Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 08/01/2021**
Policy Number: PA.CP.PMN.241	**Effective Date: 07/2020** **Revision Date: 07/2021**
Policy Name: Lactitol (Pizensy)	

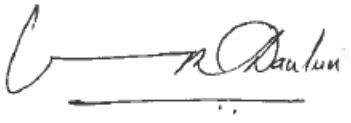
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

3Q 2021 annual review: revised medical justification why lactulose cannot be used to must use lactulose; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Lactitol (Pizensy)

Reference Number: PA.CP.PMN.241
Effective Date: 07/2020
Last Review Date: 07/2021 Revision Log

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.

It is the policy of health plans affiliated with PA Health & Wellness® 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. Member must use lactulose (Constulose®), unless contraindicated or clinically significant adverse effects are experienced;
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 the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy 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 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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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

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 policies – PA.CP.PMN.53

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
lactulose (Constulose®, Enulose®, 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 to 3 times per day as needed	Caplet: 12 caplets/day Powder: 3 tablespoons/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
FiberCon® (calcium polycarbophil)	2 tablets (1,250 mg calcium polycarbophil) PO 1 to 4 times daily	8 tablets/day(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	20 gm PO once daily. Reduce the dosage to 10 gm PO once daily for persistent loose stools.	20 gm/day

VI. Product Availability

- Multi-dose bottles: 280 and 560 gm of lactitol
- Unit-dose packets: 10 gm of lactitol

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 22, 2021.
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. Aug 2014; 109:S2-S26. doi: 10.1038/ajg.2014.187.
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 IM, 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07/2020	
3Q 2021 annual review: revised medical justification why lactulose cannot be used to must use lactulose; references reviewed and updated.	07/2021	