

# 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.

#### 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 greater than or equal to 18 years old.

## **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
- 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. 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.; September 2016.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed August 2017.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed August 2017.

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)  
 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

**CRITERIA FOR APPROVAL**

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, 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?	Yes	No
---	---	-----	----

**Guidelines for Approval**

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

**Mapping Instructions**

	<b>Yes</b>	<b>No</b>	<b>DENIAL REASONS – DO NOT USE FOR MEDICARE PART D</b>
1.	Approve, 36 Months	Deny	Your plan covers this drug when you have any of these conditions: <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</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> Your use of this drug does not meet the requirements. This is based on the information we have.