

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2020 P 3096-5 |
| Program | Step Therapy |
| Medication | Trulance (plecanatide), Zelnorm (tegaserod) |
| P&T Approval Date | 6/2017, 3/2018, 3/2019, 12/2019, 12/2020 |
| Effective Date | 3/1/2021; Oxford only: N/A |

1. Background:

Linzess (linaclotide) and Trulance (plecanatide) are indicated for the treatment of chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). Zelnorm (tegaserod) is indicated for treatment of irritable bowel syndrome with 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 Linzess before providing coverage for Trulance and Zelnorm.

If a member has a prescription for Linzess in the claims history within the previous 12 months, the claim for Trulance or Zelnorm will automatically process.

2. Coverage Criteria^a:

A. Trulance, Zelnorm will be approved on based on of the following criterion:

1. History of failure, contraindication or intolerance to 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.

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. Linzess [package insert]. Madison, NJ: Allergan USA, Inc.; September 2020
2. Trulance [package insert]. Bridgewater, NJ: Bausch Health US, LLC; February 2020.
3. Zelnorm [package insert]. Covington, LA: Alfasigma USA, Inc.; June 2020.

| Program | Step Therapy – Ibsrela, Trulance, Zelnorm |
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| 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. |