UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1004-13
Program	Prior Authorization/Notification
Medication	Amitiza® (lubiprostone)*, Linzess® (linaclotide), Motegrity (prucalopride), Movantik®*(naloxegol), Symproic (naldemedine), Trulance (plecanatide)*, and Zelnorm (tegaserod)
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, 3/2019, 12/2019, 12/2020, 12/2021
Effective Date	3/1/2022; Oxford only: 3/1/2022

1. Background:

Amitiza (lubiprostone)* is indicated for the treatment of chronic idiopathic constipation, for 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, and for irritable bowel syndrome with constipation in women aged 18 years and older. Zelnorm (tegaserod) is indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults; however, Zelnorm is only indicated in adult women less than 65 years. 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. Motegrity (prucalopride) is indicated for the treatment of chronic idiopathic constipation (CIC) in adults. 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. <u>Initial Therapy</u>

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

   a. Diagnosis of chronic idiopathic constipation

   -OR-

   b. **<u>Both</u>** 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 ≥ 18 years of age

Authorization will be issued for 12 months

3. Motegrity will be approved based on the following criterion**:**

a. Diagnosis of chronic idiopathic constipation

Authorization will be issued for 12 months

4. **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

5. Zelnorm will be approved based on all of the following criterion:

a. Diagnosis of irritable bowel syndrome with constipation

- AND –

b. Patient was female at birth

Authorization will be issued for 12 months

B. <u>Reauthorization</u>

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

a. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months

* Brand Amitiza, Movantik and Trulance are typically excluded from coverage.

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]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020.
2. Linzess [package insert]. Madison, NJ: Allergan USA Inc.; August 2021.
3. Motegrity [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020.
4. Movantik [package insert]. Wilmington, DE: AstraZeneca Pharmaceutical LP.; April 2020.
5. Symproic [package insert]. Raleigh, NC: BioDelivery Services International, Inc.; July 2021.
6. Trulance [package insert]. Bridgewater, NJ: Bausch Health US, LLC; April 2021.
7. Zelnorm [package insert]. Covington, LA: Alfasigma USA, Inc.; June 2020.

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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.
3/2019	Annual review. Added Motegrity and updated references.
12/2019	Added Ibsrela and Zelnorm to criteria.
12/2020	Annual review. Remove Ibsrela since listed as discontinued on FDA website. Updated references.
12/2021	Annual review. Updated references.