

Clinical Policy Title:	lactitol monohydrate
Policy Number:	RxA.643
Drug(s) Applied:	Pizensy™
Original Policy Date:	08/26/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Lactitol monohydrate (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; Reduce the dosage to 10 grams once daily for persistent loose stools. Administer oral medications at least 2 hours before or 2 hours after Pizensy™.	20 grams orally once daily

Dosage Forms

- 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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;

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.

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;
6. Maximum dose does not exceed 20 grams orally once daily.

Approval Duration

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy Approval

A. Chronic Idiopathic Constipation (must meet all):

1. Member is 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;
3. Maximum dose does not exceed 20 grams orally once daily.

Approval Duration

Commercial: 12 months

Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

CIC: Chronic idiopathic constipation

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
psyllium (Metamucil®)	1 rounded teaspoonful, tablespoonful, or premeasured packet in 240 mL of fluid orally, 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®)	1,250 mg calcium polycarbophil orally 1 to 4 times daily	5,000 mg of calcium polycarbophil orally once daily
methylcellulose (Citrucel®)	Caplet: 2 caplets (total 1 g methylcellulose) orally 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 orally, 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) orally twice daily	68.8 mg sennosides/day
bisacodyl (Dulcolax®)	5 to 15 mg/day (1 to 3 tablets) orally given as a single dose, or 1 suppository	15 mg/day orally or 10 mg/day rectally

Drug Name	Dosing Regimen	Maximum Dose
	<p>or retention enema (10 mg) rectally once daily</p> <p>Either a suppository or oral tablet(s) may be used up to 3 times per week</p>	

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Mechanical gastrointestinal obstruction;
 - Galactosemia.

- Boxed Warning(s):
 - None Reported.

APPENDIX D: General Information

- Lactitol exerts an osmotic effect, causing the influx of water into the small intestine leading to a laxative effect in the colon.

References

1. Pizensy™ (lactitol) powder for oral solution, prescribing information. Braintree Laboratories Inc; Braintree, MA; 2020, February; Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=579ef0af-4aaf-49b2-a5e4-fa6ea1e22cb6&type=display>. Accessed July 09, 2021.
2. Lacy E; Update on the Management of Chronic Idiopathic Constipation; Am J Manag Care. 2019;25:S55-S62; Available at: <https://pubmed.ncbi.nlm.nih.gov/31002489/>. Accessed July 09, 2021.
3. Bharucha AE, Pemberton JH, Locke GR 3rd. American Gastroenterological Association technical review on constipation. Gastroenterology 2013; 144:218. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3531555/>. Accessed July 09, 2021.
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. Available at: <https://pubmed.ncbi.nlm.nih.gov/16008640/>. Accessed July 09, 2021.
5. =Ramkumar D, Rao SS. Efficacy and safety of traditional medical therapies for chronic constipation: systematic review. Am J Gastroenterol 2005; 100:936. Available at: <https://pubmed.ncbi.nlm.nih.gov/15784043/>. Accessed July 09, 2021.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed July 9, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/26/2020	09/14/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Dosing Information dosing regimen was updated to include “Reduce the dosage to 10 grams 	07/09/2021	09/14/2021

<p>once daily for persistent loose stools. Administer oral medications at least 2 hours before or 2 hours after Pizensy™.”.</p> <ol style="list-style-type: none"> 2. Statement about provider sample “The provision of provider samples does not guarantee coverage...” was added to Clinical Policy. 3. Initial Approval Criteria I.A.6 was updated to include “Maximum dose does not exceed 20 grams orally once daily.”. 4. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...”. 5. Continued Therapy Approval Criteria II.A.3 was updated to include “Maximum dose does not exceed 20 grams orally once daily.”. 6. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..”. 7. Appendix B: Therapeutic Alternatives dosing regimen for FiberCon was updated from “1,000mg 1 to 4 times per day or as needed” to “1,250 mg calcium polycarbophil orally 1 to 4 times daily”. 8. Appendix B: Therapeutic Alternatives maximum dose for FiberCon was updated from “6,000mg/day” to “5,000 mg of calcium polycarbophil orally once daily”. 9. Statement about drug listing format in Appendix B is 		
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<p>rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only".</p> <p>10. Appendix D was updated to include "Lactitol exerts an osmotic effect, causing the influx of water into the small intestine leading to a laxative effect in the colon."</p> <p>11. References were reviewed and updated.</p>		
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