UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2015-8
Program	Prior Authorization/Medical Necessity
Medication	Amitiza (lubiprostone)
P&T Approval Date	2/2014, 10/2014, 7/2015, 7/2016, 7/2017, 11/2017, 7/2018
Effective Date	1/1/2019; Oxford only: 1/1/2019

1. Background:

Amitiza (lubiprostone) is indicated for the treatment of chronic idiopathic constipation, for opioid-induced constipation 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 and irritable bowel syndrome with constipation in women aged 18 years and older. Linzess (linaclotide) is indicated for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation in adults aged 18 years and older. Symproic (naldemedine) is an opioid antagonist indicated for the treatment of opioid-induced constipation 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.. Physicians and patients should periodically assess the need for continued treatment with Amitiza, Symproic or Linzess.

This prior authorization program is intended to encourage the use of lower cost alternatives. This program requires a member to try an over-the-counter medication (OTC) for constipation and either Linzess (linaclotide) for chronic idiopathic constipation or chronic idiopathic constipation or Symproic for opioid-induced constipation before providing coverage for Amitiza (lubiprostone).

2. Coverage Criteria[a]:

A. Opioid-induced constipation in an adult with chronic, non-cancer pain

1. Initial Authorization

a. **Amitiza** will be approved based on **both** of the following criteria:

(1) **One** of the following criteria:

i. Diagnosis of opioid-induced constipation in an adult with chronic, non-cancer pain
ii. Diagnosis of opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require

frequent (e.g., weekly) opioid dosage escalation.

-AND-

(2) History of failure, contraindication or intolerance to **both** of the following:

i. OTC medication used for the treatment of constipation (document name and date tried).
ii. Symproic (document date of trial)

Authorization will be issued for 6 months

2. Reauthorization

a. **Amitiza** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Amitiza therapy

Authorization will be issued for 12 months.

B. Diagnosis of chronic idiopathic constipation

1. **Initial Authorization**

a. **Amitiza** will be approved based on **all** of the following criteria:

(1) Diagnosis of chronic idiopathic constipation

- AND-

(2) History of failure, contraindication or intolerance to **one** OTC medication used for the treatment of constipation (document name and date tried)

-AND-

(3) **One** of the following criteria:

(a) History of failure, contraindication, or intolerance to Linzess

-OR-

(b) Age less than or equal to 17

Authorization will be issued for 6 months

2. Reauthorization

a. **Amitiza** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Amitiza therapy

Authorization will be issued for 12 months

C. Diagnosis of irritable bowel syndrome with constipation

1. Initial Authorization

a. **Amitiza** will be approved based on **all** of the following criteria:

(1) Diagnosis of irritable bowel syndrome with constipation

- AND-

(2) Patient was female at birth

-AND-

(3) History of failure, contraindication or intolerance to one OTC medication used for the treatment of constipation (document name and date tried)

-AND-

(4) **One** of the following criteria:

(a) History of failure, contraindication, or intolerance to Linzess

-OR-

(b) Age less than or equal to 17

Authorization will be issued for 6 months

2. Reauthorization

a. Amitiza will be approved based on the following criterion:

(1) Documentation of positive clinical response to Amitiza therapy

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- Notification/Prior Authorization may be in place
- Step Therapy may be in place

4. References:

1. Amitiza prescribing information. Takeda Pharmaceuticals, Inc. Deerfield. April 2018.
2. Linzess prescribing information. Allergan. Irvine, CA. March 2017.
3. . Symproic prescribing information. Shionogi Inc. Florham Park, NJ. January 2018.

Program	Prior Authorization/Medical Necessity – Amitiza
Change Control	
Date	Change
2/2014	New program
10/2014	Added age less than or equal to 17 to criteria to allow Amitiza use due to the contraindication/warning for use of Linzess in patients under 17 years of age.
7/2015	Added Movantik as preferred agent for OIC. Updated references.
7/2016	Added HCR gender dysphoria language. Updated references. Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
7/2017	Annual Review. Updated references. State mandate reference language updated.
11/2017	Updated Amitiza criteria. Updated references.
7/2018	Removed Movantik as a first line option and added Symproic. Updated references.