

Drug and Biologic Coverage Policy



Effective Date..... 2/1/2024
Next Review Date..... 2/1/2025
Coverage Policy Number IP0019

Tegaserod

Table of Contents

Overview 1
Medical Necessity Criteria 1
Reauthorization Criteria 2
Authorization Duration 2
Conditions Not Covered..... 2
Background..... 2
References 3

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 tegaserod tablets (**Zelnorm™**).

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:

Product Name	Criteria
Zelnorm (tegaserod)	Zelnorm 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)

Product Name	Criteria
	3. Documentation of failure, contraindication, or intolerance to BOTH of the following: <ol style="list-style-type: none"> A. linaclotide (Linzess®) B. plecanatide (Trulance®)

Individual and Family Plans Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Zelnorm (tegaserod)	Zelnorm is considered medically necessary when ALL of the following are met: <ol style="list-style-type: none"> 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 tegaserod (Zelnorm) 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

Zelnorm is a serotonin-4 (5-HT₄) receptor agonist indicated for the treatment of adult women less than 65 years of age with irritable bowel syndrome with constipation (IBS-C).⁶

These bowel agents are indicated for the following uses:¹⁻⁶

Table 1. Indications for Amitiza, lbsrela, Linzess, Motegrity, Trulance, and Zelnorm.¹⁻⁶

	Indications
Amitiza® (lubiprostone capsules)	<ul style="list-style-type: none"> • 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.
lbsrela®	<ul style="list-style-type: none"> • Irritable bowel syndrome with constipation in adults.

(tenapanor tablets)	
Linzess® (linaclotide capsules)	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • Chronic idiopathic constipation in adults.
Trulance® (plecanatide tablets)	<ul style="list-style-type: none"> • Chronic idiopathic constipation in adults. • Irritable bowel syndrome with constipation in adults.
Zelnorm™ (tegaserod tablets)	<ul style="list-style-type: none"> • 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.

“Cigna Companies” refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. © 2023 Cigna.