



## DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Weight Loss – Zepbound Drug Quantity Management Policy – Per Days

- Zepbound™ (tirzepatide subcutaneous injection – Lilly)

**REVIEW DATE:** 01/10/2024

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### **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**

Zepbound is indicated as an adjunct to a reduced-calorie diet and increased physical activity for **chronic weight management** in:<sup>1</sup>

- Adults with an initial body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup> (obese)
- Adults with a BMI  $\geq 27$  kg/m<sup>2</sup> (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes, obstructive sleep apnea, or cardiovascular disease).

#### **Dosing**

The recommended initial dose of Zepbound is 2.5 mg subcutaneous (SC) injection given once weekly (QW).<sup>1</sup> Following 4 weeks, the dose should be increased to 5 mg SC QW. The dose may be increased in 2.5 mg increments after at least 4 weeks on

the current dose. Of note, the 2.5 mg dose is for treatment initiation and is not intended for chronic weight management. The recommended maintenance doses of Zepbound are 5 mg, 10 mg, or 15 mg SC QW. Treatment response and tolerability should be considered when selecting the maintenance dosing. If patients do not tolerate a maintenance dose, consider a lower maintenance dose. The maximum dose of Zepbound is 15 mg SC QW.

### Availability

Zepbound is supplied in prefilled, disposable, single-dose pen-injectors.<sup>1</sup> Available strengths are listed in the Drug Quantity Limits table below. A quantity of four 2.5 mg, 7.5 mg, 12.5 mg prefilled pen-injectors will be covered per 365 days. This is enough drug for dose escalation to the maintenance dose. A quantity of four 5 mg, 10 mg, or 15 mg prefilled pen-injectors will be covered per 28 days. This is enough drug to allow for once weekly maintenance dosing. One-time exceptions for missed doses or re-initiation of treatment are provided through coverage review.

### POLICY STATEMENT

This Drug Quantity Management program has been developed to manage potential dose escalation of Zepbound. 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, unless otherwise noted below.

### Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity	Home Delivery Maximum Quantity
Zepbound™ (tirzepatide subcutaneous injection)	2.5 mg/0.5 mL pens	4 pens (2 mL) per 365 days	
	5 mg/0.5 mL pens	4 pens (2 mL) per 28 days	12 pens (6 mL) per 84 days
	7.5 mg/0.5 mL pens	4 pens (2 mL) per 365 days	
	10 mg/0.5 mL pens	4 pens (2 mL) per 28 days	12 pens (6 mL) per 84 days
	12.5 mg/0.5 mL pens	4 pens (2 mL) per 365 days	
	15 mg/0.5 mL pens	4 pens (2 mL) per 28 days	12 pens (6 mL) per 84 days

**Weight Loss – Zepbound Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

### CRITERIA

#### Zepbound 2.5 mg/0.5mL pen

1. If more than two consecutive doses are missed and re-initiation of treatment is needed, approve a one-time override for 4 additional pens at retail or home delivery.

Zepbound 5 mg/0.5 mL pen

No overrides recommended

Zepbound 7.5 mg/0.5 mL pen

1. If more than two consecutive doses are missed and re-initiation of treatment is needed, approve a one-time override for 4 additional pens at retail or home delivery.

Zepbound 10 mg/0.5 mL pen

No overrides recommended.

Zepbound 12.5 mg/0.5 mL pen

1. If more than two consecutive doses are missed and re-initiation of treatment is needed, approve a one-time override for 4 additional pens at retail or home delivery.

Zepbound 15 mg/0.5 mL pen

No overrides recommended.

**REFERENCES**

1. Zepbound™ subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; November 2023.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/10/2024

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