

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 3096-10
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, 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 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<sup>a</sup>:**

<p><b>A. Chronic Idiopathic Constipation</b></p> <p>a. <b>Trulance*</b> will be approved based on the following criterion:</p> <ol style="list-style-type: none"> <li>1. History of failure, contraindication or intolerance to <b>two</b> of the following (document drug and date tried):           <ol style="list-style-type: none"> <li>a) lubiprostone (generic Amitiza)</li> <li>b) Linzess</li> <li>c) Motegrity</li> </ol> </li> </ol> <p><b>Authorization will be issued for 12 months.</b></p> <p><b>B. Irritable Bowel Syndrome with Constipation</b></p> <p>a. <b>Ibsrela*</b> or Trulance* will be approved based on the following criterion:</p> <ol style="list-style-type: none"> <li>1. History of failure, contraindication or intolerance to <b>both</b> of the following (document date tried):           <ol style="list-style-type: none"> <li>a. lubiprostone (generic Amitiza)</li> <li>b. Linzess</li> </ol> </li> </ol>
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**Authorization will be issued for 12 months.**

<sup>a</sup> 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; March 2024.

Program	Step Therapy –Ibsrela, Trulance
<b>Change Control</b>	
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.
7/2024	Review. Added documentation requirement. Updated references.