Washington State Health Care Authority

Anorexiants/Anti-Obesity: GLP-1 Receptor Agonists – Zepbound® (tirzepatide)

Medical policy no. 61.25.25.AA-1 Effective Date: 5/1/2025

Related medical policies:

Policy Number	Policy Name
27.17.00	Antidiabetics- GLP-1 Agonists
61.25.20.AA-1	Anorexiants/Anti-Obesity: GLP-1 Receptor Agonists- Wegovy® (semaglutide)

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Medical necessity

Drug	Medical Necessity
Tirzepatide (Zepbound®)	**Tirzepatide (Zepbound®)** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
Treatment of moderate to severe obstructive sleep apnea Adults with obesity. Tirzepatide (Zepbound®)	Tirzepatide (Zepbound) may be approved when all of the following documented criteria are met: 1. Patient is ≥ 18 years of age; **AND** 2. Patient does not have diabetes or HbA1C > 6.5% (patients with T2DM or A1C > 6.5 should request GLP-1 indicated for T2DM, see policy 27.17.00); **AND**

	3. Provider attestation that patient has moderate to severe obstructive sleep apnea as defined as AHI or RDI ≥ 15 obstructive respiratory events per hour (apneas, hypopneas, or RERAs), without the use of a positive airway pressure device (PAP); **AND** 4. Patient meets one of the following criteria: a. The patient was consulted about use of PAP; **AND** b. Declined use of PAP; **OR** c. Unable to tolerate PAP therapy; **OR** d. Actively using PAP and will continue to use PAP; **AND** 5. Patient is engaged in lifestyle interventions including diet, exercise, and behavioral modification; **AND** 6. Tirzepatide will not be used in combination with another GLP-1 agonist; **AND** 7. Patient has a body mass index (BMI) > 30 kg/m^2 If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Tirzepatide (Zepbound®) may be reauthorized when all the following documented criteria are met: 1. Member has received previous authorization approval or has been established on therapy from another health plan (excludes establishing therapy from use of samples, patient assistance programs, or coupons); **AND** 2. Patient continues to meet criteria 1-6 above; **AND** 3. Documentation is submitted demonstrating a positive clinical response [e.g., weight loss, fewer AHIs per hour of sleep, or improved systolic blood pressure]. If ALL criteria are met, the request will be authorized for **12 months.**
Weight Loss Tirzepatide (Zepbound®)	Tirzepatide (Zepbound®) is not covered by Apple Health for weight loss in accordance with: • WAC 182-530-2100(1)b)(i) • SEC. 1927. [42 U.S.C. 1396r–8](d)(2)(A)

Dosage and quantity limits

Drug	Indication	Approved Dose	Dosage Form and Quantity Limit
Zepbound®	Obstructive Sleep Apnea	2.5 mg once weekly for 4 weeks. Increase by 2.5 mg per week every 4 weeks until recommended maintenance dosage is achieved. Maximum weekly dose is 15mg once weekly.	• ZEPBOUND® 2.5 MG/0.5 ML PEN • ZEPBOUND® 5 MG/0.5 ML PEN • ZEPBOUND® 7.5 MG/0.5 ML PEN • ZEPBOUND® 10 MG/0.5 ML PEN • ZEPBOUND® 12.5 MG/0.5 ML PEN • ZEPBOUND® 15 MG/0.5 ML PEN

Background:

Tirzepatide is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated in combination with a reduced calorie diet and increased physical activity for the treatment of moderate to severe obstructive sleep apnea[1]. Obstructive sleep apnea (OSA) is the most common breathing disorder associated with sleep. The Gold Standard for treating OSA has been positive airway pressure (PAP) such as CPAP or BPAP. PAP therapy reduces the incidence of respiratory events during sleep.

Tirzepatide was studied in adults with moderate to severe OSA (AHI ≥ 15 events per hour) and obesity (BMI ≥30 kg/m^2 and ≥27 in Japan)[3]. Exclusion criteria included people with Type I or Type II diabetes mellitus, change in body weight of 5 kg or more in the last 3 months, planned surgery for sleep apnea or obesity, central or mixed sleep apnea, major craniofacial abnormalities, and those that experienced a serious cardiovascular event in the last 3 months. A total of 469 people were enrolled in two randomized controlled trials, 82.9% of those randomized completed the trial. Trial 1 (N=234) compared tirzepatide to placebo over a course of 52 weeks, without using PAP. Trial 2 (N=235) included people using PAP therapy for 3 consecutive months. Trial 2 participants continued to use PAP throughout the 52-week RCT. All participants received lifestyle coaching and health nutrition guidance. The primary end point was the change in AHI from baseline. The AHI decreased significantly in both trials by up to 29.3 events per hour which was a 58.7% reduction from baseline[3]. The reduction in AHI was significant in both populations with and without the use of PAP.

References

1. Zepbound Package Insert. zepbound-uspi.pdf. Accessed 12/27/2024.
2. Malhotra and Kundel. Obstructive sleep apnea: Overview of management in adults: UpToDate 2024. Accessed 12/30/2024.
3. Malhotra, Grunstein, Fietze, Weaver, Redline, et al. Tirzepatide for Treatment of Obstructive Sleep Apnea and Obesity. NEJM 2024; 391;13: 1194-1205.
4. Miromedex. Accessed 1/2/2025

History

Approved Date	Effective Date	Version	Action and Summary of Changes
4/23/2025	5/1/2025	61.25.25.AA-1	New Policy Created