

Commercial/Healthcare Exchange PA Criteria *Effective: May 2017*

Prior Authorization: Amitiza/Motegrity/lbsrela

Products Affected: Amitiza and Lubiprostone 8 mcg and 24mcg oral capsules, Motegrity (prucalopride) 1 mg and 2 mg oral tablets, lbsrela 50mg tablets

Covered Uses:

1. Chronic Idiopathic Constipation (Amitiza/Lubiprostone OR Motegrity only);
2. Opioid-induced Constipation (OIC) (Amitiza/Lubiprostone only)
3. Irritable Bowel Syndrome with Constipation (Amitiza/Lubiprostone OR lbsrela only)

Exclusion Criteria:

1. Pediatric patients
2. Patients with known or suspected mechanical gastrointestinal obstruction

Required Medical Information:

1. Diagnosis
2. Previous therapies tried and failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions: None

Coverage Duration: 12 Months

Other Criteria

Initial Approval Criteria

1. Chronic Idiopathic Constipation (Amitiza/Lubiprostone OR Motegrity)
 - A. Patient has clinically diagnosed chronic idiopathic constipation (Amitiza/ Lubiprostone OR Motegrity); **AND**
 - B. Patient has had an intolerance to, or treatment failure of Trulance **AND** Linzess.
2. Opioid-induced Constipation (OIC) (Amitiza/ Lubiprostone only)
 - A. Patient has a diagnosis of Opioid-induced Constipation (Amitiza Lubiprostone / only); **AND**
 - B. Patient has tried and failed one OTC medication (e.g. miralax, sennoside) used for the treatment of constipation
3. Irritable Bowel Syndrome with Constipation (Amitiza/ Lubiprostone/lbsrela only)
 - A. Patient has a diagnosis of irritable bowel syndrome with constipation; **AND**
 - B. Patient has tried and failed one OTC medication (e.g. miralax, sennoside) used for the treatment of constipation; **AND**
 - C. Patient has had an intolerance to, or treatment failure of Trulance **AND** Linzess

Continuation:

1. The patient has demonstrated a beneficial response to Amitiza/Lubiprostone, Motegrity, or Ibsrela, per the prescribing physician (e.g. increased number of bowel movements from baseline).

References:

1. TRULANCE^(R) oral tablets, plecanatide oral tablets. Synergy Pharmaceuticals Inc (per manufacturer), New York, NY, 2018
2. Product Information: MOTEGRITY (TM) oral tablets, prucalopride oral tablets. Shire US Inc (per FDA), Lexington, MA, 2018.
3. Amitiza (lubiprostone) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc; November 2020.
4. Linzess (linaclotide) [prescribing information]. Madison, NJ: Allergan USA, Inc; September 2020.
5. American Gastroenterological Association. Guideline on the Pharmacological Management of Irritable Bowel Syndrome. September 14, 2014. Available at: [DOI:https://doi.org/10.1053/j.gastro.2014.09.001](https://doi.org/10.1053/j.gastro.2014.09.001). Accessed 12/30/20
6. Ibsrela tablets [package insert]. Fremont, CA, Ardelyx Inc. Updated September 2019. Accessed April 11, 2022

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	5/2017
2	Policy Revision	Updated Template from CCI to EH CCI Carry over: P&T Review History: 5/17, 11/17, 11/18 Revision Record: 1/18, 9/18	All	4/25/2019
3	Policy Update	Addition of Motegrity; Change of policy name from Trulance to Trulance/Motegrity; Changed criteria from OR to AND requirements	All	6/12/2019

4	Policy Update	<p>Removed Trulance from title, and products affected</p> <p>Added Amitiza to title, products affected,</p> <p>Added indication: Opioid-induced Constipation (OIC) (Amitiza only)</p> <p>Removed Trulance from "other criteria"</p> <p>Removed "Patient will be using no more than 1 tablet per day" from "other criteria"</p> <p>Added: Opioid-induced Constipation (OIC) (Amitiza only) 1.Patient has a diagnosis of Opioid-induced Constipation (Amitiza only); AND 2.Patient has tried and failed one OTC medication (e.g. miralax, sennoside) used for the treatment of constipation</p> <p>added IBS w/constipation as indication for Amitiza</p> <p>Added Continuation criteria</p>	All	1/2021
5	Update	Added Lubiprostone	Products Affected, Covered Uses, Other Criteria, Continuation	1/27/2021
6	Policy Update	Addition of lbsrela	Change of policy name to include lbsrela, change other criteria to include lbsrela,	5/12/2022

