Effective Date **2/1/2024**
Next Review Date **2/1/2025**
Coverage Policy Number **IP0455**

Tenapanor

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for formulary exceptions for tenapanor tablets (**Ibsrela**®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table(s):**

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Ibsrela (tenapanor)	**Ibsrela** is considered medically necessary when **ALL** of the following are met: 1. Age 18 years or older 2. Documented diagnosis of irritable bowel syndrome with constipation (IBS-C)

Non-Covered Product	Criteria
	3. Documentation of failure, contraindication, or intolerance to **BOTH** of the following: A. linaclotide (Linzess®) B. plecanatide (Trulance®)

Individual and Family Plan Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Ibsrela (tenapanor)	**Ibsrela** is considered medically necessary when **ALL** of the following are met: 1. Age 18 years or older 2. Documented diagnosis of irritable bowel syndrome with constipation (IBS-C) 3. Documentation of failure, contraindication, or intolerance to linaclotide (Linzess®)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of tenapanor (Ibsrela) is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial and reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered not medically necessary.

Background

OVERVIEW

Ibsrela is a sodium/hydrogen exchanger 3 (NHE3) inhibitor indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults.[4]

These bowel agents are indicated for the following uses:[1-6]

Table 1. Indications for Amitiza, Ibsrela, Linzess, Motegrity, Trulance, and Zelnorm.[1-6]

	Indications
Amitiza® (lubiprostone capsules)	• **Chronic idiopathic constipation** in adults. • **Irritable bowel syndrome with constipation** in women ≥ 18 years of age. • **Opioid-induced constipation** in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

Ibsrela® (tenapanor tablets)	• **Irritable bowel syndrome with constipation** in adults.
Linzess® (linaclotide capsules)	• **Chronic idiopathic constipation** in adults. • **Irritable bowel syndrome with constipation** in adults. • **Functional constipation** in pediatric patients 6 to 17 years of age.
Motegrity® (prucalopride tablets)	• **Chronic idiopathic constipation** in adults.
Trulance® (plecanatide tablets)	• **Chronic idiopathic constipation** in adults. • **Irritable bowel syndrome with constipation** in adults.
Zelnorm™ (tegaserod tablets)	• **Irritable bowel syndrome with constipation** in women ≥ 18 years and < 65 years of age.

References

1. Amitiza® [prescribing information]. Rockville, MD and Deerfield, IL: Sucampo and Takeda; December 2022.
2. Linzess® capsules [prescribing information]. Irvine, CA and Cambridge, MA: Allergan and Ironwood; June 2023.
3. Trulance® tablets [prescribing information]. New York, NY: Salix and Synergy; April 2021.
4. Ibsrela® tablets [prescribing information]. Waltham, MA: Ardelyx; April 2022.
5. Motegrity® tablets [prescribing information]. Lexington, MA: Takeda; October 2022.
6. Zelnorm™ tablets [prescribing information]. Covington, LA: Alfasigma; June 2020.