UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2167-7
Program	Prior Authorization/Medical Necessity
Medication	Motegrity® (prucalopride)
P&T Approval Date	6/2019, 6/2020, 6/2021, 6/2022, 11/2022, 6/2023, 6/2024
Effective Date	9/1/2024

1. Background:

Motegrity (prucalopride) is indicated for the treatment of chronic idiopathic constipation in adults. Physicians and patients should periodically assess the need for continued treatment with Motegrity. Linzess® (linaclotide) is indicated for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation in adults and the treatment of functional constipation (FC) in pediatric patients 6 to 17 years of age.. Linzess has a black box warning regarding the risk of serious dehydration in pediatric patients less than 2 years of age and in patients with known or suspected mechanical gastrointestinal obstruction. Amitiza®* (lubiprostone) is indicated for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation in adults and for the treatment 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.

This program is intended to encourage the use of lower cost alternatives and requires a member to try lower cost alternatives before providing coverage for Motegrity.

2. Coverage Criteria[a]:

1. **Initial Authorization**

   a. **Motegrity** will be approved based on **both** of the following criteria:

      1) Diagnosis of chronic idiopathic constipation

      - AND-

      2) History of failure, contraindication, or intolerance to **both** of the following:

         a) Linzess
         b) lubiprostone (generic Amitiza)

   Authorization will be issued for 12 months

2. **Reauthorization**

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

      (1) Documentation of positive clinical response to Motegrity 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 only Amitiza may be excluded from benefit coverage.**

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.
- Notification/Prior Authorization may be in place

4. References:

1. Amitiza [package insert]. Lexington, MA: Takeda pharmaceuticals America, Inc; November 2020.
2. Linzess [package insert]. North Chicago, IL: AbbVie, Inc.; June 2023.
3. Motegrity [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020.

Program	Prior Authorization/Medical Necessity - Motegrity
Change Control	
Date	Change
6/2019	New program
6/2020	Annual review.
6/2021	Annual review. Updated references.
6/2022	Annual review. Updated references.
11/2022	Review. The black box warning of Linzess changed the contraindication from patients less than 18 to patients less than 2 years of age therefore removed the age bypass for Amitiza.
6/2023	Clarification to change control from 11/2022 - The black box warning of Linzess changed the contraindication from patients less than 18 to patients less than 2 years of age therefore removed the age bypass of age less than or equal to 17. Removed OTC step and added step through generic Amitiza.
6/2024	Annual review. Updated background section and references. Referenced brand Amitiza exclusion.