Washington State Health Care Authority

Anorexiants/Anti-Obesity: GLP-1 Receptor Agonists- Wegovy® (semaglutide)

Medical policy no. 61.25.20.AA-1 Effective Date: 7/1/2024

Related medical policies:

Policy Number	Policy Name
27.17.00	Antidiabetics- GLP-1 Agonists

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
Semaglutide (Wegovy®)	**Semaglutide (Wegovy ®)** 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	
Patients who are either obese or overweight with established cardiovascular disease who are at risk for major adverse cardiovascular (CV) events Semaglutide (Wegovy®)	Semaglutide (Wegovy®) may be approved when all the following documented criteria are met: 1. Patient is ≥ 18 years of age or older; **AND** 2. Patient does not have diabetes or HbA1c > 6.5%; **AND** 3. Patient has established cardiovascular (CV) disease with one or more of the following: a. History of myocardial infarction (MI); **OR** b. History of stroke (ischemic or hemorrhagic); **OR**

	c. Symptomatic carotid artery disease; **OR** d. Symptomatic coronary artery disease; **OR** e. Symptomatic peripheral arterial disease (PAD); **AND** 4. BMI ≥ 27 kg/m^2; **AND** 5. Pre-treatment baseline weight and waist circumference is measured; **AND** 6. Treatment plan includes the following: a. Active member participation in comprehensive adjunct lifestyle interventions (e.g., diet modification, physical activity, and behavioral therapy); **AND** b. Concurrent use of either of the following for secondary prevention of adverse CV events unless medication is contraindicated or not tolerated (i, ii, or iii): **i.** Antiplatelet therapy (e.g., aspirin, clopidogrel); **OR** ii. Antihypertensive therapy (e.g., ACE or ARB inhibitor, β-blocker, calcium channel blocker); **OR** iii. Lipid lowering therapy (e.g., statin, fibrate, PCSK-9 inhibitor); **AND** 7. Not used in combination with another GLP-1 receptor agonist; **AND** 8. Patient must be able to titrate and maintain the therapeutic dose as recommended in the FDA-approved labeling If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Semaglutide (Wegovy®) may be approved when all the following documented criteria are met: 1. Continuation of member participation in a program that includes comprehensive adjust lifestyle interventions; **AND** 2. Continuation of secondary prevention drug therapy unless medication is contraindicated or not tolerated; **AND** 3. Not used in combination with another GLP-1 receptor agonist; **AND** 4. Patient continues to maintain either of the following: a. At least a 5% weight loss from baseline; **OR** b. Waist circumference has decreased from baseline If ALL criteria are met, the request will be authorized for **12 months.**
Weight Loss Semaglutide (Wegovy®)	Semaglutide (Wegovy®) 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
Wegovy®	Patients who are either obese or overweight with established cardiovascular disease who are at risk for major adverse cardiovascular (CV) events	Initial Dosage and Titration 0.25 mg subQ once weekly for weeks 1-4; then 0.5 mg once weekly for weeks 5-8; then 1 mg once weekly for weeks 9-12; then 1.7 mg once weekly for weeks 13-16 Maintenance 2.4 mg or 1.7 mg subQ once weekly	**0.25 mg/0.5 mL pen [#4 pen per box]** *Initial PA:* #4 pens per 28 days **0.5 mg/0.5 mL pen [#4 pen per box]** *Initial PA:* #4 pens per 28 days **1 mg/0.5 mL pen [#4 pen per box]** *Initial PA:* #4 pens per 28 days **1.7 mg/0.75 mL [#4 pen per box]** *Initial PA:* #4 pens per 28 days **2.4 mg/0.75 mL [#4 pen per box]** *Renewal PA:* #4 pens per 28 days

Background:

Overweight and obesity are conditions defined as the increase in size and amount of fat cells in the body. Overweight and obesity can be caused by many factors including eating patterns, lack of sleep or physical activity, medications, as well as genetics and family history. Obesity is a chronic health condition that raises the risk for heart disease, type 2 diabetes, hypertension, dyslipidemia, and coronary heart disease. Overweight is defined as a BMI of 25 to 29.9 kg/m^2 and obesity is defined as a BMI of ≥ 30 kg/m^2. The goal of therapy for overweight and obesity is to prevent, treat, or reverse complications and improve quality of life. There is still a lack of evidence indicating that lifestyle or pharmacologic interventions for overweight or obesity improve cardiovascular outcomes. The 2013 ACC/AHA/TOS guidelines and 2016 AACE/ACE guidelines recommend that all adults be screened annually using a body mass index (BMI) measurement to initiate evaluation for overweight and obesity. Both guidelines recommend that patients with obesity stage 1 or 2 lose at least 5% of their body weight and the AACE/ACE guidelines recommend a loss of at least 10% body weight for complication specific targets. Individuals with overweight or obesity should be prescribed aerobic exercise and resistance training along with a reduced-calorie diet and their sedentary time should be reduced. The AACE/ACE guidelines recommend that behavioral interventions be escalated for patients who do not achieve 2.5% weight loss within one month of starting treatment. The AACE/ACE guidelines also recommend that pharmacotherapy combined with lifestyle medication be considered for patients with a BMI of least 27 kg/m^2 if lifestyle therapy fails to halt weight gain.

Glucagon-like peptide-1 (GLP-1) receptor agonists are used in the management of type 2 diabetes and overweight or obesity and have been shown to reduce the risk of major adverse cardiovascular events in patients with type 2 diabetes with high cardiovascular risk. It is still unknown whether GLP-1 receptor agonists can reduce the cardiovascular risk associated with overweight and obesity. Approval of semaglutide in patients with overweight or obesity but no diabetes was based off the results of the multi-center, double blind, randomized, placebo-controlled, event-driven superiority Semaglutide Effects on Cardiovascular Outcomes in People with Overweight or Obesity (SELECT) trial. 17,604 adults with overweight or obesity, prior cardiovascular events (MI, stroke, symptomatic peripheral artery disease), but no diabetes were randomized to semaglutide (n=8803) or placebo (n=8=8801). Additional inclusion criteria were patients aged ≥ 45 years old and BMI ≥ 27 kg/m^2. The primary cardiovascular endpoint was a composite of death from cardiovascular causes, nonfatal MI, or nonfatal stroke in a time-to-first-event analysis. 90.1% of patients were taking lipid-lowering medications, 86.2% antiplatelets, 70.2% beta-blockers, 45% ACE inhibitors and 29.5% ARBs. The mean duration of exposure to semaglutide or placebo was 34.2 ± 13.7 months. A primary cardiovascular endpoint event occurred in 569/8803 patients in the semaglutide group and in 701/8801 in the placebo group (HR=0.80 95% CI, 0.72 to 0.90, $p < 0.001$). Death from cardiovascular causes, the first confirmatory secondary end point, occurred in 223 patients in the semaglutide group and 262 patients in the placebo group (HR= 0.85, 95% CI, 0.71 to 1.01, p= 0.07). The mean change in body weight over the 104 weeks was -9.39% with semaglutide and -0.88% with placebo. Adverse events leading to permanent discontinuation of semaglutide or placebo occurred in 1461 patients in the semaglutide group and 718 patients in the placebo.

References

1. Garvey WT, Mechanick JI, Brett EM, et al; Reviewers of the AACE/ACE Obesity Clinical Practice Guidelines. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. Endocr Pract. 2016;22(suppl 3):1-203. doi:10.4158/EP161365.GL
2. Jensen MD, Ryan DH, Apovian CM, et al; American College of Cardiology/American Heart Association Task Force on Practice Guidelines; Obesity Society. 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. J Am Coll Cardiol. 2014;63(25 part B):2985-3023. doi:10.1016/j.jacc.2013.11.004
3. Lincoff AM, Brown-Frandsen K, Colhoun HM, Deanfield J, Emerson SS, Esbjerg S, Hardt-Lindberg S, Hovingh GK, Kahn SE, Kushner RF, Lingvay I.. Semaglutide and cardiovascular outcomes in obesity without diabetes. N Engl J Med 2023. http://doi.org/10.1056/NEJMoa2307563.
4. Wegovy® [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc. March 2024.

History

Approved Date	Effective Date	Version	Action and Summary of Changes
07/01/2024	07/01/2024	61.25.20.AA-1	-New policy created -Approved by internal HCA team (Pharmacy/HCS)