UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Irritable Bowel Syndrome-Constipation

Program	Prior Authorization
Medication	Amitiza (lubiprostone), Linzess (linaclotide), Movantik (naloxegol), Symproic (naldemedine), Trulance (plecanatide)
Issue Date	7/2016
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

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** the following criterion**:**

   a. **Both** of the following criteria:

   (1) **One** of the following:
   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. Movantik (document date of trial)

Authorization will be issued for 12 months

-OR-

b. **Both** of the following criteria:

(1) Diagnosis of chronic idiopathic constipation

- 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)

- AND-

ii. **One** of the following:

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

-OR-

(b) Age less than or equal to 17 years

Authorization will be issued for 12 months

-OR-

c. **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 **both** of the following:

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

-AND-

ii. **One** of the following:

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

-OR-

(b) Age less than or equal to 17 years

Authorization will be issued for 12 months

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

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

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

-AND-

b. Patient is ≥ 18 years of age

Authorization will be issued for 12 months

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

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

4. **Trulance** will be approved based **all** of the following criteria**:**

a. a. One of the following:
(1) Diagnosis of chronic idiopathic constipation
(2) Irritable bowel syndrome with constipation

-AND-

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

-AND-

c. History of failure, contraindication, or intolerance to Linzess

Authorization will be issued for 12 months

B. Reauthorization

1. **Amitiza, Trulance, or Symproic** will be approved based on the following criterion**:**

a. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months

3. References:

1. Amitiza prescribing information. 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. Trulance prescribing information. Synergy Pharmaceuticals Inc. New York, NY. January 2018.

Program	Prior Authorization - Irritable Bowel Syndrome- Constipation
Change Control	
7/2016	New drug policy. IBS- Constipation policy terminated. Movantik policy terminated. Amitiza, Linzess, Movantik combined into one drug policy.
11/2016	Linzess added to PDL. Added step through Linzess for IBS-C and idiopathic constipation sections of Amitiza criteria.
3/2017	Updated policy template. Updated all authorization durations to

	12 months.
6/2017	Added Trulance to policy. Updated references.
9/2017	Removed Movantik and Linzess from reauthorization criteria to allow for Dx to Rx implementation. Added new indication for Movantik. Added new indication for Amitiza.
3/2018	Renamed Irritable Bowel Syndrome-Constipation (replacing previous title of Amitiza, Linzess, Movantik, Trulance). Added Symproic to the criteria. Updated Trulance criteria based on new indication for irritable bowel syndrome with constipation.