

Clinical Policy: Lubiprostone (Amitiza)

Reference Number: MDN.CP.PMN.142

Effective Date: 04.01.22

Last Review Date: 04.22

Line of Business: Illinois Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Lubiprostone (Amitiza[®]) is a chloride channel activator.

FDA Approved Indication(s)

Amitiza is indicated for the treatment of:

- Chronic idiopathic constipation (CIC) in adults
- Irritable bowel syndrome with constipation (IBS-C) in women ≥ 18 years old
- Opioid-induced constipation (OIC) in adults with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
 - Limitation(s) of use: Effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids (e.g., methadone) has not been established.

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 Centene Corporation[®] that Amitiza 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 clinically significant adverse effects are experienced or all are contraindicated;
4. Failure of one stimulant laxative (e.g., bisacodyl, senna) unless clinically significant adverse effects are experienced or all are contraindicated;
5. Failure of polyethylene glycol (MiraLax[®]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects experienced;
6. Member must use generic lubiprostone, unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 48 mcg (2 capsules) per day.

Approval duration: 12 months

B. Irritable Bowel Syndrome with Constipation (must meet all):

1. Diagnosis of IBS-C;
2. Age \geq 18 years;
3. Failure of one bulk forming laxative (e.g., psyllium (Metamucil), methylcellulose (Citrucel), calcium polycarbophil (FiberCon)) unless clinically significant adverse effects are experienced or all are contraindicated;
4. Failure of polyethylene glycol (MiraLax[®]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects experienced;
5. Member must use generic lubiprostone, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 16 mcg (2 capsules) per day.

Approval duration: 12 months

C. Opioid-Induced Constipation (must meet all):

1. Diagnosis of OIC;
2. Age \geq 18 years;
3. Member has been taking opioid(s) for \geq 4 weeks due to chronic pain, not caused by active cancer;
4. Failure of one agent from each of the following classes while on opioid therapy, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
 - a. Stimulant laxative (e.g., bisacodyl, senna);
 - b. Osmotic laxative (e.g., lactulose, polyethylene glycol);
 - c. Stool softener (e.g., docusate);
5. Member has used one of the aforementioned agents in the past 30 days, unless contraindicated;
6. Member must use generic lubiprostone, unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 48 mcg (2 capsules) per day.

Approval duration: 6 months

D. 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): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (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. Member must use generic lubiprostone, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed (a or b):
 - a. IBS-C: 16 mcg (2 capsules) per day;
 - b. CIC or OIC: 48 mcg (2 capsules) per day.

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): CP.PMN.53 for 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 – CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

| | |
|---|---|
| CIC: chronic idiopathic constipation | IBS-C: irritable bowel syndrome with constipation |
| FDA: Food and Drug Administration | OIC: opioid-induced constipation |
| PAMORA: peripherally acting mu-opioid receptor antagonist | |

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 [®]) | 1,250 mg calcium polycarbophil 1 to 4 times PO per day or as needed | 5,000 mg/day calcium polycarbophil |
| 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 g/day |
| bisacodyl (Dulcolax [®]) | Oral: 5 to 15 mg QD | 15 mg/day PO; 10 mg/day rectally |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|--|--|--|
| | Rectal: Enema, suppository: 10 mg (1 enema or suppository) QD | |
| senna (Senokot [®]) | 1 to 2 tablets (8.6 to 17.2 mg sennosides) PO BID | 8 tablets/day (68.8 mg sennosides/day) |
| lactulose | 10 to 20 g (15 to 30 mL or 1 to 2 packets) PO QD; may increase to 40 g (60 mL or 2 to 4 packets) QD if necessary | 40 g/day (60 mL or 2 to 4 packets/day) |
| polyethylene glycol 3350 (MiraLax [®]) | 17 g (approximately 1 heaping tablespoon) of powder in 120 to 240 mL of fluid given PO QD | 34 g/day |
| docusate sodium (Colace [®]) | 50 to 300 mg/day PO given in single or divided doses | 360 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): patients with known or suspected mechanical gastrointestinal obstruction
- Boxed warning(s): none reported

V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|-------------|----------------|--------------|
| CIC and OIC | 24 mcg PO BID | 48 mcg/day |
| IBS-C | 8 mcg PO BID | 16 mcg/day |

VI. Product Availability

Capsules: 8 mcg and 24 mcg

VII. References

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Chronic Idiopathic Constipation
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Irritable Bowel Syndrome

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Opioid-Induced Constipation

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| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|----------|-------------------|
| Policy created, adapted from CP.PMN.142 | 03.15.22 | 04.22 |

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.

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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.

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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.

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