

5.50.022

Section:	Prescription Drugs	Effective Date:	January 1, 2023
Subsection:	Gastrointestinal Agents	Original Policy Date:	December 8, 2017
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Last Review Date: December 2, 2022

Amitiza

Description

Amitiza* (lubiprostone)

*Prior authorization for certain non-covered formulations applies only to formulary exceptions

Preferred product: lubiprostone

Background

Amitiza is a chloride channel activator. Amitiza is a specific activator of CIC-2 chloride channels in the intestinal epithelium and bypasses the antisecretory action of opiates by activation of apical CIC-2 channels. Amitiza has a mechanism of action that works locally in the intestine to increase fluid secretion, resulting in increased passage of stool and alleviating symptoms associated with chronic idiopathic constipation (1).

Regulatory Status

FDA-approved indication: Amitiza is a chloride channel activator indicated for: (1)

1. Treatment of chronic idiopathic constipation (CIC) in adults
2. Treatment of opioid-induced constipation (OIC) in adult patients 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
3. Treatment of irritable bowel syndrome with constipation (IBS-C) in women \geq 18 years old

Limitations of Use:

Effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids (e.g., methadone) has not been established (1).

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Amitiza is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction (1).

Safety and effectiveness of Amitiza in pediatric patients have not been established (1).

Related policies

Ibsrela, Linzess, Motegrity, Opioid Antagonist Drug Class, 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.

Amitiza may be considered **medically necessary** for patients 18 years of age or older with the diagnosis of chronic idiopathic constipation (CIC), opioid-induced constipation (OIC), or irritable bowel syndrome with constipation (IBS-C); and if the conditions indicated below are met.

Amitiza 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

Diagnoses

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

1. Chronic idiopathic constipation (CIC)
2. Opioid-induced constipation (OIC) with **ONE** of the following:
 - a. Patient has chronic non-cancer pain
 - b. Patient has chronic pain related to prior cancer or its treatment and does **NOT** require frequent opioid dosage increases
3. Irritable bowel syndrome with constipation (IBS-C)
 - a. Patient is female

AND ALL of the following for **ALL** indications:

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- 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

Diagnoses

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

1. Chronic idiopathic constipation (CIC)
2. Opioid-induced constipation (OIC) with **ONE** of the following:
 - a. Patient has chronic non-cancer pain
 - b. Patient has chronic pain related to prior cancer or its treatment and does **NOT** require frequent opioid dosage increases
3. Irritable bowel syndrome with constipation (IBS-C)
 - a. Patient is female

AND ALL of the following for **ALL** indications:

- a. Improvement in constipation symptoms
- b. Absence of gastrointestinal obstruction
- c. **NO** dual therapy with other legend constipation medications (see Appendix 1)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

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Medication	Quantity Limit
8 mcg	180 capsules per 90 days OR
24 mcg	180 capsules per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Amitiza is a specific activator of CIC-2 chloride channels in the intestinal epithelium and bypasses the antisecretory action of opiates by activation of apical CIC-2 channels. Amitiza has a mechanism of action that works locally in the intestine to increase fluid secretion. Safety and effectiveness of Amitiza in pediatric patients have not been established (1).

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

References

1. Amitiza [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; November 2020.

Policy History

Date	Action
December 2017	Addition to PA
March 2018	Annual editorial review Change in duration from 3 months to 12 months and an update to the no dual therapy statement with the addition of Appendix 1
September 2018	Addition of OIC for patients with chronic pain related to prior cancer or its treatment and does not require frequent opioid dosage increases Addition of advanced illness requirement to opioid-induced constipation diagnosis
November 2018	Annual review
March 2019	Annual review and reference update
June 2019	Annual review

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July 2019	Removed advanced illness requirement for OIC due to non-cancer pain diagnosis per FEP
September 2019	Annual review
December 2019	Annual review
March 2020	Annual review. Added “absence of gastrointestinal obstruction” to renewal requirements
June 2020	Annual review
March 2021	Annual review and reference update
March 2022	Annual review
July 2022	Addition of Ibsrela to Appendix 1
September 2022	Annual review
December 2022	Annual review. Amitiza brand name changed to require FE + PA

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 2, 2022 and is effective on January 1, 2023.

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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
tegaserod	Zelnorm
tenapanor	Ibsrela