Clinical Policy: Lactitol (Pizensy)

Reference Number: ERX.NPA.145
Effective Date: 09.01.20
Last Review Date: 08.20
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Lactitol (Pizensy™) is an osmotic laxative.

FDA Approved Indication(s)
Pizensy is indicated for the treatment of chronic idiopathic constipation (CIC) in adults.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Pizensy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Idiopathic Constipation (must meet all)**:**

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 all are contraindicated or clinically significant adverse effects are experienced;
4. Failure of polyethylene glycol (MiraLax®) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Medical justification why lactulose (Constulose®) cannot be used;
6. Dose does not exceed 20 gm (2 unit-dose packets) per day or one bottle per month.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

Chronic Idiopathic Constipation (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request if for dose increase, new dose does not exceed 20 gm (2 unit dose packets) per day or one bottle per month.

Approval duration: 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CIC: chronic idiopathic constipation
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
lactulose (Constulose®, Enulose®, Generlac®, Kristalose®)	Oral solution: Initially, 15 to 30 mL PO once daily, increasing to 60 mL PO once daily if needed. Response may take 24 to 48 hours	Individualized depending on route, indication, and frequency of bowel movements
polyethylene glycol 3350 (MiraLax®, GaviLAX®, GlycoLax®, HealthyLax®, PEGyLAX®)	17 g PO dissolved in 120 to 240 mL of fluid	Maximum daily dosage is age and product specific
psyllium (Metamucil®)	1 rounded teaspoonful, tablespoonful, or premeasured packet in 240 mL of fluid PO, 1 to 3 times per day	7.2 grams (as soluble dietary fiber)/day
Citrucel® (methylcellulose)	Caplet: 2 caplets PO up to 6 times daily Powder: 1 heaping tablespoonful in at least 240 ml of water PO, given 1-3 times per day as needed	Caplet: 12 caplets/day Powder: 3 tablespoons/day
FiberCon® (calcium polycarbophil)	2 tablets (1,250 mg) PO 1 to 4 times daily	8 tablets/day PO (5,000 mg/day)

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): mechanical gastrointestinal obstruction; galactosemia
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CIC	Adults: 20 grams PO QD. Reduce the dosage to 10 grams PO QD for persistent loose stools.	20 gm/day

VI. Product Availability

- Multi-dose bottles: 280 and 560 grams

- Unit-dose packets: 10 grams

VII. References

1. Pizensy Prescribing Information. Braintree, MA: Braintree Laboratories, Inc.; February 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/211281s000lbl.pdf. Accessed: March 5, 2020.
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. June 2018; 113 (Suppl 2):1-18.
3. Black C, Ford AC. Chronic idiopathic constipation in adults: epidemiology, pathophysiology, diagnosis and clinical management. Med J Aust. July 2018; 209(2):86-91.
4. Paquette I, Varma M, Ternent C, et al. The American Society of Colon and Rectal Surgeons' clinical practice guideline for the evaluation and management of constipation. Dis. Colon Rectum. June 2016; 59(6):479-92.
5. Drug Monographs. Clinical Pharmacology. Tampa, FL: Gold Standard Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com. Accessed March 5, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.31.20	08.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.