

Clinical Policy: Tirzepatide (Zepbound) - Citizens Bank Only

Reference Number: AR.QC.CP.CPA.359

Effective Date: 01.01.26

Last Review Date: 06.26

Line of Business: QualChoice Commercial-Select BPLs

[Coding Implications](#)[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

****This policy is only applicable to QualChoice members in BPL 2JX62130 and 2JX62131.***

Zepbound is an excluded benefit for all other groups.

Description

Tirzepatide (Zepbound®) is a glucose-dependent insulintropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist.

FDA Approved Indication(s)

Zepbound is 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
- To treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity

Limitation(s) of use: Coadministration with other tirzepatide-containing products or any GLP-1 receptor agonist is not recommended.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of the above referenced health plans affiliated with AR QualChoice Commercial, Centene Corporation® that Zepbound is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Weight Management** (must meet all):

1. Member meets one of the following (a or b):
 - a. Body mass index (BMI) ≥ 30 kg/m²;
 - b. BMI ≥ 27 kg/m² with at least one indicator of increased cardiovascular risk (e.g., coronary artery/heart disease, hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
2. Age ≥ 18 years;
3. For members with concurrent type 2 diabetes mellitus (T2DM), both of the following (a and b):

CLINICAL POLICY

Tirzepatide

- a. Member has received optimal diabetic standard of care therapy as evidenced by a trial of ≥ 3 consecutive months of Ozempic[®] or Rybelsus[®], Trulicity[®], liraglutide (generic Victoza[®]), and Mounjaro, unless clinically significant adverse effects are experienced or all are contraindicated;*
- *Prior authorization may be required*
- b. If member is currently receiving a GLP-1 receptor agonist and is requesting to switching to Zepbound, medical justification* supports necessity for Zepbound;
- *Intolerance due to common adverse effects of the GLP-1 receptor agonists class such as gastrointestinal symptoms is not considered acceptable medical justification*
4. Zepbound is not prescribed concurrently with other tirzepatide-containing products or any other GLP-1 receptor agonist(s);
5. Documentation of member's baseline body weight in kg;
6. Dose does not exceed the following:
 - a. Week 1 through 4: 2.5 mg once weekly;
 - b. Week 5 through 8: 5 mg once weekly;
 - c. Week 9 through 12: 7.5 mg once weekly;
 - d. Week 13 through 16: 10 mg once weekly;
 - e. Week 17 through 20: 12.5 mg once weekly;
 - f. Week 21 through 24: 15 mg once weekly;
 - g. One of the following (i or ii):
 - i. Single-dose formulation: One pen or vial per week;
 - ii. Multi-dose formulation: One vial or KwikPen[®] every 4 weeks.

Approval duration: 6 months or to the member's renewal date, whichever is longer

B. Obstructive Sleep Apnea (must meet all):

1. Diagnosis of moderate to severe OSA confirmed by recent polysomnography or home sleep apnea test (within the past 12 months) with an apnea-hypopnea index (AHI) ≥ 15 respiratory events per hour;
2. Age ≥ 18 years;
3. BMI ≥ 30 kg/m²;
4. Member does not have central or mixed sleep apnea;
5. For members with concurrent T2DM, both of the following (a and b):
 - a. Member has received optimal diabetic standard of care therapy as evidenced by a trial of ≥ 3 consecutive months of Ozempic[®] or Rybelsus[®], Trulicity[®], liraglutide (generic Victoza[®]), and Mounjaro, unless clinically significant adverse effects are experienced or all are contraindicated;*
 - *Prior authorization may be required*
 - b. If member is currently receiving a GLP-1 receptor agonist and is requesting to switching to Zepbound, medical justification* supports necessity for Zepbound;
 - *Intolerance due to common adverse effects of the GLP-1 receptor agonists class such as gastrointestinal symptoms is not considered acceptable medical justification*
6. Member meets one of the following (a or b):
 - a. Member 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. Member is not a candidate for PAP therapy (e.g., upper airway anatomic abnormalities, etc.);
- 7. Zepbound is not prescribed concurrently with other tirzepatide-containing products or any other GLP-1 receptor agonist(s);
- 8. Documentation of member's baseline body weight in kg;
- 9. Dose does not exceed the following:
 - a. Week 1 through 4: 2.5 mg once weekly;
 - b. Week 5 through 8: 5 mg once weekly;
 - c. Week 9 through 12: 7.5 mg once weekly;
 - d. Week 13 through 16: 10 mg once weekly;
 - e. Week 17 through 20: 12.5 mg once weekly;
 - f. Week 21 through 24: 15 mg once weekly;
 - g. One of the following (i or ii):
 - i. Single-dose formulation: One pen or vial per week;
 - ii. Multi-dose formulation: One vial or KwikPen every 4 weeks

Approval duration: 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2):

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for commercial; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.33 for commercial; or
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for commercial.

II. Continued Therapy

A. Weight Management (must meet all):

- 1. Member is currently receiving medication via Centene benefit or member has previously met initial approval criteria;
- 2. Member is responding positively to therapy as evidenced by one of the following (a or b):
 - a. If this is the first renewal request, member has lost $\geq 5\%$ of baseline body weight;
 - b. If this is a second or subsequent renewal request, member has lost weight and/or maintained weight loss on therapy;
- 3. Documentation of member's current body weight in kg;
- 4. Zepbound is not prescribed concurrently with other tirzepatide-containing products or any other GLP-1 receptor agonist(s);
- 5. Request meets all the following (a, b, and c):

- a. Dose does not exceed 15 mg once weekly;
- b. After the initial dose escalation period (*see Section V*), maintenance dose is ≥ 5 mg once weekly;
- c. Requested quantity does not exceed one of the following (i or ii):
 - i. Single-dose formulation: One pen or vial per week;
 - ii. Multi-dose formulation: One vial or KwikPen every 4 weeks.

Approval duration: 6 months or to the member's renewal date, whichever is longer

B. Obstructive Sleep Apnea (must meet all):

1. Member is currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by one of the following (a or b):
 - a. If this is the first renewal request, both of the following (i and ii):
 - i. Member has lost $\geq 5\%$ of baseline body weight;
 - ii. Any of the following parameters (1, 2, or 3):
 - 1) AHI reduction from baseline;
 - 2) Improvement from baseline in the sleep apnea-specific hypoxic burden (SASHB) score;
 - 3) Improvement from baseline in any one of the sleep-related patient reported outcomes scores (e.g., ESS, Calgary SAQLI, FOSQ, PROMIS sleep-related impairment or sleep disturbance; *see Appendix D*);
 - b. If this is a second or subsequent renewal request, both of the following (i and ii):
 - i. Member has lost weight and/or maintained weight loss on therapy;
 - ii. Stabilization or improvement in any of the following parameters (1, 2, or 3):
 - 1) AHI;
 - 2) SASHB;
 - 3) Sleep-related patient reported outcomes scores (e.g., ESS, Calgary SAQLI, FOSQ, PROMIS sleep-related impairment or sleep disturbance);
3. Zepbound is not prescribed concurrently with other tirzepatide-containing products or any other GLP-1 receptor agonist(s);
4. Request meets all the following (a, b, and c):
 - a. Dose does not exceed 15 mg once weekly;
 - b. After the initial dose escalation period (*see Section V*), maintenance dose is ≥ 10 mg once weekly;
 - c. Requested quantity does not exceed one of the following (i or ii):
 - i. Single-dose formulation: One pen or vial per week;
 - ii. Multi-dose formulation: One vial or KwikPen every 4 weeks.

Approval duration: 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

- a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for commercial; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.33 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.CPA.09 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AHI: apnea-hypopnea index	MTC: medullary thyroid carcinoma
BMI: body mass index	OSA: obstructive sleep apnea
ESS: Epworth sleepiness scale	PAP: positive airway pressure
FDA: Food and Drug Administration	PROMIS: patient-reported outcomes measurement information system
FOSQ: functional outcomes of sleep questionnaire	QOL: quality of life
GIP: glucose-dependent insulintropic polypeptide	PSG: polysomnography
GLP-1: glucagon-like peptide-1	SAQLI: sleep apnea QOL index
MEN 2: multiple endocrine neoplasia syndrome type 2	SASHB: sleep apnea-specific hypoxic burden
	T2DM: type 2 diabetes mellitus

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications / Boxed Warnings

- Contraindication(s): personal or family history of medullary thyroid carcinoma (MTC) or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2), known serious hypersensitivity to tirzepatide or to any of the excipients in Zepbound
- Boxed warning(s): risk of thyroid C-cell tumors

Appendix D: General Information – Weight Management

- BMI = $703 \times [\text{weight (lbs)/height (inches)}^2]$.
- Examples of coronary artery/heart disease include coronary artery bypass graft, angina, and history of myocardial infarction or stroke.

- The Endocrine Society practice guideline on pharmacological management of obesity states that a weight loss < 5% after 3 months of therapy indicates the weight loss medication is ineffective. In such cases, the Endocrine Society recommends that the medication be discontinued and alternative medications be considered.

Appendix E: Health Plan-Approved Weight Loss Program

Health Plan	Approved Weight Loss Program
CA	Weight watchers, Active&Fit

Appendix F: General Information – Obstructive Sleep Apnea

- The American Academy of Sleep Medicine (AASM) classifies the severity of OSA based on polysomnography-derived AHI cutoffs:
 - Mild: ≥ 5 to < 15 events per hour
 - Moderate: ≥ 15 to < 30 events per hour
 - Severe: ≥ 30 events per hour
- The American Thoracic Society practice guidelines recommends that patients with OSA who are overweight or obese be treated with comprehensive lifestyle intervention consisting of 1) a reduced-calorie diet, 2) exercise or increased physical activity, and 3) behavioral guidance.
- The American Association of Clinical Endocrinologists and American College of Endocrinology practice guidelines also recommends patients with OSA who are overweight or obese be treated with weight-loss therapy including lifestyle intervention and additional modalities as needed. The weight loss goal should be at least 7 or 11% or more.
- Sleep apnea-specific and sleep-related patient reported scores:

Name	Description	Interpretation
Calgary sleep apnea QOL index (SAQLI)	A 35-item, interview-administered scale, the SAQLI evaluates four domains of quality of life associated with sleep apnea: daily functioning, social interactions, emotional functioning, and symptoms. Optional 5 th domain assessing treatment-related symptoms.	Higher scores indicate better quality of life
Epworth sleepiness scale (ESS)	A very short, self-administered questionnaire with 8 questions intended to measure daytime sleepiness. Respondents are asked to rate on a 4-point scale.	A score of 10 or greater indicates excessive (abnormal) daytime sleepiness .
Functional outcomes of sleep questionnaire (FOSQ)	Consisting of 30 questions related to the effects of fatigue on daily activities, evaluating the respondent's	Lower scores designate more acute

Name	Description	Interpretation
	quality of life as it relates to disorders of excessive sleepiness. Five domains of day-to-day life are examined: activity levels, vigilance, intimacy and sexual relationships, productivity, and social outcomes.	issues with sleepiness.
Patient-reported outcomes measurement information system (PROMIS) sleep-related impairment and sleep disturbance	The PROMIS Short Form v1.0 Sleep-related Impairment 8a assesses self-reported perceptions of alertness, sleepiness, and tiredness during usual waking hours, and the perceived functional impairments associated with sleep problems or impaired alertness. It consists of 8 items each rated on a 5-point scale. The PROMIS Short Form v1.0 Sleep Disturbance 8b assesses self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep, including perceived difficulties and concerns with getting to sleep or staying asleep, as well as perceptions of the adequacy of and satisfaction with sleep. It consists of 8 items each rated on a 5-point scale.	Higher scores indicating more sleep-related impairment. Higher scores indicating more sleep disturbance.
Sleep apnea-specific hypoxic burden (SASHB)	SASHB is calculated by measuring the area under the oxygen desaturation curve during an overnight sleep study. It considers the frequency, depth, and duration of respiratory events, which are key features of the disease.	Higher values of SASHB are associated with higher risk of cardiovascular events and mortality.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Weight management, OSA	The recommended starting dosage is 2.5 mg SC once weekly for 4 weeks and increased by 2.5 mg every 4 weeks until the maximum tolerated recommended maintenance dosage is achieved. Recommended maintenance dosage: Weight management: 5 mg, 10 mg, or 15 mg SC once weekly	15 mg/week

Indication	Dosing Regimen	Maximum Dose
	• OSA: 10 mg or 15 mg SC once weekly	

VI. Product Availability

- Pre-filled, single-dose pens: 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg
- Pre-filled, single-dose vials: 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg
- Multi-dose vials: 10 mg/2.4 mL (4.17 mg/mL) for four 2.5 mg/0.6 mL doses, 20 mg/2.4 mL (8.33 mg/mL) for four 5 mg/0.6 mL doses, 30 mg/2.4 mL (12.5 mg/mL) for four 7.5 mg/0.6 mL doses, 40 mg/2.4 mL (16.7 mg/mL) for four 10 mg/0.6 mL doses, 50 mg/2.4 mL (20.8 mg/mL) for four 12.5 mg/0.6 mL doses, 60 mg/2.4 mL (25 mg/mL) for four 15 mg/0.6 mL doses •
- Single-patient-use KwikPens: 10 mg/2.4 mL (4.17 mg/mL) for four 2.5 mg/0.6 mL doses, 20 mg/2.4 mL (8.33 mg/mL) for four 5 mg/0.6 mL doses, 30 mg/2.4 mL (12.5 mg/mL) for four 7.5 mg/0.6 mL doses, 40 mg/2.4 mL (16.7 mg/mL) for four 10 mg/0.6 mL doses, 50 mg/2.4 mL (20.8 mg/mL) for four 12.5 mg/0.6 mL doses, 60 mg/2.4 mL (25 mg/mL) for four 15 mg/0.6 mL doses

VII. References

1. Zepbound Prescribing Information. Indianapolis, IN: Lilly USA, LLC; December 2024. Available at: <https://uspl.lilly.com/zepbound/zepbound.html#pi>. Accessed January 15, 2025.
2. *Weight Management*
3. Jastreboff AM, Aronne LJ, Ahmad NN, et al.; SURMOUNT-1 Investigators. Tirzepatide Once Weekly for the Treatment of Obesity. *N Engl J Med*. 2022 Jul 21;387(3):205-216.
4. Garvey WT, Frias JP, Jastreboff AM, et al.; SURMOUNT-2 investigators. Tirzepatide once weekly for the treatment of obesity in people with type 2 diabetes (SURMOUNT-2): a double-blind, randomised, multicentre, placebo-controlled, phase 3 trial. *Lancet*. 2023 Aug 19;402(10402):613-626.
5. Hampl SE, Hassink SG, Skinner AC, et al. Clinical practice guideline for the evaluation and treatment of children and adolescents with obesity [published online ahead of print, 2023 Jan 9]. *Pediatrics*. 2023;e2022060640.
6. Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *Circulation*. 2014; 129 (suppl 2): S102–S138.
7. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological management of obesity: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2015; 100(2): 42-362.
8. Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. *Endocrine Practice* 2016;22(suppl 3): 1-203.
9. Grunvald E, Shah R, Hernaez R, et al. AGA clinical practice guideline on pharmacological interventions for adults with obesity. *Gastroenterology* 2022;163:1198-1225.

CLINICAL POLICY

Tirzepatide

Obstructive Sleep Apnea

9. Malhotra A, Grunstein RR, Fietze I, et al. Tirzepatide for the treatment of obstructive sleep apnea and obesity. NEJM. 2024 Jun 21. doi: 10.1056/NEJMoa2404881. Epub ahead of print.
10. Clinicaltrials.gov. Obstructive sleep apnea master protocol GPIF: A study of tirzepatide (LY3298176) in participants with obstructive sleep apnea (SURMOUNT-OSA). Available at: <https://clinicaltrials.gov/study/NCT05412004>. Accessed September 12, 2024.
11. 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.
12. 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.
13. 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.
14. Mediano O, Gonzalez Mangado N, Montserrat JM, et al. [Translated article] International consensus document on obstructive sleep apnea. Archivos de Bronconeumologia 2022. 58:T52-T68.
15. 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.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy reviewed & adapted for AR QualChoice specific use. Removed requirement for weight-management program, updated off-label & no coverage criteria policies referenced.	12/19/25	
Revised language for members with concurrent T2DM language from "failure" to "member has received optimal diabetic standard of care therapy as evidenced by a trial" to align with drug class; added new multi-dose vial dosage form and new KwikPen dosage form	6/19/26	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions. Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

CLINICAL POLICY
Tirzepatide



©2023 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.