UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1475-1
Program	Prior Authorization/Non-Formulary
Medication	Zepbound® (tirzepatide) – Obstructive Sleep Apnea Only
P&T Approval Date	3/2025
Effective Date	7/1/2025

1. Background:

Zepbound is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

Zepbound is also indicated in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.

Medications for the purpose of weight loss are typically a benefit exclusion. The program allows for coverage of Zepbound for obesity with obstructive sleep apnea.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Zepbound** will be approved based on **all** the following criteria:

   a. Treatment is being requested for obstructive sleep apnea

   -AND-

   b. Patient is 18 years of age or older

   -AND-

   c. Submission of medical records documenting **all** the following:

      (1) BMI ≥ 30 kg/m^2

      (2) Moderate-to-severe obstructive sleep apnea evidenced by **both** of the following:

         (a) a sleep study
         (b) **One** of the following: i. apnea-hypopnea index (AHI) ≥ 15 events per hour

         i. respiratory event index (REI) ≥ to 15 events per hour

ii. respiratory disturbance index (RDI) ≥ 15 events per hour

(3) Patient has symptoms consistent with OSA such as excessive daytime sleepiness, loud snoring, choking, gasping, difficulty maintaining sleep throughout the night or impairment in daily functioning related to OSA.

(4) At least one previous unsuccessful dietary effort to lose weight

(5) **One** of the following:

(a) Patient has continued symptoms of OSA despite adherence to positive airway pressure (PAP) therapy. Adherence is defined as ≥ 4 hours of use per night for ≥ 70 percent of nights.
(b) Patient is not a candidate for PAP therapy (e.g. upper airway anatomic abnormalities, etc).

-AND-

d. Used in combination with a reduced calorie diet and increased physical activity

-AND-

e. Patient does **not** have a diagnosis of diabetes or HgA1c ≥ 6.5%

-AND-

f. Provider attests to **both** of the following:

(1) patient counseled on appropriate positional therapy
(2) patient counseled on avoidance of alcohol and/or sedatives before bedtime

-AND-

g. Prescriber attests the patient does not have **any** of the following:

(1) Planned surgery for sleep apnea or obesity
(2) Significant craniofacial abnormalities
(3) A diagnosis of central or mixed sleep apnea

-AND-

h. Prescribed by or in consultation with a sleep specialist

Authorization will be issued for 6 months.

B. Reauthorization

1. **Zepbound** will be approved based on **all** of the following criteria:

a. **One** of the following:

(1) Both of the following.
a) Patient has been on Zepbound for less than 52 weeks of consecutive therapy

-AND-

b) Submission of medical records confirming a decrease from baseline in one of the following:

i. Apnea Hypopnea Index (AHI)
ii. Respiratory Disturbance Index (RDI)
iii. Respiratory Event Index (REI)

-OR-

(2) Both of the following:

a) Patient has been on Zepbound for greater than or equal to 52 weeks of consecutive therapy

b) Submission of medical records confirming a 50% decrease from baseline in one of the following:

i. Apnea Hypopnea Index (AHI)
ii. Respiratory Disturbance Index (RDI)
iii. Respiratory Event Index (REI)

-AND-

b. Patient has had a weight loss of greater than or equal to 10% of baseline body weight

-AND-

c. Used in combination with a reduced calorie diet and increased physical activity

-AND-

d. Patient does **not** have a diagnosis of diabetes or HgA1c $\geq$ 6.5%

-AND-

e. Patient continues to require treatment for obstructive sleep apnea

Patients who have been on Zepbound therapy for fewer than 52 weeks of consecutive therapy: Authorization of 6 months

Patients who have been on Zepbound therapy for greater than or equal to 52 weeks of consecutive therapy: Authorization of 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Supply limits may be in place.

4. References:

1. Zepbound [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2024.
2. Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of adult obstructive sleep apnea with positive airway pressure: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2019;15(2):335–343.
3. Practice Guidlines : Obstructive Sleep Apnea and Chronic Insomnia Disorder : Updated Guidelines from the VA/DoD. Ann Intern Med. March 3, 2020; 172(5):325-336.
4. Task Force Members Guidelines Committee Members on behalf of the Governing Council of the World Sleep Society, Endorsement of: "clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American academy of sleep medicine clinical practice guideline" by the World Sleep Society, Sleep Medicine, https://doi.org/10.1016/j.sleep.2020.12.044.
5. Nancy Collop. Home sleep apnea testing for obstructive sleep apnea in adults. UpToDate, Collop N, Finlay G, UpToDate, Waltham, MA, December 2024.
6. Malhorta A, Kundel V, et al. Obstructive sleep apnea: Overview of management in adults. In: UpToDate, Coop N, Finlay G, UpToDate, Waltham, MA, 2024.

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Change Control	
Date	Change
3/2025	New program.