

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Bowel Disease – Lubiprostone Drug Quantity Management Policy – Per Rx

- Amitiza® (lubiprostone capsules – Sucampo/Takeda, generic)

REVIEW DATE: 06/08/2022

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 ≥ 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

POLICY STATEMENT

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.

Automation: None.

Drug Quantity Limits

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

CRITERIA

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.

REFERENCES

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