



5.99.031

Section:	Prescription Drugs	Effective Date:	January 1, 2026
Subsection:	Miscellaneous Products	Original Policy Date:	September 9, 2022
Subject:	Zepbound	Page:	1 of 8

Last Review Date: December 12, 2025

Zepbound

Description

Zepbound (tirzepatide)

Background

Obesity rates have increased dramatically in the 21st century and obesity contributes to increased morbidity, mortality, and the burden of healthcare costs. There are anti-obesity medications approved by the FDA for the treatment of obesity including glucose-dependent insulintropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonists such as Zepbound. GLP-1 is the physiological regulator of appetite and caloric intake. GIP receptors are also thought to contribute to appetite regulation. Zepbound likely lowers body weight by decreasing calorie intake by mediating appetite (1-4).

Regulatory Status

FDA-approved indications: (4)

- Zepbound is a glucose-dependent insulintropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity
 - to reduce excess body weight and maintain weight reduction long term in adults with obesity (30 kg/m² or greater) or overweight (27 kg/m² or greater) in the presence of at least one weight-related comorbid condition.
 - to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

Limitations of Use (4):

- Coadministration with other tirzepatide-containing products or with any GLP-1 receptor agonist is not recommended.

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Zepbound contains a boxed warning regarding the development of thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in both genders of rats. The relevance of this to the development of human thyroid C-cell tumors is unknown. Zepbound is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness) (4).

Patients should be periodically assessed for response to therapy. Evaluate decrease in BMI after 12-16 weeks of treatment. If a patient has not shown an appropriate decrease in BMI, discontinue the medication as it is unlikely that the patient will achieve and sustain clinically meaningful decrease in BMI with continued treatment (4).

The safety and effectiveness of Zepbound in pediatric patients less than 18 years of age have not been established (4).

Related policies

Imcivree, Saxenda Wegovy, Weight Loss Medications

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Zepbound may be considered **medically necessary** if the conditions indicated below are met.

Zepbound may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must be using for the following:

Chronic weight management

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AND ALL of the following with provided documentation (e.g., medical records, laboratory reports):

1. Patient has **ONE** of the following:
 - a. Body mass index (BMI) ≥ 30 kg/m²
 - b. Body mass index (BMI) ≥ 27 kg/m² **AND ONE** of the following:
 - i. Patient has established cardiovascular disease (e.g., congenital heart disease, cerebrovascular disease, peripheral artery disease, coronary heart disease, acute coronary syndrome (ACS), myocardial infarction (MI), unstable angina, coronary or other arterial revascularization, or prior percutaneous coronary intervention/coronary bypass surgery)
 - ii. Patient has at least one weight related comorbid condition (e.g., type 2 diabetes mellitus, dyslipidemia, or hypertension)
2. Inadequate treatment response, intolerance, or contraindication to at least **TWO** oral medications for weight management (e.g., benzphetamine, diethylpropion, phentermine, Qsymia, etc.)
3. Patient has participated in a comprehensive weight management program (e.g., Teladoc or another weight loss program)
4. **NO** dual therapy with other glucagon-like peptide-1 (GLP-1) receptor agonists (see Appendix 1)
5. **NO** dual therapy with another Prior Authorization (PA) medication for weight loss (see Appendix 2)
6. Patient **MUST** have tried the preferred product(s) (see Appendix 3) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

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Patient must be using for the following:

Chronic weight management

AND ALL of the following with provided documentation (e.g., medical records, laboratory reports):

1. The patient has lost at least 5 percent of baseline body weight **OR** the patient has continued to maintain their initial 5 percent weight loss
2. Patient has participated in a comprehensive weight management program (e.g., Teladoc or another weight loss program)
3. **NO** dual therapy with other glucagon-like peptide-1 (GLP-1) receptor agonists (See Appendix 1)
4. **NO** dual therapy with another Prior Authorization (PA) medication for weight loss (see Appendix 2)
5. Patient **MUST** have tried the preferred product(s) (see Appendix 3) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Medication	Quantity Limit
Zepbound	12 single-dose pens per 84 days

Duration 6 months

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Prior – Approval *Renewal* Limits

Quantity

Medication	Quantity Limit
Zepbound	12 single-dose pens per 84 days

Duration 12 months

Rationale

Summary

Weight loss is a pathway to health improvement for patients with obesity-associated risk factors and comorbidities. Medications approved for chronic weight management can be useful adjuncts to lifestyle change for patients who have been unsuccessful with diet and exercise alone (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Zepbound while maintaining optimal therapeutic outcomes.

References

1. Tchang BG, Aras M, Kumar RB, Aronne LJ. Pharmacologic Treatment of Overweight and Obesity in Adults. 2021 Aug 2. South Dartmouth (MA): MDText.com, Inc.; 2000. PMID: 25905267.
2. Apovian CM, Aronne LJ, Bessesen DH, McDonnell ME, M. Hassan M, Uberto Pagotto, Ryan DH, Still CD. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 100, Issue 2, 1 February 2015, Pages 342–362.
3. Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity. Pediatrics. 2023;151(2):e2022060640. doi:10.1542/peds.2022-060640
4. Zepbound [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2024.

Policy History

Date	Action
January 2023	Weight loss medications added to PA
February 2023	Per PI update: Wegovy age expanded to 12 years of age and older

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March 2023	Annual review
December 2023	Annual review. Pediatric reference added. Added initiation requirement to participate in comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity
January 2024	Addition of Zepbound to policy as non-preferred option on MedEx
March 2024	Annual review
April 2024	Revised indication to include established CVD for overweight patients. Per FEP, made the list of co-morbid and established cardiovascular conditions specific
September 2024	Annual review
December 2024	Annual review. Per FEP, placed Zepbound on its own policy 5.99.030 from 5.99.027, added behavior modification requirement for initiation, changed requirement for adults to achieve/maintain a 5% BMI reduction and pediatrics to have clinically significant weight loss for continuation
February 2025	Per PI update, addition of patients with obesity and sleep apnea indication added to regulatory section and added boxed warning for GLP1s thyroid cancer risk.
December 2025	Annual editorial review. Added documentation requirement. Modified t/f requirement to standard verbiage

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

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Generic Name	Brand Name
dulaglutide	Trulicity
exenatide	Byetta
exenatide	Bydureon, Bydureon BCise
liraglutide	Saxenda
liraglutide	Victoza
liraglutide and insulin degludec	Xultophy
lixisenatide	Adlyxin
lixisenatide and insulin glargine	Soliqua
semaglutide	Ozempic
semaglutide	Rybelsus
semaglutide	Wegovy
tirzepatide	Mounjaro
tirzepatide	Zepbound

Appendix 2 - List of PA Weight Loss Medications

Generic Name	Brand Name
benzphetamine	N/A
carboxymethylcellulose-cellulose-citric acid	Plenity
diethylpropion	N/A
liraglutide	Saxenda
naltrexone/bupropion	Contrave
orlistat	Xenical
phendimetrazine	N/A
phentermine	Adipex-P/Lomaira
phentermine/topiramate ER	Qsymia
semaglutide	Wegovy
setmelanotide	Imcivree
tirzepatide	Zepbound

Appendix 3 - List of Preferred Products

List of preferred products:

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Refer to formulary documents for confirmation of coverage:
<https://www.fepblue.org/pharmacy/prescriptions#drug-lists>