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Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	February 24, 2017
Subject:	Trulance	**Page:**	1 of 5

Last Review Date: June 13, 2024

Trulance

Description

Trulance (plecanatide)

Background
Trulance (plecanatide) is a guanylate cyclase-C (GC-C) agonist. Activation of GC-C results in an increase in both intracellular and extracellular concentrations of cyclic guanosine monophosphate (cGMP). Elevation of intracellular cGMP stimulates secretion of chloride and bicarbonate into the intestinal lumen, mainly through activation of the cystic fibrosis transmembrane conductance regulator (CFTR) ion channel, resulting in increased intestinal fluid and accelerated transit (1).

Regulatory Status
FDA-approved indications: Trulance is a guanylate cyclase-C agonist indicated in adults for treatment of: (1)

1. Chronic idiopathic constipation (CIC)
2. Irritable bowel syndrome with constipation (IBS-C)

Trulance has a boxed warning for children under the age of 6 due to risk of serious dehydration. Avoid use of Trulance in patients 6 years to less than 18 years of age (1).

The use of this medication is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction (1).

Safety and effectiveness in pediatric patients less than 18 years of age has not been established, avoid the use of Trulance in patients 6 years to less than 18 years of age (1).

Related policies
Amitiza, Ibsrela, Linzess, Motegrity, Opioid Antagonist Drug Class

Policy

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

Trulance may be considered **medically necessary** if the conditions indicated below are met.

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

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Chronic Idiopathic Constipation (CIC)
2. 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

Diagnoses

Patient must have **ONE** of the following:

1. Chronic Idiopathic Constipation (CIC)
2. 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 90 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Trulance (plecanatide) is a guanylate cyclase-C (GC-C) agonist. Activation of GC-C results in an increase in both intracellular and extracellular concentrations of cyclic guanosine monophosphate (cGMP), eventually resulting in increased intestinal fluid and accelerated transit. Trulance is indicated in adults for treatment of chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C) (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Trulance while maintaining optimal therapeutic outcomes.

References

1. Trulance [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; March 2024.

Policy History

Date	Action
February 2017	Addition to PA
June 2017	Annual review Change of T/F from saline laxatives to bulk-forming laxatives
February 2018	Addition of irritable bowel syndrome with constipation (IBS-C) and change in duration from 3 months to 12 months and an update to the no dual therapy statement with the addition of Appendix 1
March 2018	Annual review
March 2019	Annual review and reference update
June 2019	Annual review
December 2019	Annual review and reference update
March 2020	Annual review. Added “absence of gastrointestinal obstruction” to renewal requirements
June 2020	Annual review and reference update
December 2021	Annual review and reference update
July 2022	Addition of Ibsrela to Appendix 1
September 2022	Annual review
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
June 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 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