



PREFERRED STEP THERAPY POLICY

- POLICY:** Bowel Disease – Chronic Idiopathic Constipation and Irritable Bowel Syndrome with Constipation Preferred Step Therapy Policy
- Amitiza® (lubiprostone capsules – Sucampo/Takeda)
 - Ibsrela® (tenapanor tablets – Ardelyx)
 - Linzess® (linaclotide capsules – Allergan/Ironwood)
 - Trulance® (plecanatide tablets – Synergy)

REVIEW DATE: 09/22/2021; selected revision 05/25/2022

OVERVIEW

Amitiza is indicated for the following uses:¹

- **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 is indicated for the treatment of **irritable bowel syndrome with constipation** in adults.⁴

Linzess and Trulance are indicated in adults for the following uses:^{2,3}

- **Chronic idiopathic constipation.**
- **Irritable bowel syndrome with constipation.**

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Preferred Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Preferred Step Therapy criteria below. All approvals are provided for 1 year in duration. Note: Motegrity is also indicated for the treatment of chronic idiopathic constipation in adults but will not be targeted or preferred in this policy.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: Linzess, Trulance

Step 2: Amitiza, Ibsrela

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. Approve Amitiza if it is being prescribed for the treatment of opioid-induced constipation for a patient ≥ 18 years of age with chronic non-cancer pain.
3. No other exceptions are recommended.

REFERENCES

1. Amitiza[®] [prescribing information]. Rockville, MD and Deerfield, IL: Sucampo/Takeda; April 2021.
2. Linzess[®] capsules [prescribing information]. Irvine, CA and Cambridge, MA: Allergan/Ironwood; August 2021.
3. Trulance[®] tablets [prescribing information]. New York, NY: Synergy; April 2021.
4. Ibsrela[®] tablets [prescribing information]. Waltham, MA: Ardelyx; April 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/23/2020
Annual Revision	No criteria changes.	09/22/2021
Selected Revision	Policy Title: The title of the policy was changed to include "Irritable Bowel Syndrome with Constipation". Ibsrela: Effective 07/01/2022. Ibsrela was added to the policy as a Step 2 product.	05/25/2022