

5.50.022

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| Section: | Prescription Drugs | Effective Date: | July 1, 2023 |
| Subsection: | Gastrointestinal Agents | Original Policy Date: | December 8, 2017 |
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Last Review Date: June 15, 2023

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 indications: 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

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** if the conditions indicated below are met.

Amitiza 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. 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. Inadequate treatment response to **ALL** of the following laxative therapies:
 - i. Bulk-forming laxative [e.g., psyllium (Metamucil)]
 - ii. Stimulant laxative [e.g., senna (Senokot)]

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- 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

| Medication | Quantity Limit |
|------------|------------------------------------|
| 8 mcg | 180 capsules per 90 days OR |

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|--------|--------------------------|
| 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 |
| July 2019 | Removed advanced illness requirement for OIC due to non-cancer pain diagnosis per FEP |
| September 2019 | Annual review |

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| 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 |
| March 2023 | Annual review |
| June 2023 | Annual review |

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 15, 2023 and is effective on July 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 |
| tenapanor | Ibsrela |