

Clinical Policy: Lubiprostone (Amitiza)

Reference Number: HIM.PA.79

Effective Date: 12/14

Last Review Date: 08/17

Line of Business: Health Insurance Marketplace

[Coding Implications](#)
[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

Amitiza is indicated:

- For the treatment of chronic idiopathic constipation in adults
- For the treatment of irritable bowel syndrome with constipation in women \geq 18 years old
- For the treatment of opioid-induced constipation (OIC) in adults with chronic, non-cancer pain

Limitation 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 (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

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

1. Diagnosis of chronic idiopathic constipation;
2. Failure of a \geq 4 week trial of one bulk forming laxative [e.g., psyllium (Metamucil), methylcellulose (Citrucel), calcium polycarbophil (FiberCon)] at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
3. Failure of a \geq 4 week trial of one stimulant laxative (e.g., bisacodyl, senna) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects experienced;
4. Failure of a \geq 4 week trial of an osmotic laxative (e.g., polyethylene glycol (MiraLax), lactulose) at maximally indicated doses unless contraindicated or clinically significant adverse effects experienced;
5. At least one of the aforementioned medication trials (bulk forming laxative, stimulant laxative, or osmotic laxative) must have occurred within the past 90 days, unless contraindicated to such therapies;
6. Dose does not exceed 48 mcg/day (2 capsules/day).

Approval duration: 12 months

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

Lubiprostone

1. Diagnosis of irritable bowel syndrome with constipation;
2. Failure of a ≥ 4 week trial of one bulk forming laxative [e.g., psyllium (Metamucil), methylcellulose (Citrucel), calcium polycarbophil (FiberCon)] at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed 16 mcg/day (2 capsules/day).

Approval duration: 12 months

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

1. Diagnosis of opioid-induced constipation;
2. Member has been taking opioid(s) for ≥ 4 weeks for non-cancer pain;
3. Failure of 1 agent from each of the following classes while on opioid therapy, unless all are contraindicated or clinically significant adverse effects are experienced:
 - a. Stimulant laxative (e.g., bisacodyl, senna);
 - b. Osmotic laxative (e.g., lactulose, polyethylene glycol);
 - c. Stool softener (e.g., docusate);
4. Member has used one of the aforementioned agents in the past 30 days, unless contraindicated;
5. Dose does not exceed 48 mcg/day (2 capsules/day).

Approval duration: 12 months

D. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy (e.g., increased number of bowel movements from baseline);
3. If request is for a dose increase, new dose does not exceed (a or b):
 - a. IBS-C: 16 mcg/day (2 capsules/day);
 - b. CIC or OIC: 48 mcg/day (2 capsules/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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 policy – HIM.PHAR.21 or evidence of coverage documents;

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CIC: chronic idiopathic constipation

FDA: Food and Drug Administration

IBS-C: irritable bowel syndrome with constipation

OIC: opioid-induced constipation

V. References

1. Amitiza Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; September 2016. Available at <https://www.amitiza.com/>. Accessed April 18, 2017.
2. American Gastroenterological Association, Bharucha AE, Dorn SD et al. American Gastroenterological Association medical position statement on constipation. *Gastroenterology*. 2013 Jan;144(1):211-7. doi: 10.1053/j.gastro.2012.10.029.
3. 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* 2014; 109: S2-S26.
4. Argoff CE, Brennan MJ, Camilleri M, et al. Consensus Recommendations on Initiating Prescription Therapies for Opioid-Induced Constipation. *Pain Med*. 2015 Dec;16(12):2324-37.
5. Pergolizzi JV, Raffa RB, Pappagallo M, et al. Peripherally acting μ -opioid receptor antagonists as treatment options for constipation in noncancer pain patients on chronic opioid therapy. Patient preference and adherence. 2017;11:107-119. doi:10.2147/PPA.S78042.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Reformatted guideline to new format. Added Workflow reference document.	12/15	12/15
Removed requirement of documentation of ≥ 6 month history of <3 spontaneous bowel movement per week AND at least 25% of bowel movements with hard stools, sensation of incomplete evacuation, or straining AND documentation that the member does not have GI obstruction, which is all a definition of chronic idiopathic constipation; -CIC - added requirements related to trial and failure of a bulk forming laxative and an osmotic laxative (e.g., polyethylene glycol, lactulose) per recommendations of American College of Gastroenterology and that a laxative trial must have occurred within the past 60 days, unless contraindicated. Updated references.	09/16	11/16
Converted to new template	04/17	08/17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added FDA Approved Indications Added Limitation of Use Removed requirement of female gender for Irritable Bowel Syndrome with Constipation (IBS-C) as it is not an absolute contraindication. Per PI insufficient to determine whether men with IBS-C respond differently to Amitiza from women. Added requirement of a trial of one bulk forming laxative for IBS-C per ACG recommendation that fiber provides overall symptom relief in IBS. Opioid-Induced Constipation: Changed requirement of concurrent use of docusate and bisacodyl as well as use of docusate and lactulose to a trial of a simulant laxative, osmotic laxative, or stool softener. Per Pergolizzi stimulant laxatives can be used as monotherapy.		

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.

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.

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