

Initial Prior Authorization

Amitiza

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Amitiza	lubiprostone

Indications

FDA-approved Indications

Chronic Idiopathic Constipation in Adults

Amitiza is indicated for the treatment of chronic idiopathic constipation (CIC) in adults.

Opioid-Induced Constipation in Adult Patients with Chronic Non-Cancer Pain

Amitiza is indicated for the 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.

Limitations of Use

Effectiveness of Amitiza in the treatment of opioid-induced constipation in patients taking diphanylheptane opioids (e.g., methadone) has not been established.

Irritable Bowel Syndrome with Constipation

Amitiza is indicated for the treatment of irritable bowel syndrome with constipation (IBS-C) in women at least 18 years old.

Coverage Criteria

Chronic Idiopathic Constipation (CIC)

Authorization may be granted when the requested drug is being prescribed for the treatment of chronic idiopathic constipation (CIC) in an adult patient.

Irritable Bowel Syndrome with Constipation (IBS-C)

Authorization may be granted when the requested drug is being prescribed for the treatment of irritable bowel syndrome with constipation (IBS-C) in a biological female or a person that self-identifies as a female when the following criteria is met:

- The patient is 18 years of age or older.

Opioid-Induced Constipation (OIC)

Authorization may be granted when the requested drug is being prescribed for the treatment of opioid-induced constipation (OIC) in an adult patient with chronic, non-cancer pain, including chronic pain related to prior cancer or its treatment, who does NOT require frequent (e.g., weekly) opioid dosage escalation.

Duration of Approval (DOA)

- 13-A: DOA: 36 months
- 990-A: DOA: 12 months

References

1. Amitiza [package insert]. Webster Groves, MO: SpecGx LLC; Bridgewater, NJ: Sucampo Pharma Americas LLC; January 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed August 1, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 08/01/2024).

Document History

Written by: UM Development (CT)

Amitiza PA 13-A 10-2024_R.docx

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Date Written: 02/2006

Revised: (NB) 02/2007; (CT) 02/2008, 04/2008 (new indication), 09/2008(2); (SE) 02/2009; (AS) 12/2009; (SE) 10/2010; (CY) 10/2011; (CT) 10/2012 (changed to MDC-1), 04/2013 (new indication added); (PL) 10/2013; (JH) 10/2014, 09/2015, 09/2016 (updated for TGC), 09/2016 (annual update, removed safety question), (TM) 09/2017 (no clinical changes); (JG) 09/2018 (added new indication); (DS) 09/2019 (combined documents; removed MDC designation; no clinical changes; expanded indication question into 3 questions); (SE/RZ) 09/2020 (no clinical changes); (AK) 07/2021 (no clinical changes); (VLS) 09/2022 (no clinical changes); (SS) 09/2023 (no clinical changes); (DMH) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (MM) 02/2006; (WLF) 02/2007, 02/2008, 04/2008, 09/2008, 02/2009, 12/2009; (KP) 10/2010, 10/2011; (LMS) 10/2012; (DNC) 04/2013; (LMS) 10/2013; (SES) 10/2014; (GAD) 09/2015; (ME) 09/2016 (off-cycle), 09/2016; (CHART) 09/26/2019, 09/24/2020, 09/30/2021, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 04/2006, 06/2007, 06/2008, 08/2008, 10/2008, 04/2009, 02/2010, 12/2010, 02/2012, 12/2012, 12/2013, 12/2014, 12/2015, 12/2016, 12/2017, 12/2018, 12/2019, 12/2020, 12/2021, 12/2022, 12/2023, 12/2024

CRITERIA FOR APPROVAL

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|---|--|-----|----|
| 1 | Is the requested drug being prescribed for the treatment of chronic idiopathic constipation (CIC) in an adult patient?
[If Yes, then no further questions. If No, then go to 2.] | Yes | No |
| 2 | Is the requested drug being prescribed for the treatment of opioid-induced constipation (OIC) in an adult patient with chronic, non-cancer pain, including chronic pain related to prior cancer or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation?
[If Yes, then no further questions. If No, then go to 3.] | Yes | No |
| 3 | Is the requested drug being prescribed for the treatment of irritable bowel syndrome with constipation (IBS-C) in a biological female or a person that self-identifies as a female?
[If Yes, then go to 4. If No, then no further questions.] | Yes | No |
| 4 | Is the patient 18 years of age or older?
[No further questions] | Yes | No |

Mapping Instructions

	Yes	No	DENIAL REASONS
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Reference number(s)
13-A, 990-A

1.	Approve, 36 Months	Go to 2	
2.	Approve, 36 Months	Go to 3	
3.	Go to 4	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered uses are for A) Chronic idiopathic constipation (CIC) in an adult, B) Opioid-induced constipation (OIC) in an adult with specific types of pain and you do not need frequent dose changes, and C) Irritable bowel syndrome with constipation (IBS-C) in a biological female or a person that self-identifies as a female. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
4.	Approve, 36 Months	Deny	<p>Your plan only covers this drug if you are 18 years old or older. We reviewed the information we had. Your request has been denied. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Age]</p>