DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Weight Loss – Zepbound Drug Quantity Management Policy – Per Days
- Zepbound® (tirzepatide subcutaneous injection – Lilly)

REVIEW DATE: 10/30/2024; selected revisions 01/07/2025, 01/08/2025, and 03/12/2025

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 in combination with a reduced-calorie diet and increased physical activity[1]:
- **To reduce excess body weight and maintain weight reduction long term** in adults with overweight in the presence of at least one weight-related comorbid condition and in adults with obesity; and
- To treat **moderate-to-severe obstructive sleep apnea** (OSA) in adults with obesity.

Dosing

The recommended initial dose of Zepbound is 2.5 mg subcutaneous (SC) injection given once weekly (QW).[1] After 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. The recommended maintenance doses of Zepbound for weight reduction and long-term maintenance are 5 mg, 10 mg, or 15 mg SC QW. The recommended maintenance dose in OSA is 10 mg or 15 mg SC QW. Treatment response and tolerability should be considered when selecting the maintenance dosing. If a patient does 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.[1] It is also available as 2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, and 10 mg/0.5 mL single-dose vials.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Zepbound. There are no overrides to the Per Days quantity limits outlined 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	2 mL (4 pens or vials) per 28 days	6 mL (12 pens or vials) per 84 days
	2.5 mg/0.5 mL vials		
	5 mg/0.5 mL pens	2 mL (4 pens or vials) per 28 days	6 mL (12 pens or vials) per 84 days
	5 mg/0.5 mL vials		
	7.5 mg/0.5 mL pens	2 mL (4 pens or vials) per 28 days	6 mL (12 pens or vials) per 84 days
	7.5 mg/0.5 mg vials		
	10 mg/0.5 mL pens	2 mL (4 pens or vials) per 28 days	6 mL (12 pens or vials) per 84 days
	10 mg/0.5 mL vials		
	12.5 mg/0.5 mL pens	2 mL (4 pens) per 28 days	6 mL (12 pens) per 84 days
	15 mg/0.5 mL pens	2 mL (4 pens) per 28 days	6 mL (12 pens) per 84 days

CRITERIA

Zepbound 2.5 mg/0.5mL pens and vials

No overrides recommended.

Zepbound 5 mg/0.5 mL pens and vials

No overrides recommended.

Zepbound 7.5 mg/0.5 mL pens and vials
No overrides recommended.

Zepbound 10 mg/0.5 mL pens and vials
No overrides recommended.

Zepbound 12.5 mg/0.5 mL pens
No overrides recommended.

Zepbound 15 mg/0.5 mL pens
No overrides recommended.

Any other exception is considered not medically necessary.

REFERENCES

1. Zepbound® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; February 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
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	**Zepbound 2.5 mg/0.5 mL vials:** 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. **Zepbound 5 mg/0.5 mL vials:** 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.	09/11/2024
Early Annual Revision	The quantity limit of ONE claim of ONE glucagon-like peptide-1 (GLP-1) agonist or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) agonist to be dispensed every 21 days at retail or home delivery was removed from this policy (refer to the "Weight Loss – Glucagon-	10/30/2024

	Like Peptide-1 Agonists Drug Quantity Management Policy – Claim Per Days" document for additional information). **Zepbound 2.5 mg/0.5mL pens and vials:** The override criteria were updated to approve a one-time override for an additional 2 mL (4 pens or vials) at retail or home delivery, if the patient requires re-initiation or re-titration of their Zepbound dose. Previously, this criterion approved if the patient missed more than two consecutive doses and re-initiation of treatment was needed. Existing "Per Days" quantity limits were not changed. **Zepbound 7.5 mg/0.5 mL pens:** The override criteria were updated to approve a one-time override for an additional 2 mL (4 pens) at retail or home delivery, if the patient requires re-initiation or re-titration of their Zepbound dose. Previously, this criterion approved if the patient missed more than two consecutive doses and re-initiation of treatment was needed. Existing "Per Days" quantity limits were not changed. **Zepbound 12.5 mg/0.5 mL pens:** The override criteria were updated to approve a one-time override for an additional 2 mL (4 pens) at retail or home delivery, if the patient requires re-initiation or re-titration of their Zepbound dose. Previously, this criterion approved if the patient missed more than two consecutive doses and re-initiation of treatment was needed. Existing "Per Days" quantity limits were not changed.	
Selected Revision	Overview was updated to reflect new obstructive sleep apnea indication and dosing. Quantity limit table was updated to clarify that the quantity limits for the 2.5 mg pens and vials accumulate across both dosage forms. Quantity limit table was updated to clarify that the quantity limits for the 5 mg pens and vials accumulate across both dosage forms.	01/07/2025

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	**Zepbound 2.5 mg/0.5mL pens and vials:** Quantity limits were changed to 2 mL (4 pens or vials) per 28 days at retail and 6 mL (12 pens or vials) per 84 days at home delivery. Previously, the limits were 2 mL (4 pens or vials) per 365 days at retail or home delivery. Override criteria were removed. No overrides apply to the updated quantity limits. **Zepbound 7.5 mg/0.5 mL pens:** Quantity limits were changed to 2 mL (4 pens) per 28 days at retail and 6 mL (12 pens) per 84 days at home delivery. Previously, the limits were 2 mL (4 pen) per 365 days at retail or home delivery. Override criteria were removed. No overrides apply to the updated quantity limits. **Zepbound 12.5 mg/0.5 mL pens:** Quantity limits were changed to 2 mL (4 pens) per 28 days at retail and 6 mL (12 pens) per 84 days at home delivery. Previously, the limits were 2 mL (4 pen) per 365 days at retail or home delivery. Override criteria were removed. No overrides apply to the updated quantity limits.	01/08/2025
Selected Revision	**Zepbound 7.5 mg/0.5 mL vials:** 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 overrides apply.	03/12/2025

	Zepbound 10 mg/0.5 mL vials: 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 overrides apply.	