Clinical Policy: Lactitol (Pizensy)

Reference Number: AZ.CP.PMN.241
Effective Date: 09.01.20
Last Review Date: 08.21
Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) Revision Log

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

Description
Lactitol (Pizensy™) is an osmotic laxative.

AHCCCS preferred drugs in this class include: lubiprostone (Amitiza®), linaclotide (Linzess®). Note: PA required for both preferred products.

AHCCCS non-preferred drugs in this class include: lactitol (Pizensy).

FDA approved indications
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 Arizona Complete Health-Complete Care Plan and Care1st 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. Failure of Amitiza and Linzess at up to maximally indicated doses, each used for 4 weeks, unless contraindicated or clinically significant adverse effects are experienced;
7. 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 for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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 Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid.

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 policies – AZ.CP.PMN.53 for Arizona Medicaid.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
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
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

CLINICAL POLICY
Lactitol

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
FiberCon® (calcium polycarbophil)	2 tablets (1,250 mg calcium polycarbophil) PO 1 to 4 times daily	8 tablets/day(5,000 mg/day)
lubiprostone (Amitiza®)	CIC: 24mcg twice daily	24mcg /day
linaclotide (Linzess®)	CIC: 145mcg once daily or 72mcg once daily based on tolerability	290mcg /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
- Unit-dose packets: 10 gm

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	07.20.20	07.20
Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st.	5.10.21	04.21
3Q 2021 annual review: no significant changes; revised medical justification to add requirement for use of lactulose in alignment with Corp criteria. References updated.	07.14.21	07.21

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

CLINICAL POLICY
Lactitol

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.