



## Clinical Edit Criteria Proposal

Drug/Drug Class: Amitiza<sup>®</sup> and **Linzess<sup>®</sup>** Capsules Clinical Edit

Date: November 7, 2013

Prepared for:

Prepared by: MO HealthNet

New Criteria

Revision of Existing Criteria

### Executive Summary

**Purpose:** Ensure appropriate utilization and control of Amitiza<sup>®</sup> (lubiprostone capsules) and **Linzess<sup>®</sup> (linaclotide capsules)**.

**Why was this Issue Selected:**

Amitiza<sup>®</sup> is a branded drug product containing lubiprostone indicated for the treatment of chronic idiopathic constipation in adults. **Linzess<sup>®</sup> is a branded drug product containing linaclotide.** These medications locally target intestinal chloride channels to help regulate fluid balance. Chronic idiopathic constipation is generally defined as infrequent and difficult passage of stool and is one of the most common disorders suffered by Americans. This condition affects women more often than men and also affects those over the age of 65 more frequently. Symptoms include abdominal pain and discomfort, bloating, straining, and hard stools. **Linzess<sup>®</sup> is available in 145 mcg and 290 mcg, dosed once daily** and Amitiza<sup>®</sup> is available in a 24 mcg capsule, dosed BID, and are priced higher than other agents used to treat this condition.

	<b>Drug</b>	<b>Cost per Claim</b>
<b>Program-specific information:</b>	• Senokot-S <sup>®</sup>	\$4.30MAC
	• Polyethylene Glycol Pwdr	\$20.18MAC
	• Amitiza <sup>®</sup>	\$249.18WAC
	• <b>Linzess<sup>®</sup></b>	<b>\$203.43WAC</b>

**Setting & Population:** Patients ages 18 years and older

- Type of Criteria:  Increased risk of ADE  Non-Preferred Agent  
 Appropriate Indications
- Data Sources:  Only administrative databases  Databases + Prescriber-supplied

## Setting & Population

- Drug for review: Amitiza<sup>®</sup> (lubiprostone capsules) and **Linzess<sup>®</sup> (linaclotide capsules)**
- Age range: Patients ages 18 years and older
- Gender: Male and female

## Approval Criteria

- Appropriate diagnosis for Amitiza
  - Chronic Idiopathic Constipation
  - Irritable Bowel Syndrome with Constipation
    - Females
- **Appropriate diagnosis for Linzess**
  - **Chronic Idiopathic Constipation**
  - **Irritable Bowel Syndrome with Constipation (male and female)**
- Trial and failure on at least 2 different covered laxative preparations
- ADE/ADR to covered laxative products
- Contraindication to covered laxative products

## Denial Criteria

- No prior prescription claims for covered laxative product in the most recent 45 days
- Lack of ADE/ADR and/or lack of contraindication to covered laxative products
- Lack of appropriate diagnoses

## References

1. Facts and Comparisons, p.1164a – 1164b. 2011.
2. USPDI, Micromedex, 2011.

3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2011.
4. Takeda Pharmaceuticals America Inc., "Amitiza, Lubiprostone Capsules Product Submission", Lincolnshire, IL 60069; March 2006.
5. **Forest Pharmaceuticals, Inc., "Linzess, Linaclotide Capsules Product Submission", St. Louis, MO 63045; August 2012**