UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Constipation Agents

Program	Prior Authorization
Medication	Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride), Movantik (naloxegol), Symproic (naldemedine), Trulance (plecanatide), Zelnorm (tegaserod)
Markets in Scope	California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, South Carolina
Issue Date	7/2016
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	3/2021

1. Background:

Amitiza (lubiprostone) is indicated for the treatment of chronic idiopathic constipation (CIC), for 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 for irritable bowel syndrome with constipation (IBS-C) in women aged 18 years and older. Zelnorm (tegaserod) is indicated for treatment of irritable bowel syndrome with constipation in adult women less than 65 years. Linzess (linaclotide) and Trulance (plecanatide) are indicated for the treatment of CIC and IBS-C in adults aged 18 years and older. Motegrity (prucalopride) is indicated for the treatment of CIC in adults. Movantik (naloxegol) and Symproic (naldemedine) are opioid antagonists indicated for the treatment of 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. Physicians and patients should periodically assess the need for continued treatment with these agents.

Trulance and Linzess contain a black box warning for risk of serious dehydration in pediatric patients.

2. Coverage Criteria:

A. Initial Therapy

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

   a. **Both** of the following:

      (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 **all** of the following:

- Lactulose
- Polyethylene glycol (Miralax)
- Movantik

-OR-

b. **Both** of the following:

(1) Diagnosis of chronic idiopathic constipation

- AND-

(2) Both of the following:

i. History of failure, contraindication or intolerance to **one** of the following:

- Lactulose
- Polyethylene glycol (Miralax)

- AND-

ii. History of failure, contraindication, or intolerance to **both** of the following:

- Trulance
- Motegrity

-OR-

c. **All** of the following:

(1) Diagnosis of irritable bowel syndrome with constipation

-AND-

(2) Patient was female at birth

-AND-

(3) History of failure, contraindication or intolerance to **all** of the following:
- Lactulose
- Polyethylene glycol (Miralax)
- Trulance

-OR-

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

a. **All** of the following:

(1) Diagnosis of chronic idiopathic constipation

- AND-

(2) **Both** of the following:

i. History of failure, contraindication or intolerance to **one** of the following:
- Lactulose
- Polyethylene glycol (Miralax)

- AND-

ii. History of failure, contraindication, or intolerance to **both** of the following:
- Trulance
- Motegrity

- OR-

b. **All** of the following:

(1) Diagnosis of irritable bowel syndrome with constipation

- AND-

(2) History of failure, contraindication or intolerance to **all** of the following:
- Lactulose
- Polyethylene glycol (Miralax)
- Trulance

-OR-

3. **Trulance** will be approved based on the following criteria**:**

   a. **<u>One</u>** of the following:

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

-OR-

4. **Motegrity** will be approved based on the following criteria**:**

   a. Diagnosis of chronic idiopathic constipation

-OR-

5. **Movantik** 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

-OR-

6. **Symproic** will be approved based on **<u>both</u>** of the following criteria**:**

   a. One of the following:
      (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

-AND-

   b. History of failure, contraindication or intolerance to **<u>all</u>** of the following:
      - Lactulose
      - Polyethylene glycol (Miralax)
      - Movantik

7. **Zelnorm** will be approved based on **all** of the following criteria:

   a. Diagnosis of irritable bowel syndrome with constipation

   -AND-

   b. Patient was female at birth

   -AND-

   c. History of failure, contraindication or intolerance to **all** of the following:
      - Lactulose
      - Polyethylene glycol (Miralax)
      - Trulance

   Authorization will be issued for 12 months

B. Reauthorization

1. **Amitiza, Symproic, Linzess, or Zelnorm** will be approved based on the following criterion**:**
   NOTE: Reauthorization requests for Movantik, Motegrity and Trulance should go through the initial authorization criteria.

   a. Documentation of positive clinical response to therapy

   Authorization will be issued for 12 months

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.

4. References:

1. Amitiza [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2019.
2. Linzess [package insert]. Madison, NJ:Allergan USA, Inc.; September 2020.
3. Trulance [package insert]. Bridgewater, NJ: Bausch Health US, LLC; February 2020.
4. Zelnorm [package insert]. Covington, LA: Alfasigma USA, Inc.; June 2020.

5. Motegrity [package insert]. Lexington, MA: Shire US Inc.; December 2018.
6. Movantik [package insert]. Wilmington, DE: AstraZeneca Pharmaceutical LP.; April 2020.
7. Symproic [package insert]. Raleigh, NC: BioDelivery Services International, Inc.; May 2020.

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.
7/2018	Revised Trulance criteria to match Linzess criteria for 10/1/18 PDL change. Trulance will become preferred and part of Dx2Rx at that time. Revised step therapy medications for Amitiza IBS-C and CIC requests. Updated references.
10/2018	Revised policy to move Linzess to a non-preferred status for 1/1/19.
3/2019	Renamed policy Constipation Agents. Added Motegrity and updated references.
7/2019	Updated criteria to reflect that Motegrity is preferred with DX2RX for 10/1/19 PDL change. Updated references.
1/2020	Added Ibsrela and Zelnorm to criteria.
12/2020	Removed Ibsrela since noted as discontinued on FDA website. Updated references.