Reference number(s)
4774-C

Initial Prior Authorization with Quantity Limit
Wegovy
Weight Loss Management

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Wegovy	semaglutide	injection

Indications

FDA-approved Indications

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.

Coverage Criteria

Reduction in Excess Body Weight, Maintenance of Weight Reduction Long Term

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity to reduce excess body weight or maintain weight reduction long term when ALL of the following criteria are met:

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced-calorie diet, AND increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy
- If the patient is 18 years of age or older, then the patient meets ONE of the following:
    - The patient has a baseline body mass index (BMI) greater than or equal to 30 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 has a baseline 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.] In addition, the following criteria is met:
        - The patient has at least ONE weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia) [ACTION REQUIRED: Documentation is required for approval.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their weight-related comorbid condition(s) at the start of any drug therapy.]
- If the patient is 12 to 17 years of age, then the following criteria is met:
    - The patient has a baseline BMI in the 95th percentile or greater standardized for age and sex (obesity) [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.]

Risk Reduction of Major Adverse Cardiovascular Events

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 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

Reduction in Excess Body Weight, Maintenance of Weight Reduction Long Term

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity to reduce excess body weight or maintain weight reduction long term when ONE of the following criteria is met:

- The patient is 18 years of age or older and ALL of the following criteria are met:
    - The patient has completed at least 3 months of therapy with the requested drug at a stable maintenance dose
    - 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 [ACTION REQUIRED: Documentation is required for approval.]
- The patient is 12 to 17 years of age and ALL of the following criteria are met:
    - The patient has successfully titrated to a stable maintenance dose
    - The patient has had a reduction from their baseline body mass index (BMI) OR the patient has continued to maintain their initial BMI reduction [ACTION REQUIRED: Documentation is required for approval.]

Risk Reduction of Major Adverse Cardiovascular Events

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 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

Quantity Limit

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 Month 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

Duration of Approval (DOA)

- 4774-C: Initial therapy DOA: 7 months; Continuation of therapy DOA: 12 months

References

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4. Jensen MD, Ryan DH, Apovian DM, 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.
5. 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):342–362.
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7. 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.
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