

# 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
Wegovy	semaglutide
Wegovy HD	semaglutide

## Indications

### FDA-approved Indications

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

- To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV 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.

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- For the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults. This indication is approved under accelerated approval based on improvement of MASH and fibrosis. Continued approval for this indication may be contingent upon the verification and description of clinical benefit in a confirmatory trial.

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

- To reduce the risk of major adverse CV events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight.
- To reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition.

#### **Limitations of Use**

- Concomitant use of Wegovy (semaglutide) tablets or Wegovy (semaglutide) injection with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended.

## **Coverage Criteria**

### **Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis (Adult) – Wegovy Injection ONLY (EXCLUDING Wegovy HD 7.2 mg Injection)**

Authorization may be granted when the requested drug is being prescribed for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in an adult when ALL of the following criteria are met:

- The request is NOT for Wegovy (semaglutide) HD 7.2 mg injection OR Wegovy (semaglutide) tablets.
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The requested drug is being prescribed by, or in consultation with, a gastroenterologist or hepatologist.
- The patient's moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) at baseline has been confirmed by ONE of the following: non-invasive liver disease assessment (e.g., ultrasound-based elastography, magnetic resonance elastography [MRE]) OR historical liver biopsy. [ACTION REQUIRED: Documentation is required for approval.]

## Reduction in Excess Body Weight, Maintenance of Weight Reduction Long Term (Adult)

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 is 18 years of age or older.
- 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.
- The patient meets ONE of the following:
  - The patient has a baseline body mass index (BMI) greater than or equal to 30 kg/m<sup>2</sup>. [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.] [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has a baseline BMI greater than or equal to 27 kg/m<sup>2</sup>. [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.] [ACTION REQUIRED: Documentation is required for approval.] 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). [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.] [ACTION REQUIRED: Documentation is required for approval.]

## Reduction in Excess Body Weight, Maintenance of Weight Reduction Long Term (Pediatric) – Wegovy Injection ONLY (EXCLUDING Wegovy HD 7.2 mg Injection)

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 is 12 to 17 years of age.
- The request is NOT for Wegovy (semaglutide) HD 7.2 mg injection OR Wegovy (semaglutide) tablets.
- 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.
- The patient has a baseline BMI in the 95th percentile or greater standardized for age and sex (obesity). [NOTE: If the patient is transitioning from another drug therapy for weight loss, please

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consider their baseline BMI at the start of any drug therapy.] [ACTION REQUIRED: Documentation is required for approval.]

## Risk Reduction of Major Adverse Cardiovascular Events (Adult)

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 NOT for Wegovy (semaglutide) HD 7.2 mg injection.
- 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<sup>2</sup>. [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.] [ACTION REQUIRED: Documentation is required for approval.]
- 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 a clinical reason not to be treated with GDMT for cardiovascular disease. [ACTION REQUIRED: Documentation is required for approval.]

## Continuation of Therapy

### Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis (Adult) – Wegovy Injection ONLY (EXCLUDING Wegovy HD 7.2 mg Injection)

Authorization may be granted when the requested drug is being prescribed for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic

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steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in an adult when ALL of the following criteria are met:

- The request is NOT for Wegovy (semaglutide) HD 7.2 mg injection OR Wegovy (semaglutide) tablets.
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has achieved or maintained a positive clinical response to the requested drug (e.g., improvement in liver function such as reduction in alanine aminotransferase [ALT], improvement in Enhanced Liver Fibrosis [ELF] score, improvement in liver stiffness measurement [LSM] by ultrasound-based elastography, magnetic resonance elastography [MRE]). [ACTION REQUIRED: Documentation is required for approval.]
- The patient is being treated with a maintenance dosage of the requested drug which is based on individual treatment response and tolerability.

## Reduction in Excess Body Weight, Maintenance of Weight Reduction Long Term (Adult)

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 is 18 years of age or older.
- 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.]

## Reduction in Excess Body Weight, Maintenance of Weight Reduction Long Term (Pediatric) – Wegovy Injection ONLY (EXCLUDING Wegovy HD 7.2 mg Injection)

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 is 12 to 17 years of age.
- The request is NOT for Wegovy (semaglutide) HD 7.2 mg injection OR Wegovy (semaglutide) tablets.
- 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 (Adult)

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 NOT for Wegovy (semaglutide) HD 7.2 mg injection.
- 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 is being treated with a maintenance dosage of the requested drug which is based on individual treatment response and tolerability.

## 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.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	Dosage	1 Month Limit	3 Month Limit
Wegovy (semaglutide) injection	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) injection	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) injection	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) injection	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

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Drug	Dosage	1 Month Limit	3 Month Limit
Wegovy (semaglutide) injection	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
Wegovy (semaglutide) HD injection	7.2 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) tablet	1.5 mg, 4 mg, 9 mg, 25 mg	30 tablets / 25 days	90 tablets / 75 days

## Duration of Approval (DOA)

- 4774-C:
  - Wegovy (semaglutide) HD 7.2 mg injection:
    - Reduction in excess body weight, maintenance of weight reduction long term in patients 18 years of age and older: Initial therapy DOA: 8 months; Continuation of therapy DOA: 12 months
  - Wegovy (semaglutide) Injection:
    - Reduction in excess body weight, maintenance of weight reduction long term in patients 18 years of age and older: Initial therapy DOA: 8 months; Continuation of therapy DOA: 12 months
    - Reduction in excess body weight, maintenance of weight reduction long term in patients 12 to 17 years of age: Initial therapy DOA: 7 months; Continuation of therapy DOA: 12 months
    - Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis (MASH): DOA: 12 months
    - Risk reduction of major adverse cardiovascular events: DOA: 12 months
  - Wegovy (semaglutide) Tablet:
    - Reduction in excess body weight, maintenance of weight reduction long term: Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months
    - Risk reduction of major adverse cardiovascular events: DOA: 12 months

## References

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