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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	October 11, 2019
Subject:	Ibsrela	**Page:**	1 of 5

Last Review Date: December 8, 2023

Ibsrela

Description

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

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** if the conditions indicated below are met.

Ibsrela may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

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** dual therapy with other legend constipation medications (see Appendix 1)
d. Patient **MUST** have completed an adequate 3-month trial of the preferred product (Linzess) unless the patient has a valid medical exception (e.g., intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Irritable bowel syndrome with constipation (IBS-C)

AND ALL of the following:

a. Improvement in constipation symptoms
b. Absence of gastrointestinal obstruction
c. **NO** dual therapy with other legend constipation medications (see Appendix 1)
d. Patient **MUST** have completed an adequate 3-month trial of the preferred product (Linzess) unless the patient has a valid medical exception (e.g., intolerance, contraindication)

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. Ibsrela is indicated for use in patients with irritable bowel syndrome with constipation (IBS-C). 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

1. Ibsrela [package insert]. Fremont, CA: Ardelyx, Inc.; April 2022.

Policy History

Date	Action
October 2019	Addition to PA
December 2019	Annual review
March 2020	Annual review. Added “absence of gastrointestinal obstruction” to renewal requirements
June 2020	Annual review
June 2022	Annual editorial review and reference update
July 2022	Removal of Pizensy from Appendix 1
September 2022	Annual review and reference update
December 2022	Annual review. Addition of requirement to t/f preferred product Linzess
June 2023	Annual review
October 2023	Per FEP, the requirement to t/f Linzess was modified to require an adequate 3-month trial
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.

Appendix 1 - List of Legend Constipation Medications

Generic Name	Brand Name
linaclotide	Linzess
lubiprostone	Amitiza
methylnaltrexone	Relistor
naldemedine	Symproic
naloxegol	Movantik
plecanatide	Trulance
prucalopride	Motegrity
tenapanor	Ibsrela