



## DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

- Zepbound® (tirzepatide subcutaneous injection – Lilly)

**REVIEW DATE:** 07/17/2024; selected revision 09/11/2024

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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 an initial 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. If a dose of Zepbound is missed, the patient should administer as soon as possible within 4 days (96 hours)

after the missed dose. If more than 4 days have passed, the missed dose should be skipped and administered on the next regularly scheduled day. In either scenario, patients may then resume their regular QW dosing schedule. The day of weekly administration may be changed, if needed, as long as the time between the two doses is at least 3 days (72 hours).

### Availability

Zepbound is supplied in prefilled, disposable, single-dose pen-injectors in the following strengths: 2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10 mg/0.5 mL, 12.5 mg/0.5 mL, and 15 mg/0.5 mL.<sup>1</sup> It is also available as 2.5 mg/0.5 mL and 5 mg/0.5 mL single-dose vials.

### POLICY STATEMENT

This Drug Quantity Management program has been developed to manage potential dose escalation of Zepbound. Two quantity limits (Limit A and Limit B) are in place for Zepbound and are outlined below. If the Drug Quantity Management rules are not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

**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.**

### Drug Quantity Limit A

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

SC – Subcutaneous.

### CRITERIA A

#### Zepbound 2.5 mg/0.5mL pens and vials

1. If more than two consecutive doses are missed and re-initiation of treatment is needed, approve a one-time override for 2 mL (4 pens or vials) at retail or home delivery.

Zepbound 5 mg/0.5 mL pens and vials

No overrides recommended

Zepbound 7.5 mg/0.5 mL pens

1. If more than two consecutive doses are missed and re-initiation of treatment is needed, approve a one-time override for 2 mL (4 pens) at retail or home delivery.

Zepbound 10 mg/0.5 mL pens

No overrides recommended.

Zepbound 12.5 mg/0.5 mL pens

1. If more than two consecutive doses are missed and re-initiation of treatment is needed, approve a one-time override for 2 mL (4 pens) at retail or home delivery.

Zepbound 15 mg/0.5 mL pens

No overrides recommended.

**Drug Quantity Limit B**

<b>Product</b>	<b>Strength and Form</b>	<b>Retail and Home Delivery Maximum Quantity Per 21 Days</b>
Zepbound® (tirzepatide SC injection)	2.5 mg/0.5 mL pens	<b>ONE claim collectively for ONE GLP-1 agonist or GLP-1/GIP agonist may be approved every 21 days.<sup>a</sup></b>
	2.5 mg/0.5 mL vials	
	5 mg/0.5 mL pens	
	5 mg/0.5 mL vials	
	7.5 mg/0.5 mL pens	
	10 mg/0.5 mL pens	
	12.5 mg/0.5 mL pens	
	15 mg/0.5 mL pens	

SC – Subcutaneous; GLP-1 – Glucagon-like peptide-1; GIP – Glucose-dependent insulinotropic peptide

<sup>a</sup> Refer to Appendix A for a list of the drugs included in this limit.

**CRITERIA B**

Zepbound pens/vials (all strengths)

No overrides recommended.

**REFERENCES**

1. Zepbound™ subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; March 2024.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/10/2024
Early Annual Revision	New policy created to add additional quantity limits to approve ONE claim collectively for ONE glucagon-like peptide-1 (GLP-1) agonist or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) agonist every 21 days at retail or home delivery. No clinical overrides apply to these limits. Existing "Per Days" quantity limits were not changed and no overrides apply.	07/17/2024
Selected Revision	<p><b>Zepbound 2.5 mg/0.5 mL vials:</b> New quantity limits of 2 mL (4 vials) per 365 days at retail and home delivery were added to the policy. An override for a one-time override for 2 mL (4 vials) at retail or home delivery is provided if more than two consecutive doses are missed and re-initiation of treatment is needed. The existing quantity limit of ONE claim collectively for ONE glucagon-like peptide-1 (GLP-1) agonist or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) agonist every 21 days at retail or home delivery also applies to the vials. No clinical overrides apply to this limit.</p> <p><b>Zepbound 5 mg/0.5 mL vials:</b> New quantity limits of 2 mL (4 vials) per 28 days at retail and 6 mL (12 vials) per 84 days at home delivery were added to the policy. No clinical overrides apply. The existing quantity limit of ONE claim collectively for ONE glucagon-like peptide-1 (GLP-1) agonist or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) agonist every 21 days at retail or home delivery also applies to the vials. No clinical overrides apply to this limit.</p>	09/11/2024

## APPENDIX A

**Table 1. GLP-1 Agonists and GLP-1/GIP Agonists.**

Brand (Generic Name)	Dosage Form
Adlyxin® (lixisenatide SC injection)	10-20 mcg Starter Pack (discontinued) 20 mcg Maintenance Pack (discontinued)
Bydureon® (exenatide extended-release SC injection)	2 mg/0.65 mL pen
Bydureon BCise® (exenatide extended-release SC injection)	2 mg/0.85 mL prefilled auto-injector
Byetta® (exenatide SC injection)	5 mcg/0.02 mL dose pen (1.2 mL) 10 mcg/0.04 mL dose pen (2.4 mL)
Mounjaro® (tirzepatide SC injection)	2.5 mg/0.5 mL pen 5 mg/0.5 mL pen 7.5 mg/0.5 mL pen 10 mg/0.5 mg pen 12.5 mg/0.5 mL pen 15 mg/0.5 mL pen
Ozempic® (semaglutide SC injection)	0.25 mg and 0.5 mg dose pen (2 mg/1.5 mL) [discontinued] 0.25 mg and 0.5 mg dose pen (2 mg/3 mL) 1 mg dose pen (2 mg/1.5 mL) [discontinued] 1 mg dose pen (4 mg/3 mL) 2 mg dose pen (8 mg/3 mL)
Rybelsus® (semaglutide tablets)	3 mg tablet 7 mg tablet 14 mg tablet
Saxenda® (liraglutide SC injection)	18 mg/3 mL pen
Trulicity® (dulaglutide SC injection)	0.75 mg/0.5 mL pen 1.5 mg/0.5 mL pen

	3 mg/0.5 mL pen 4.5 mg/0.5 mL pen
Victoza® (liraglutide SC injection, generic)	18 mg/3 mL pen (2-pack) 18 mg/3 mL pen (3-pack)
Wegovy® (semaglutide SC injection)	0.25 mg/0.5 mL pen 0.5 mg/0.5 mL pen 1 mg/0.5 mL pen 1.7 mg/0.75 mL pen 2.4 mg/0.75 mL pen
Zepbound® (tirzepatide SC injection)	2.5 mg/0.5 mL pen 5 mg/0.5 mL pen 7.5 mg/0.5 mL pen 10 mg/0.5 mL pen 12.5 mg/0.5 mL pen 15 mg/0.5 mL pen

GLP – Glucagon-like peptide-1; GIP – Glucose-dependent insulinotropic polypeptide; SC – Subcutaneous.

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