Clinical Policy: Linaclotide (Linzess)

Reference Number: PA.CP.PMN.71
Effective Date: 01/18
Last Review Date: 07/17/19

Coding Implications
Revision Log

Description
Linaclotide (Linzess®) is a guanylate cyclase-C agonist.

FDA approved indication
- Irritable bowel syndrome with constipation (IBS-C)
- Chronic idiopathic constipation (CIC)

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

It is the policy of Pennsylvania Health and Wellness ® that Linzess is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Irritable Bowel Syndrome with Constipation (IBS-C) (must meet all)**:**

1. Diagnosis of IBS-C;
2. Age ≥ 18 years;
3. Failure of ≥ 4 week trial of one bulk forming laxative [e.g., psyllium (Metamucil), methylcellulose (Citrucel), calcium polycarbophil (FiberCon)] within the past 90 days, unless member experiences clinically significant adverse effects or has contraindication(s) to bulk forming laxatives;
4. Request does not exceed 290 mcg per day.

Approval duration: 12 months

B. Chronic Idiopathic Constipation (CIC)

1. Diagnosis of CIC;
2. Age ≥ 18 years;
3. Failure of one bulk forming laxative [e.g., psyllium (Metamucil), methylcellulose (Citrucel), calcium polycarbophil (FiberCon)], unless member experiences clinically significant adverse effects or has contraindication(s) to bulk forming laxatives;
4. Failure of one stimulant laxative (e.g., bisacodyl, senna), unless member experiences clinically significant adverse effects or has contraindications to stimulant laxatives;
5. Failure of polyethylene glycol (MiraLax) at maximum indicated doses, unless member experiences clinically significant adverse effects or has contraindications to polyethylene glycol;
6. Request does not exceed 145 mcg per day and health plan approved daily quantity limit.

Approval duration: 12 months

C. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. All Indications (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
    a. IBS-C: 290 mcg per day (1 capsule per day);
    b. CIC: 145 mcg per day (1 capsule per day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
CIC: chronic idiopathic constipation
IBS-C: irritable bowel syndrome with constipation

V. Dosage and Administration

- **IBS-C:** The recommended dose of Linzess is 290 mcg taken orally once daily on an empty stomach, at least 30 minutes prior to the first meal of the day.
- **CIC:** The recommended dose of Linzess is 145 mcg taken orally once daily on an empty stomach, at least 30 minutes prior to the first meal of the day.
- For patients who have difficulty swallowing capsules or those with a nasogastric or gastrostomy tube, see full prescribing information for instructions for opening the capsule and administering with applesauce or water.

VI. Product Availability

Linzess is supplied as gelatin capsules in the following strengths: 145 mcg and 290 mcg.

VII. References

1. Linzess Prescribing Information. Irvine, CA: Allergan; January 2017. Available at: https://www.linzess.com/. Accessed November 7, 2017.
2. Ford AC, Moayyedi P, Lacy BE, et al. American College of Gastroenterology monograph on the management of irritable bowel syndrome and chronic idiopathic constipation. Am J Gastroenterol 2014; 109: S2-S26.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	Approval Date
Removed duration and timeframe of trial related to laxative use since they are available OTC and may not be verifiable via claims history. Modified initial approval duration from 6 to 12 months for both indications. References reviewed and updated.		
3Q 2019 annual review: No changes per Statewide PDL implementation 01/01/2020	07/17/19	