

Protocol for Wegovy

DURB Approval Date	7/2024; 10/2025
Commissioners Approval Date	1/2025; 2/2026

Addendum:

Added new Food and Drug Administration (FDA) for metabolic dysfunction-associated steatohepatitis (MASH). The indication for MASH is approved under accelerated approval based on MASH and fibrosis improvement. Continued approval may be contingent on clinical benefit in a confirmatory trial.

Background:

Wegovy, approved by the Food and Drug Administration in June 2021, is a glucagon-like peptide-1 (GLP-1) receptor agonist. Wegovy is available for patients to reduce the risk of major adverse cardiovascular (CV) events in adults with established CV disease who are obese or overweight and for the treatment of noncirrhotic MASH who have moderate to advanced liver fibrosis.

Criteria for approval:

1. Patient is of the FDA labeled or compendial age; **AND**
2. Patient does not have any contraindications to therapy; **AND**
3. Patient is not utilizing another GLP-1 receptor agonist concomitantly; **AND**
4. Documentation that the member has received individualized healthy lifestyle counseling and will use Wegovy together with a reduced calorie diet and increased physical activity

Major Adverse Cardiovascular Event

- a. Patient has established cardiovascular disease as evidenced by at least one of the following:
 - a) Prior myocardial infarction
 - b) Prior ischemic or hemorrhagic stroke or transient ischemic attack
 - c) 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
 - d) Positive nuclear stress test
 - e) Ischemic cardiomyopathy
 - f) History of revascularization (coronary artery bypass grafting, percutaneous coronary intervention, or angioplasty); **AND**
- b. Documentation that the patient has a body mass index (BMI) ≥ 27 kg/m²; **AND**
- c. Medication is prescribed by or in consultation with a cardiologist, vascular specialist or endocrinologist; **AND**
- d. Prescriber will maintain the patient on appropriate cardiovascular pharmacotherapy for their cardiovascular disease; **AND**
- e. Patient's target dose will be in the range of manufacturer dosing shown to reduce major cardiovascular events as tolerated

Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis

- a. Patient has documented or confirmed moderate to advanced liver fibrosis; **AND**
- b. Patient has a liver fibrosis stage of F2 or F3 and documentation is received; **AND**
- c. The patient does not have evidence of cirrhosis as documented by clinical notes or laboratory values; **AND**
- d. Medication is prescribed by or in consultation with a hepatologist, gastroenterologist or endocrinologist; **AND**
- e. Patient's target dose is in the range of manufacturer dosing for treatment of MASH

Continuation of therapy:

1. There is no evidence of disease progression (documentation received); **AND**

2. The patient continues to follow lifestyle modifications; AND
3. For MACE requests patient remains on appropriate CV pharmacotherapy for their CV disease; AND
4. Patient is not utilizing another GLP-1 receptor agonist concomitantly

NOTE: Wegovy has a black box warning regarding thyroid C-cell tumors. Please see full prescribing information for details.

Approval Duration and Quantity Restrictions:

- Initial Approval: 7 months
- Renewal Approval: 12 months

Quantity Level Limit:

Drug	Dosage	1 Month Limit
Wegovy (semaglutide)	0.25 mg/0.5 mL	2 mL (1 package of 4 pens each) / 30 days
	0.5 mg/0.5 mL	
	1 mg/0.5 mL	
	1.7 mg/0.75 mL	3 mL (1 package of 4 pens each) / 30 days
	2.4 mg/0.75 mL	

References:

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