

# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME\***  
(generic)

**AMITIZA**  
(lubiprostone)

**Status: CVS Caremark Criteria**  
**Type: Initial Prior Authorization**

**Ref # 13-A**

*\* Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated*

## **FDA-APPROVED INDICATIONS**

### **Amitiza**

#### **Chronic Idiopathic Constipation**

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

#### **Opioid-induced Constipation**

Amitiza is indicated for the treatment of opioid-induced constipation (OIC) 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.

#### **Limitations of Use:**

Effectiveness of Amitiza in the treatment of opioid-induced constipation in patients taking diphenylheptane 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 of age.

## **COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when prescribed for the treatment of any of the following:

- Chronic idiopathic constipation in an adult patient
- Opioid-induced constipation (OIC) in an adult patient 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
- Irritable bowel syndrome with constipation (IBS-C) in a biological female or a person that self-identifies as a female who is 18 years of age or older

## **RATIONALE**

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Amitiza is indicated for the treatment of chronic idiopathic constipation in adults. Amitiza is indicated for the treatment of irritable bowel syndrome with constipation (IBS-C) in women greater than or equal to 18 years of age. Amitiza is indicated for the treatment of opioid-induced constipation (OIC) 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. Effectiveness of Amitiza in the treatment of opioid-induced constipation in patients taking diphenylheptane opioids (e.g., methadone) has not been established.

## **REFERENCES**

1. Amitiza [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc; Rockville MD: Sucampo Pharma Americas LLC.; June 2018.

2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed September 2018.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed September 2018.

Written by: UM Development (CT)  
 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)  
 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); (ME) 09/2016  
 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

## **CRITERIA FOR APPROVAL**

	Yes	No
1 Is the requested drug being prescribed for the treatment of any of the following: A) Chronic idiopathic constipation in an adult patient, B) Opioid-induced constipation (OIC) in an adult patient 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, C) Irritable bowel syndrome with constipation (IBS-C) in a biological female or a person that self-identifies as a female who is 18 years of age or older?		

### **Guidelines for Approval**

Duration of Approval	36 Months
<b>Set 1</b>	
<b>Yes to question(s)</b>	<b>No to question(s)</b>
1	None

### **Mapping Instructions**

	Yes	No	<b>DENIAL REASONS – DO NOT USE FOR MEDICARE PART D</b>
1.	Approve, 36 Months	Deny	<p>You do not meet the requirements of your plan. Your plan covers this drug when you have any of these conditions:</p> <ul style="list-style-type: none"> <li>- Chronic idiopathic constipation in an adult patient</li> <li>- Opioid-induced constipation (OIC) in an adult patient 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</li> <li>- Irritable bowel syndrome with constipation (IBS-C) in a biological female or a person that self-identifies as a female who is 18 years of age or older</li> </ul> <p>Your request has been denied based on the information we have.</p> <p>[Short Description: No approvable diagnosis]</p>