

## 5.50.26

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2022
<b>Subsection:</b>	Gastrointestinal Agents	<b>Original Policy Date:</b>	October 11, 2019
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**Last Review Date:** June 16, 2022

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## 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).

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## Related policies

Amitiza, Linzess, Motegrity, Opioid Antagonist Drug Class, Pizensy, 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.*

lbsrela may be considered **medically necessary** for patients 18 years of age or older with the diagnosis of IBS-C and if the conditions indicated below are met.

lbsrela 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:

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)

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

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## Diagnosis

Patient must have the following:

Irritable bowel syndrome with constipation (IBS-C)

**AND ALL** of the following:

- Improvement in constipation symptoms
- Absence of gastrointestinal obstruction
- 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

lbsrela (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. lbsrela is indicated for use in patients with irritable bowel syndrome with constipation (IBS-C). The safety and effectiveness of lbsrela 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 lbsrela while maintaining optimal therapeutic outcomes.

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## References

1. Ibsrela [package insert]. Fremont, CA: Ardelyx, Inc.; May 2021.

## 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

## Keywords

**This policy was approved by the FEP® Pharmacy Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.**

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## Appendix 1 - List of Legend Constipation Medications

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