Zelnorm

Description

Zelnorm (tegaserod)

Background
Zelnorm is an agonist of serotonin type-4 (5-HT₄) receptors that stimulates the peristaltic reflex and intestinal secretion, inhibits visceral sensitivity, enhances basal motor activity, and normalizes impaired motility throughout the gastrointestinal tract (1).

Regulatory Status
FDA-approved indication: Zelnorm is a serotonin-4 (5-HT₄) receptor agonist indicated for treatment of adult women less than 65 years of age with irritable bowel syndrome with constipation (IBS-C) (1).

Limitations of Use:
The safety and effectiveness of Zelnorm in men with IBS-C have not been established (1).

Zelnorm is contraindicated in patients with: (1)
1. A history of myocardial infarction (MI), stroke, transient ischemic attack (TIA), or angina.
2. A history of ischemic colitis or other forms of intestinal ischemia.
3. Severe renal impairment (eGFR < 15 mL/min/1.73 m²) or end-stage renal disease.
4. Moderate and severe hepatic impairment (Child-Pugh B or C).
5. A history of bowel obstruction, symptomatic gallbladder disease, suspected sphincter of Oddi Dysfunction, or abdominal adhesions.
The safety and effectiveness of Zelnorm in pediatric patients less than 18 years of age have not been established (1).

Related policies
Amitiza, Ibsrela, Linzess, Motegrity, Opioid Antagonist Drug Class, Trulance

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Zelnorm may be considered medically necessary for female patients 18 years of age to 64 years of age with irritable bowel syndrome with constipation and if the conditions indicated below are met.

Zelnorm may be considered investigational for all other indications.

Prior-Approval Requirements

Age 18 to 64 years of age
Gender Female

Diagnosis

Patient must have the following:

Irritable bowel syndrome with constipation (IBS-C)

AND ALL of the following:

a. Inadequate response to ALL of the following laxative therapies:
   i. Bulk-forming laxative (e.g. psyllium (Metamucil))
   ii. Stimulant laxative (e.g. senna (Senokot))
   iii. Osmotic laxative (e.g. polyethylene glycol 3350 (Miralax))

b. Absence of gastrointestinal obstruction

c. NO history of myocardial infarction (MI), stroke, transient ischemic attack (TIA), or angina

d. NO dual therapy with other legend constipation medications (see Appendix 1)
Prior – Approval Renewal Requirements

Age 18 to 64 years of age
Gender Female

Diagnoses

Patient must have the following:

Irritable bowel syndrome with constipation (IBS-C)

AND ALL of the following:

a. Improvement in constipation symptoms
b. NO history of myocardial infarction (MI), stroke, transient ischemic attack (TIA), or angina
c. NO dual therapy with other legend constipation medications (see Appendix 1)

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity

<table>
<thead>
<tr>
<th>Medication</th>
<th>Quantity Limit per 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 mg</td>
<td>180 tablets per 90 days</td>
</tr>
</tbody>
</table>

Duration 3 months

Prior – Approval Renewal Limits

Quantity

<table>
<thead>
<tr>
<th>Medication</th>
<th>Quantity Limit per 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 mg</td>
<td>180 tablets per 90 days</td>
</tr>
</tbody>
</table>
Duration: 12 months

Rationale

Summary
Zelnorm is an agonist of serotonin type-4 (5-HT₄) receptors that stimulates the peristaltic reflex and intestinal secretion, inhibits visceral sensitivity, enhances basal motor activity, and normalizes impaired motility throughout the gastrointestinal tract. The safety and effectiveness of Zelnorm in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Zelnorm while maintaining optimal therapeutic outcomes.

References


Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2019</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review</td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual review</td>
</tr>
</tbody>
</table>

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.
### Appendix 1 - List of Legend Constipation Medications

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>linaclotide</td>
<td>Linzess</td>
</tr>
<tr>
<td>lubiprostone</td>
<td>Amitiza</td>
</tr>
<tr>
<td>methylnaltrexone</td>
<td>Relistor</td>
</tr>
<tr>
<td>naldemedine</td>
<td>Symproic</td>
</tr>
<tr>
<td>naloxegol</td>
<td>Movantik</td>
</tr>
<tr>
<td>plecanatide</td>
<td>Trulance</td>
</tr>
<tr>
<td>prucalopride</td>
<td>Motegrity</td>
</tr>
<tr>
<td>tegaserod</td>
<td>Zelnorm</td>
</tr>
<tr>
<td>tenapanor</td>
<td>Ibsrela</td>
</tr>
</tbody>
</table>