

Clinical Policy Title:	lactitol monohydrate
Policy Number:	RxA.643
Drug(s) Applied:	Pizensy™
Original Policy Date:	08/26/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Pizensy is an osmotic laxative indicated for the treatment of chronic idiopathic constipation (CIC) in adults.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
lactitol monohydrate (Pizensy)	chronic idiopathic constipation (CIC)	20 grams orally once daily	20gram

Dosage Forms

- For Oral Solution:
 - 280 grams of lactitol in multi-dose bottles
 - 560 grams of lactitol in multi-dose bottles
 - 10 grams of lactitol in unit-dose packets

Clinical Policy

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

I. Initial Approval Criteria

A. Chronic Idiopathic Constipation (CIC) (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®), wheat dextrin (Benefiber®)), unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of one stimulant laxative (e.g., bisacodyl, senna), unless all are contraindicated, or clinically significant adverse effects are experienced;
5. Failure of one osmotic laxative (e.g., polyethylene glycol (MiraLax®), lactulose, magnesium citrate) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced

Approval Duration

Commercial: 12 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Medicaid: 12 months

II. Continued Therapy Approval

A. Chronic Idiopathic Constipation (must meet all):

1. Currently receiving medication that has been authorized via RxAdvance benefit or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;

Approval Duration

Commercial: 12 months

Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

CIC: Chronic idiopathic constipation

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
psyllium (Metamucil®)	1 rounded teaspoonful, tablespoonful, or premeasured packet in 240 mL of fluid PO, 1 to 3 times per day (2.4 g of soluble dietary fiber per dose)	7.2 g (as soluble dietary fiber)/day
calcium polycarbophil (FiberCon®)	1,000 mg 1 to 4 times per day or as needed	6,000 mg/day
methylcellulose (Citrucel®)	Caplet: 2 caplets (total 1 g methylcellulose) PO with at least 240 ml (8 oz) of liquid, up to 6 times per day as needed Powder: 1 heaping tablespoonful (2 g methylcellulose per 19 g powder) in at least 240 ml (8 oz) of water PO, given 1 to 3 times per day as needed	Caplet: 12 caplets/day Powder: 6 grams/day
sennosides (Senokot®)	1 to 2 tablets (8.6 to 17.2 mg sennosides) PO BID	68.8 mg sennosides/day

bisacodyl (Dulcolax®)	5 to 15 mg/day (1 to 3 tablets) PO given as a single dose, or 1 suppository or retention enema (10 mg) PR QD	15 mg/day PO or 10 mg/day PR
	Either a suppository or oral tablet(s) may be used up to 3 times per week	

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

APPENDIX D: General Information

N/A

References

1. Pizensy (lactitol) powder for oral solution, prescribing information. Braintree Laboratories Inc; Braintree, MA; 2020, February; Accessed August 17, 2020;
2. Lacy E; Update on the Management of Chronic Idiopathic Constipation; Am J Manag Care. 2019;25:S55-S62; Accessed August 26, 2020.
3. Bharucha AE, Pemberton JH, Locke GR 3rd. American Gastroenterological Association technical review on constipation. Gastroenterology 2013; 144:218.
4. American College of Gastroenterology Chronic Constipation Task Force. An evidence-based approach to the management of chronic constipation in North America. Am J Gastroenterol 2005; 100 Suppl 1:S1.
5. Ramkumar D, Rao SS. Efficacy and safety of traditional medical therapies for chronic constipation: systematic review. Am J Gastroenterol 2005; 100:936.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/26/2020	09/14/2020