Ibsrela (tenapanor)

Background
Ibsrela (tenapanor) is a locally acting inhibitor of the sodium/hydrogen exchanger 3 (NHE3), an antiporter expressed on the apical surface of the small intestine and colon primarily responsible for the absorption of dietary sodium. By inhibiting NHE3 on the apical surface of the enterocytes, Ibsrela reduces absorption of sodium from the small intestine and colon, resulting in an increase in water secretion into the intestinal lumen, which accelerates intestinal transit time and results in softer stool consistency (1).

Regulatory Status
FDA-approved indication: Ibsrela is a sodium/hydrogen exchanger 3 (NHE3) inhibitor indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults (1).

Ibsrela has a boxed warning regarding the risk of serious dehydration in pediatric patients. Ibsrela is contraindicated in patients less than 6 years of age. Use should be avoided in patients 6 years to less than 12 years of age. The safety and effectiveness of Ibsrela have not been established in pediatric patients less than 18 years of age (1).

Ibsrela is also contraindicated in patients with known or suspected mechanical gastrointestinal obstruction (1).

The safety and effectiveness of Ibsrela in pediatric patients less than 18 years of age have not been established (1).
Related policies
Amitiza, Linzess, Motegrity, Opioid Antagonist Drug Class, Trulance, Zelnorm

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

Ibsrela may be considered medically necessary for patients 18 years of age or older with the diagnosis of chronic idiopathic constipation and if the conditions indicated below are met.

Ibsrela may be considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic Idiopathic Constipation (CIC)

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 dual therapy with other legend constipation medications (see Appendix 1)

Prior – Approval Renewal Requirements

Age 18 years of age or older
Diagnosis

Patient must have the following:

Chronic Idiopathic Constipation (CIC)

AND ALL of the following:
   a. Improvement in constipation symptoms
   b. NO dual therapy with other legend constipation medications (see Appendix 1)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity       180 tablets per 90 days
Duration       12 months

Prior – Approval Renewal Limits

Same as above

Rationale

Summary

Ibsrela (tenapanor) is a locally acting inhibitor of the sodium/hydrogen exchanger 3 (NHE3), an antiporter expressed on the apical surface of the small intestine and colon primarily responsible for the absorption of dietary sodium. By inhibiting NHE3 on the apical surface of the enterocytes, Ibsrela reduces absorption of sodium from the small intestine and colon, resulting in an increase in water secretion into the intestinal lumen, which accelerates intestinal transit time and results in softer stool consistency. The safety and effectiveness of Ibsrela 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 Ibsrela while maintaining optimal therapeutic outcomes.
References


Policy History

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

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

<table>
<thead>
<tr>
<th>Generic Name</th>
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<tr>
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<td>Linzess</td>
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