MEDICAL MUTUAL®

Drug Policy

Policy:	Amitiza (lubiprostone)	Annual Review Date: 05/19/2022 Last Revised Date: 05/19/2022

OVERVIEW

Amitiza is a type-2 chloride channel activator that stimulates chloride secretion in the GI tract. Through this action, Amitiza enhances GI fluid secretion and transit time which alleviates constipation. Amitiza is minimally absorbed and has low systemic bioavailability after oral administration. Amitiza is indicated for the treatment of 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; chronic idiopathic constipation (CIC) in adults; and irritable bowel syndrome with constipation (IBS-C) in women ≥ 18 years of age. A limitation of use for Amitiza in OIC is that its efficacy has not been established in patients taking diphenylheptane opioids (e.g., methadone).

POLICY STATEMENT

This policy involves the use of Amitiza. Prior authorization is recommended for pharmacy benefit coverage of Amitiza. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Amitiza as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Amitiza be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Amitiza is recommended in those who meet the following criteria:

1. <u>Opioid-Induced Constipation (OIC), Initial Therapy</u>

Criteria. *Patient must meet the following criteria (A, B, C, D, E, <u>and</u> F):*

A. The patient has a documented diagnosis of chronic non-cancer pain, including chronic pain related to prior cancer or prior cancer treatment if the patient does not require frequent dosage escalations; AND
B. The patient is 18 years of age or older; AND
C. The patient has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND

D. The patient has failed on or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months (a, b, or c):
    a. At least one stimulant laxative (e.g. bisacodyl); OR
    b. At least one osmotic laxative (e.g. PEG 3350); OR
    c. At least one saline laxative (e.g. magnesium citrate); AND
E. The patient is not taking diphenylheptane opioids (e.g. methadone); AND
F. The patient does not have a known or suspected gastrointestinal obstruction and is not at increased risk of recurrent obstruction

2. Chronic Idiopathic Constipation (CIC), Initial Therapy

Criteria. *Patient must meet the following criteria (A, B, C, D, E, and F):*

A. The patient is 18 years of age or older; AND
B. Amitiza is prescribed by or in consultation with a gastroenterologist or a physician who specializes in the management of gastrointestinal disease; AND
C. The patient has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
D. The patient has failed on or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months (a, b, c, or d):
    a. At least one bulk forming laxative (e.g. psyllium); OR
    b. At least one osmotic laxative (e.g. PEG 3350); OR
    c. At least one saline laxative (e.g. magnesium citrate); OR
    d. At least one stimulant laxative (e.g. bisacodyl); AND
E. The patient is not taking diphenylheptane opioids (e.g. methadone); AND
F. The patient does not have a known or suspected gastrointestinal obstruction and is not at increased risk of recurrent obstruction.

3. Irritable Bowel Syndrome with Constipation (IBS-C) in Women, Initial Therapy

Criteria. *Patient must meet the following criteria (A, B, C, D, and E):*

A. The patient is 18 years of age or older; AND
B. The patient has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
C. The patient has failed on or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months (a, b, c, or d):
    a. At least one bulk forming laxative (e.g. psyllium); OR
    b. At least one osmotic laxative (e.g. PEG 3350); OR
    c. At least one saline laxative (e.g. magnesium citrate);
    d. At least one stimulant laxative (e.g. bisacodyl); AND
D. The patient is not taking diphenylheptane opioids (e.g. methadone); AND
E. The patient does not have a known or suspected gastrointestinal obstruction and is not at increased risk of recurrent obstruction.

4. Continuation of Therapy (Renewals)

Criteria. *Patient must meet the following criteria (A, B, and C):*

A. The patient is 18 years of age or older; AND
B. The patient has demonstrated a beneficial response to Amitiza, per the prescribing physician (e.g. increased number of bowel movements from baseline) AND
C. The patient has no contraindications to Amitiza.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Amitiza has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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