UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1004-17
Program	Prior Authorization/Notification
Medication	Amitiza® (lubiprostone)*, Ibsrela® (tenapanor)*, Linzess® (linaclotide), Motegrity® (prucalopride), Movantik®*(naloxegol), Symproic® (naldemedine), 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, 3/2019, 12/2019, 12/2020, 12/2021, 4/2022, 11/2022, 7/2023, 7/2024
Effective Date	10/1/2024

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. Ibsrela (tenapanor)* is indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults. Linzess (linaclotide) is indicated in adults for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation and for the treatment of functional constipation (FC) in pediatric patients 6 to 17 years of age. Trulance (plecanatide)* is indicated in adults for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation. 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]:

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. **Ibsrela*** will be approved based on the following criterion**:**

a. Irritable bowel syndrome with constipation

Authorization will be issued for 12 months

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

a. Chronic idiopathic constipation
b. Irritable bowel syndrome with constipation
c. Functional constipation

Authorization will be issued for 12 months

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

a. Chronic idiopathic constipation
b. Irritable bowel syndrome with constipation

Authorization will be issued for 12 months

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

a. Diagnosis of chronic idiopathic constipation

Authorization will be issued for 12 months

6. **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*, Ibsrela*, Linzess, Motegrity, 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

[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.

* Brand Amitiza, Ibsrela, 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. Ibsrela [package insert]. Waltham, MA: Ardelyx, Inc.; April 2022.
3. Linzess [package insert]. North Chicago IL: AbbVie; June 2023
4. Motegrity [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020.
5. Movantik [package insert]. Wilmington, DE: AstraZeneca Pharmaceutical LP.; April 2020.
6. Symproic [package insert]. Raleigh, NC: BioDelivery Services International, Inc.; July 2021.
7. Trulance [package insert]. Bridgewater, NJ: Bausch Health US, LLC; March 2024.

Program	Prior Authorization/Notification – Constipation agents
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.
4/2022	Added Ibsrela to criteria.
11/2022	Review. The black box warning of Linzess and Trulance changed the contraindication from patients less than 18 to patients less than 2 years of age therefore removed the age restriction. Zelnorm was removed because discontinued from the market. Added state mandate language.
7/2023	Added new indication for Linzess. Updated references.
7/2024	Annual review. Removed criteria for Ibsrela that patient is 18 or older. Updated references.