DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Bowel Agents – Lubiprostone Drug Quantity Management Policy – Per Rx
- Amitiza® (lubiprostone capsules – Sucampo/Takeda, generic)

REVIEW DATE: 06/19/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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 Recomendations.[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.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Amitiza® (lubiprostone capsules, generic)	8 mg capsules	60 capsules	180 capsules
	24 mg capsules	60 capsules	180 capsules

Bowel Agents – Lubiprostone Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Lubiprostone 8 mcg capsules (Amitiza, generic)

1. If the patient requires a dose of 16 mcg twice daily, approve 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery.

Lubiprostone 24 mcg capsules (Amitiza, generic)

No overrides recommended.

REFERENCES

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

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy Name was updated from "Bowel Disease – Lubiprostone Drug Quantity Management Policy – Per Rx" to "Bowel Agents – Lubiprostone Drug Quantity Management Policy – Per Rx". Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	06/08/2023
Annual Revision	No criteria changes.	06/19/2024