

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3029-12
Program	Step Therapy
Medication	Amitiza (lubiprostone)
P&T Approval Date	2/2014, 10/2014, 7/2015, 10/2015, 9/2016, 7/2017, 3/2018, 7/2018, 7/2019, 7/2020
Effective Date	10/1/2020; Oxford only: N/A

1. Background:

Amitiza (lubiprostone) is indicated for the treatment of chronic idiopathic constipation (CIC) in adults, 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, and the treatment of irritable bowel syndrome with constipation (IBS-C) in women at least 18 years old. Linzess (linaclotide) is indicated in adults for the treatment of IBS-C and CIC. Linzess has a black box warning regarding the risk of serious dehydration in pediatric patients less than 17 years of age, and use of Linzess should be avoided in pediatric patients. Symproic (naldemedine) is indicated for 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.

Step therapy programs are intended to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Linzess for CIC or IBS-C or Symproic for OIC in chronic non-cancer pain in adults including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation before providing coverage for Amitiza (lubiprostone).

2. Coverage Criteria^a:

<p>A. Amitiza will be approved on one of the following criteria:</p> <ol style="list-style-type: none"> 1. Diagnosis of chronic idiopathic constipation or irritable bowel syndrome with constipation and history of failure, contraindication or intolerance to the following: <ol style="list-style-type: none"> a. Linzess (unless age less than or equal to 17 years) <p style="text-align: center;">-OR-</p> <ol style="list-style-type: none"> 2. Diagnosis of opioid induced constipation in chronic non-cancer pain in adults including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation and
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history of failure, contraindication or intolerance to the following:

- a. Symproic

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
- Prior Authorization/Medical Necessity may be in place

4. References:

1. Amitiza [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.; October 2018.
2. Linzess [package insert]. Madison, NJ: Allergan; October 2018.
3. Symproic [package insert] Raleigh, NC: BioDelivery Sciences International. April 2019

Program	Step Therapy – Amitiza
Change Control	
Date	Change
2/2014	New program
10/2014	Age of less than or equal to 17 added to criteria
7/2015	Added Movantik as preferred agent for OIC. Updated references.
8/2015	Administrative update. Added Maryland Continuation of Care.
10/2015	Added irritable bowel syndrome with constipation to criteria.
7/2016	Added Indiana and West Virginia coverage information.
9/2016	Annual Review. Updated references.
11/2016	Administrative change. Added California coverage information.
7/2017	Annual review. Updated references. State mandate reference language updated.
3/2018	Updated Amitiza indication.
7/2018	Removed Movantik as a first line option and added Symproic. References updated.
7/2019	Annual review. Updated background section and references.
7/2020	Annual review. Updated background section and references.