

      - AND-

      2) History of failure, contraindication, or intolerance to **two** of the following (document drug and date tried):

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

   Authorization will be issued for 12 months

2. Reauthorization

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

1) Documentation of positive clinical response to therapy

Authorization will be issued for 12 months

B. Irritable Bowel Syndrome with Constipation

1. Initial Authorization

a. **Ibsrela*** will be approved based on **both** of the following criteria:

1) Diagnosis of irritable bowel syndrome with constipation

-AND-

2) 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

b. **Trulance*** will be approved based on **both** of the following criteria:

1) Diagnosis of irritable bowel syndrome with constipation

-AND-

2) 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

2. Reauthorization

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

1) Documentation of positive clinical response to therapy

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

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; March 2024.

Program	Prior Authorization/Medical Necessity – Ibsrela (tenapanor), Trulance (plecanatide)
Change Control	
Date	Change
6/2017	New program
3/2018	Added newly approved indication for irritable bowel syndrome with constipation.
3/2019	Annual review. Modified documentation language, added statement regarding use of automated process and updated references.
12/2019	Added Ibsrela and Zelnorm to criteria.
12/2020	Removed Ibsrela since noted as discontinued on FDA website. Updated references.
12/2021	Annual review. Added a step through Motegrity for Trulance for CIC. Added that Trulance is typically excluded form coverage.
4/2022	Added criteria for Ibsrela. Updated references.
11/2022	Zelnorm removed since discontinued from market. Updated references.
11/2023	Annual review. Removed OTC step requirement and added lubiprostone. Updated references.
7/2024	Review. Added documentation requirement. Updated references.