

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1004-9
Program	Prior Authorization/Notification
Medication	Amitiza® (lubiprostone), Linzess® (linaclotide), Movantik® (naloxegol), Symproic (naldemedine) and Trulance (plecanatide)
P&T Approval Date	9/11/2007, 6/10/2008, 6/9/2009, 7/2010, 7/2011, 7/2012, 8/2012, 7/2013, 7/2014, 7/2015, 7/2016, 6/2017, 10/2017, 3/2018
Effective Date	6/1/2018; Oxford only: 6/1/2018

1. Background:

Amitiza (lubiprostone) is indicated for the treatment of chronic idiopathic constipation, for 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 for irritable bowel syndrome with constipation in women aged 18 years and older. Linzess (linaclotide) and Trulance (plecanatide) are indicated for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation in adults aged 18 years and older. Movantik (naloxegol) and Symproic (naldemedine) are opioid antagonists 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 these agents.

2. Coverage Criteria:

A. Initial Therapy

1. **Amitiza** will be approved based on **one of** the following:

a. Diagnosis of chronic idiopathic constipation

-OR-

b. **Both** of the following:

(1) Diagnosis of irritable bowel syndrome with constipation

-AND-

(2) Patient was female at birth

-OR-

c. **One** of the following criteria:

- (1) Diagnosis of opioid-induced constipation in patients being treated for chronic, non-cancer pain
- (2) 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.

Authorization will be issued for 12 months

2. **Linzess or Trulance** will be approved based on **both** of the following criteria:

- a. **One** of the following:

- (1) Chronic idiopathic constipation
- (2) Irritable bowel syndrome with constipation

-AND-

- b. Patient is \geq 18 years of age

Authorization will be issued for 12 months

3. **Movantik or Symproic** will be approved based on **one** of the following criteria:

- a. Diagnosis of opioid-induced constipation in patients being treated for chronic, non-cancer pain
- b. 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.

Authorization will be issued for 12 months

B. Reauthorization

1. **Amitiza, Linzess, Movantik, Symproic or Trulance** will be approved based on the following criterion:
 - a. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months

3. Additional Clinical Programs:

- 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
- Step therapy may be in place
- Prior Authorization/Medical Necessity may be in place

4. References:

1. Amitiza package insert. Takeda Pharmaceuticals, Inc. Deerfield, IL. August 2017.
2. Linzess package insert. Allergan USA Inc. Irvine CA. March 2017.
3. Movantik prescribing information. AstraZeneca Pharmaceutical LP. Wilmington, DE. August 2017.
4. Symproic prescribing information. Shionogi Inc. Florham Park, NJ. August 2017.
5. Trulance prescribing information. Synergy Pharmaceuticals Inc. New York, NY. January 2018.

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Change Control	
7/2014	Annual review. No changes to the criteria.
10/2014	Modification to implementation date
7/2015	Added appropriate use criteria for Movantik. Updated references.
7/2016	Added HCR gender dysphoria language. Updated references.
6/2017	Added Trulance. Updated references.
10/2017	Updated Movantik and Amitiza criteria. Updated references.
3/2018	Added Symproic to criteria. Updated Trulance criteria based on new indication for irritable bowel syndrome with constipation.
12/2018	Administrative change to add statement regarding use of automated processes.