



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 3096-8
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
Effective Date	2/1/2023; Oxford only: N/A

1. Background:

Ibsrela (tenapanor)* is indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults. Linzess (linaclotide) and Trulance (plecanatide)* are indicated for the treatment of chronic idiopathic constipation (CIC) and IBS-C. Motegrity is indicated for the treatment of chronic idiopathic constipation 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:

<p>A. Chronic Idiopathic Constipation</p> <p>a. Trulance will be approved based on the following criterion:</p> <ol style="list-style-type: none">History of failure, contraindication or intolerance to both of the following:<ol style="list-style-type: none">LinzessMotegrity <p>Authorization will be issued for 12 months.</p> <p>B. Irritable Bowel Syndrome with Constipation</p> <p>a. Ibsrela* will be approved based on the following criterion:</p> <ol style="list-style-type: none">History of failure, contraindication or intolerance to Linzess <p>b. Trulance will be approved based on the following criterion:</p> <ol style="list-style-type: none">History of failure, contraindication or intolerance to Linzess <p>Authorization will be issued for 12 months.</p> <p>^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</p>

management programs may apply.

***Ibsrela and Trulance 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. Ibsrela [package insert]. Waltham, MA: Ardelyx; May 2021.
2. Linzess [package insert]. Madison, NJ: Allergan USA, Inc.; August 2021.
3. Motegrity [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020
4. 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.