



## Montana Healthcare Programs Drug Prior Authorization Criteria

### **Linzess ® (linaclotide)**

#### **I. Medication Description**

Linzess ® is a guanylate cyclase-C agonist indicated for treatment of:

- Irritable bowel syndrome with constipation (IBS-C) in adults.
- Chronic idiopathic constipation (CIC) in adults.
- Functional constipation (FC) in pediatric patients 6 to 17 years of age.

#### **II. Position Statement**

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

#### **III. Initial Coverage Criteria**

##### **Irritable bowel syndrome with constipation (IBS-C) OR Chronic idiopathic constipation (CIC) in adults**

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have had a trial and inadequate response or contraindication to at least ONE (1) osmotic laxative (i.e., polyethylene glycol, lactulose, etc.) for at least 14 days.
- If nonpreferred, has had a trial and inadequate response or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List, available at <https://medicaidprovider.mt.gov/19>.

##### **Functional constipation (FC) in pediatric patients 6 to 17 years of age**

Member must meet all of the following criteria:

- Be 6 years of age or older.
- Have had a trial and inadequate response, or contraindication to at least ONE (1) osmotic laxative (i.e., polyethylene glycol, lactulose, etc.) for at least 14 days.
- If nonpreferred, has had a trial and inadequate response or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List, available at <https://medicaidprovider.mt.gov/19>.

Limitations:

Dosed per package labeling based on indication.

#### **IV. Quantity Limits**

Maximum Daily Dose: 1 capsule daily

#### **V. Coverage Duration**

Initial approval: 1 year

Renewal approval duration: 1 year

#### References:

[https://www.rxabbvie.com/pdf/linzess\\_pi.pdf](https://www.rxabbvie.com/pdf/linzess_pi.pdf)

[https://www.uptodate.com/contents/chronic-functional-constipation-and-fecal-incontinence-in-infants-children-and-adolescents-treatment?search=lactulose%20in%20children&source=search\\_result&selectedTitle=2~68&usage\\_type=default&display\\_rank=1](https://www.uptodate.com/contents/chronic-functional-constipation-and-fecal-incontinence-in-infants-children-and-adolescents-treatment?search=lactulose%20in%20children&source=search_result&selectedTitle=2~68&usage_type=default&display_rank=1)

#### **General Criteria applying to all gastrointestinal (GI) motility agents, except Lotronex, Relistor and Xifaxan:**

Failure on at least ONE (1) osmotic laxative (i.e., polyethylene glycol, lactulose, etc.) for at least 14 days

#### **LINZESS: CIC, IBS-C, FC**

- Patient must be > 18 years of age.
- Patient must have a diagnosis of chronic idiopathic constipation or irritable bowel syndrome with constipation.
- Treatment for chronic idiopathic constipation will be approved for 72mcg OR 145mcg with a maximum daily dose of 1 capsule.
- Treatment for irritable bowel syndrome with constipation will be approved for 290mcg with a maximum daily dose of 1 capsule.