



## Protocol for Zepbound® (tirzepatide) for Obstructive Sleep Apnea (OSA) April 2025

### Background:

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

### Criteria for Approval:

1. Patient is of the FDA-labeled or compendial approved age; **AND**
2. Patient does not have any contraindications to Zepbound; **AND**
3. Patient has a documented diagnosis of moderate to severe obstructive sleep apnea (OSA) shown by an apnea-hypopnea index (AHI)  $\geq 15$  respiratory events per hour of sleep within the past 12 months; **AND**
4. Documentation is provided that the patient has a body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup> ; **AND**
5. The medication is used in combination with a reduced-calorie diet and increased physical activity; **AND**
6. Patient is not utilizing another GLP-1 receptor agonist or tirzepatide-containing products

### Continuation of therapy:

1. Patient is responding positively to therapy at optimal dosage; **AND**
2. Patient is not utilizing another GLP-1 receptor agonist or tirzepatide-containing products

### Approval Duration and Quantity Restrictions:

Initial Approval: 6 months  
Renewal Approval: 12 months

### Quantity Level Limit:

Drug	Dosage	Quantity Limit
Zepbound (tirzepatide)	2.5 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 28 days
Zepbound (tirzepatide)	5 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 28 days
Zepbound (tirzepatide)	7.5 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 28 days
Zepbound (tirzepatide)	10 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 28 days
Zepbound (tirzepatide)	12.5 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 28 days
Zepbound (tirzepatide)	15 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 28 days

**References:**

1. Zepbound® [package insert]. Lilly; 2024. Accessed January 28, 2025
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically.
3. Epstein LJ, Kristo D, Strollo PJ, et al. Adult obstructive sleep apnea task force of the American Academy of Sleep Medicine: Clinical guideline for the evaluation, management, and long-term care of obstructive sleep apnea in adults. *Journal of Clinical Sleep Medicine* 2009. 5(3): 263-276.
4. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. *Journal of Clinical Sleep Medicine* 2017. 13(3):479-504.
5. Patil SP, Ayappa IA, Caples SM, et al. Treatment of adult obstructive sleep apnea with positive airway pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. *Journal of Clinical Sleep Medicine* 2019. 15(2): 335-343.
6. Hudgel DW, Patel SR, Ahasic AM, et al. The role of weight management in the treatment of adult obstructive sleep apnea. An Official American Thoracic Society Clinical Practice Guideline. *Am J Respir Crit Care Med*. 2018 Sep 15;198(6):e70-e87.