### 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. Prucalopride is a 5-HT₄ receptor agonist whose action at the receptor site promotes cholinergic and noradrenergic, noncholinergic neurotransmission by enteric neurons leading to stimulation of the peristaltic reflex, intestinal secretions, and gastrointestinal motility.

### 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 patients 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.)
   d. Motegrity only: The member has a diagnosis of chronic idiopathic constipation and previous treatment with either Amitiza or Linzess

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 approved for 12 months
2. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Product</th>
<th>Limit</th>
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</thead>
<tbody>
<tr>
<td>Amitiza</td>
<td>60 capsules per 30 days</td>
</tr>
<tr>
<td>Trulance</td>
<td>30 tablets per 30 days</td>
</tr>
<tr>
<td>Linzess</td>
<td>30 capsules per 30 days</td>
</tr>
<tr>
<td>Motegrity</td>
<td>30 tablets per 30 days</td>
</tr>
</tbody>
</table>

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:**
- 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
- 01/22/20 – Added Motegrity, added QL for Amitiza, Linzess, and Trulance

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