



Drug Quantity Management – Per Rx Bowel Disease – Lubiprostone capsules (Amitiza[®], generic)

Table of Contents

National Formulary Medical Necessity 1
 Conditions Not Covered.....2
 Background.....2
 References2
 Revision History.....2

Product Identifier(s)

Effective 1/1/23 to 2/6/23: 107982
Effective 2/7/23: 67817

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of lubiprostone (Amitiza, generic). If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per Rx
Amitiza [®] (lubiprostone capsules, generic)	8 mg capsules	60 capsules
	24 mg capsules	60 capsules

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Lubiprostone 8 mcg capsules (Amitiza, generic)

1. If the patient requires a dose of 16 mcg twice daily, approve 120 capsules per dispensing.

Lubiprostone 24 mcg capsules (Amitiza, generic)
No overrides recommended.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Lubiprostone (Amitiza, generic), a chloride channel activator, is indicated for the following uses:¹

- **Chronic idiopathic constipation (CIC)** in adults.
- **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 of Use: Effectiveness of lubiprostone in the treatment of OIC in patients taking diphenylheptane opioids (e.g., methadone) has not been established.

- **Irritable bowel syndrome with constipation (IBS-C)** in women \geq 18 years old.

Dosing

The recommended dose of lubiprostone for CIC and OIC is 24 mcg twice daily (BID).¹ For IBS-C, the recommended dose is 8 mg BID. For patients with moderate and severe hepatic impairment, dose reductions are recommended (Table 1).

Table 1. Lubiprostone Hepatic Dosing Recommendations.¹

	CIC and OIC	IBS-C
Moderate Hepatic Impairment (Child-Pugh Class B)	16 mg BID*	No adjustment necessary
Severe Hepatic Impairment (Child-Pugh Class C)	8 mg BID*	8 mg QD*

CIC – Chronic idiopathic constipation; OIC – Opioid-induced constipation; IBS-C – Irritable bowel syndrome with constipation; BID – Twice daily; * If the dose is tolerated and an adequate response has not been obtained after an appropriate interval, doses can then be escalated to full dosing with appropriate monitoring of patient response; QD – Once daily.

Availability

Lubiprostone (Amitiza, generic) is available as 8 mg and 24 mg capsules supplied in bottles of 60 capsules.¹

References

1. Amitiza[®] capsules [prescribing information]. Bedminster, NJ and Lexington, MA: Sucampo/Takeda; November 2020.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	The duration of approval was changed from 3 years to 1 year. Amitiza branded generic was added to the policy. Lubiprostone 8 mcg capsules (Amitiza, generic): Override criteria were updated to note that it is for a patient who requires a dose of 16 mcg twice daily (previously it stated “for a patient who requires a dose reduction to 16 mcg twice daily”).	06/08/2022

“Cigna Companies” refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc. and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2023 Cigna.