Overview
Lubiprostone is a chloride channel activator that acts locally on the gastrointestinal membrane to increase intestinal fluid secretion and improve fecal transit. Linaclotide and plecanatide bind and agonize an intestinal enzyme (guanylate cyclase-C) resulting in increased intestinal fluid and GI transit.

FDA Approved Indications
1. Treatment of Chronic idiopathic constipation (CIC) in adults
2. Treatment of irritable bowel syndrome (IBS) with constipation in adults
3. Treatment of opioid-induced constipation in adults with chronic noncancer pain, including patient with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation (Amitiza only)
4. Chronic constipation (not otherwise specified) and all other causes of constipation have been ruled out (medication-induced constipation, gastrointestinal [GI] motility issues, GI obstruction, etc.)

Coverage Guidelines
1. Authorization may be granted for members, 18 years of age and older, who are currently receiving treatment for an approved indication, excluding when the product is obtained as samples or via manufacturer’s patient assistance program.

OR
2. Authorization may be granted for members, 18 years of age and older, when all the following criteria are met:
   a. The member requires treatment for an approved indication
   b. The member has failed dietary and lifestyle modifications
   c. The member has experienced an allergy or side effect with or has had at least a 1-week trial resulting in treatment failure or inadequate response with one (1) laxative agent such as saline, stimulant, bulk, or osmotic laxatives (e.g., milk of magnesia, lactulose, polyethylene glycol [PEG], psyllium, methylcellulose, magnesium citrate, senna, bisacodyl, etc.)

**Continuation of Therapy**
Reauthorizations may be approved when a physician assessment of improvement in the member’s condition has been submitted.

**Limitations**
1. Authorizations will be granted for 12 months

**References**
1. Amitiza (lubiprostone) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America; June 2018
2. Linzess (linaclotide) [prescribing information]. Madison, NJ: Allergan USA, Inc; October 2018.
3. Trulance (plecanatide) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals, a division of Bausch Health US, LLC; May 2019

**Review History**
**Trulance Program:**
399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org
Implemented: 01/01/18  
Reviewed: 09/18/17 P&T Mtg

Linzess Program:
06/24/13 – Reviewed
08/12/13 – Implemented
04/07/14 – Reviewed
06/23/14 – Reviewed

Amitiza Program:
04/23/07 – Reviewed
06/01/07 – Implemented
06/16/08 – Added IBS-C indication
06/15/09 – Updated warnings
06/21/10 – Reviewed
06/27/11 – Updated hepatic dosing
06/25/12 – Updated dosing
06/24/13 – Updated
04/07/14 – Reviewed
06/23/14 – Reviewed

Criteria Programs combined:
06/22/15 – Reviewed
06/27/16 – Reviewed
06/26/17 – Reviewed
02/26/18 – Reviewed
02/20/19 – Reviewed
11/20/19 – Changed laxative trials from two to one required

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.