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). Ibsrela (tenapanor) and Zelnorm (tegaserod) are 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 Ibsrela, Trulance and Zelnorm.

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

2. **Coverage Criteria**:  

   **A. Ibsrela, Trulance, Zelnorm** will be approved based on 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.

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• Supply limits may be in place.
• Notification/Prior Authorization may be in place
  Prior Authorization/Medical Necessity may be in place

4. References:


<table>
<thead>
<tr>
<th>Program</th>
<th>Step Therapy – Ibsrela, Trulance, Zelnorm</th>
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<tr>
<td>Date</td>
<td>Change</td>
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<tr>
<td>6/2017</td>
<td>New program</td>
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<tr>
<td>3/2018</td>
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<tr>
<td>3/2019</td>
<td>Annual review. Updated background section, added statement regarding use of automated process and references.</td>
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<tr>
<td>12/2019</td>
<td>Added Ibsrela and Zelnorm to criteria.</td>
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