MEDICAL MUTUAL®

# Drug Policy

| Policy: | Linzess (linaclotide) | Annual Review Date: 11/19/2020<br>Last Revised Date: 11/19/2020 |
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## OVERVIEW

Linzess is a guanylate cyclase-C agonist indicated in adults for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC). Linzess is contraindicated in patients less than 6 years of age because of the risk of death due to dehydration and has a boxed warning to avoid use in patients ages 6 to less than 18 years.

## POLICY STATEMENT

This policy involves the use of Linzess. Prior authorization is recommended for pharmacy benefit coverage of Linzess. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Linzess as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Linzess be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Linzess is recommended in those who meet the following criteria:

**1. <u>Chronic Idiopathic Constipation, Initial Therapy</u>**
**Criteria.** *Patient must meet the following criteria*

- **A.** The patient is 18 years of age or older; AND
- **B.** Linzess is prescribed by or in consultation with a gastroenterologist or a physician who specializes in the management of gastrointestinal disease; AND
- **C.** The patient has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
- **D.** The patient has failed or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months:
  - **a.** At least one bulk forming laxative (e.g. psyllium)
  - **b.** At least one osmotic laxative (e.g. PEG 3350)

   **c.** At least one saline laxative (e.g. magnesium citrate)
   **d.** At least one stimulant laxative (e.g. bisacodyl); AND
**E.** The patient does not have any known or suspected mechanical gastrointestinal obstruction

**2. <u>Irritable Bowel Syndrome with Constipation (IBS-C), Initial Therapy</u>**
**Criteria.** *Patient must meet the following criteria*

**A.** The patient is 18 years of age or older; AND
**B.** Linzess is prescribed by or in consultation with a gastroenterologist or a physician who specializes in the management of gastrointestinal disease; AND
**C.** The patient has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
**D.** The patient has failed or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months:
   **a.** At least one bulk forming laxative (e.g. psyllium)
   **b.** At least one osmotic laxative (e.g. PEG 3350)
   **c.** At least one saline laxative (e.g. magnesium citrate)
   **d.** At least one stimulant laxative (e.g. bisacodyl); AND
**E.** The patient does not have any known or suspected mechanical gastrointestinal obstruction

**3. <u>Continuation of Therapy (Renewals)</u>**
**Criteria.** *Patient must meet the following criteria*

**A.** The patient is 18 years of age or older; AND
**B.** The patient has demonstrated a beneficial response to Linzess, per the prescribing physician (e.g. increased number of bowel movements from baseline); AND
**C.** The patient does not have any contraindications to therapy with Linzess

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 1 year
**B)** *Extended Approval:* 1 year

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Linzess has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

1. Linzess [package insert]. Madison, NJ: Allergan USA, Inc.; September 2020.
2. Linaclotide. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 6 December 2019. Accessed 12 November 2020.