State of Mississippi
Prior Authorization with Quantity Limit
Wegovy – Zepbound
Supplemental Indications Only

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths except Zepbound vials, which are covered under the LillyDirect manufacturer program. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Wegovy	semaglutide
Zepbound	tirzepatide

Indications

FDA-approved Indications

Wegovy

Wegovy is indicated in combination with a reduced calorie diet and increased physical activity:

- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.
- to reduce excess body weight and maintain weight reduction long term in:
  - Adults and pediatric patients aged 12 years and older with obesity
  - Adults with overweight in the presence of at least one weight-related comorbid condition.

Limitations of Use

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

Zepbound

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.

Limitations of Use

- Zepbound contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.

Coverage Criteria

Obstructive Sleep Apnea – Zepbound ONLY

Authorization may be granted when the requested drug is being used to treat moderate to severe obstructive sleep apnea (OSA) in an adult with obesity when ALL of the following criteria are met:

- The request is for Zepbound (tirzepatide).
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has an established diagnosis of moderate to severe OSA with an apnea-hypopnea index (AHI) of at least 15 events per hour on polysomnography (PSG) or home sleep apnea test (HSAT) with a technically adequate device. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has a current body mass index (BMI) greater than or equal to 30 kg/m^2. [ACTION REQUIRED: Documentation is required for approval.]

Risk Reduction of Major Adverse Cardiovascular Events – Wegovy ONLY

Authorization may be granted when the requested drug is being used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction (MI), or non-fatal stroke) in an adult with established cardiovascular disease AND either obesity or overweight when ALL of the following criteria are met:

- The request is for Wegovy (semaglutide).
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has established cardiovascular disease with a history of ONE of the following: [ACTION REQUIRED: Documentation is required for approval.]
    - Previous MI.
    - Previous stroke.
    - Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease.
    - Prior history of revascularization (coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI), or angioplasty).
- The patient has a baseline body mass index (BMI) greater than or equal to 27 kg/m^2. [ACTION REQUIRED: Documentation is required for approval.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.]
- The patient does NOT have type 2 diabetes. [NOTE: Ozempic is indicated to reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease. Patients with type 2 diabetes may be treated for risk reduction of cardiovascular events with Ozempic.]

- The patient is currently receiving guideline-directed management and therapy (GDMT) for cardiovascular disease (e.g., lipid-lowering agent, antiplatelet, beta-blocker, renin-angiotensin inhibitor, etc.) OR the patient has clinical reason not to be treated with GDMT for cardiovascular disease. [ACTION REQUIRED: Documentation is required for approval.]

Continuation of Therapy

Obstructive Sleep Apnea – Zepbound ONLY

Authorization may be granted when the requested drug is being used to treat moderate to severe obstructive sleep apnea (OSA) in an adult with obesity when ALL of the following criteria are met:

- The request is for Zepbound (tirzepatide).
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has an established diagnosis of moderate to severe OSA with an apnea-hypopnea index (AHI) of at least 15 events per hour on polysomnography (PSG) or home sleep apnea test (HSAT) with a technically adequate device. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has achieved or maintained a positive response to treatment from baseline, evidenced by a decrease in OSA symptoms.
- The patient is being treated with a maintenance dosage, 10 mg or 15 mg once weekly, of the requested drug.

Risk Reduction of Major Adverse Cardiovascular Events – Wegovy ONLY

Authorization may be granted when the requested drug is being used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction (MI), or non-fatal stroke) in an adult with established cardiovascular disease AND either obesity or overweight when ALL of the following criteria are met:

- The request is for Wegovy (semaglutide).
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has established cardiovascular disease with a history of ONE of the following:
    - Previous MI.
    - Previous stroke.
    - Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease.
    - Prior history of revascularization (coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI), or angioplasty).
- The patient is being treated with a maintenance dosage of the requested drug.

Quantity Limits Apply

The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.

Drug	Dosage	1 Month Limit	3 Months Limit
Wegovy (semaglutide)	0.25 mg / 0.5 mL	2 mL (1 package of 4 pens each) / 21 days	6 mL (3 packages of 4 pens each) / 63 days
Wegovy (semaglutide)	0.5 mg / 0.5 mL	2 mL (1 package of 4 pens each) / 21 days	6 mL (3 packages of 4 pens each) / 63 days
Wegovy (semaglutide)	1 mg / 0.5 mL	2 mL (1 package of 4 pens each) / 21 days	6 mL (3 packages of 4 pens each) / 63 days
Wegovy (semaglutide)	1.7 mg / 0.75 mL	3 mL (1 package of 4 pens each) / 21 days	9 mL (3 packages of 4 pens each) / 63 days
Wegovy (semaglutide)	2.4 mg / 0.75 mL	3 mL (1 package of 4 pens each) / 21 days	9 mL (3 packages of 4 pens each) / 63 days
Zepbound (tirzepatide)	2.5 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days	6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days
Zepbound (tirzepatide)	5 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days	6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days
Zepbound (tirzepatide)	7.5 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days	6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days
Zepbound (tirzepatide)	10 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days	6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days
Zepbound (tirzepatide)	12.5 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days	6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days
Zepbound (tirzepatide)	15 mg / 0.5 mL	2 mL (1 package of 4 pens each or 4 single-dose vials) / 21 days	6 mL (3 packages of 4 pens each or 12 single-dose vials) / 63 days

Duration of Approval (DOA)

- Wegovy: Initial therapy DOA: 7 months; Continuation of therapy DOA: 12 months
- Zepbound: Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months

References

1. Wegovy [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; March 2024.
2. Zepbound [package insert]. Indianapolis, IN: Lilly USA, LLC; December 2024.

3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed June 28, 2024.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 06/28/2024).
5. Lincoff AM, Brown-Frandsen K, Colhoun HM, et al. Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. N Engl J Med. 2023;389:2221-2232.
6. Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. Circulation. 2023;148:e9-e119.
7. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association. Stroke. 2021;52(7):e364-e467.
8. Gornik HL, Aronow HD, Goodney PP, et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2024;83(24):2497-2604.
9. Malhorta A, Grunstein RR, Fietze I, et al. Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity. New Engl J Med. 2024;391:1193-1205.
10. 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. J Clin Sleep Med. 2017;13(3):479-504.