Clinical Policy: Semaglutide (Wegovy)

Reference Number: ERX.NPA.158
Effective Date: 09.01.21
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Semaglutide (Wegovy™) is a glucagon-like peptide-1 (GLP-1) receptor agonist.

FDA Approved Indication(s)

Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obese), or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia.

Limitation(s) of use:

- Wegovy should not be used in combination with other semaglutide-containing products or any other GLP-1 receptor agonist.
- The safety and effectiveness of Wegovy in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- Wegovy has not been studied in patients with a history of pancreatitis.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Wegovy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Weight Management (must meet all)**:**

1. Member meets one of the following (a or b):
   a. BMI ≥ 30 kg/m^2;
   b. BMI ≥ 27 kg/m^2 with at least one indicator of increased cardiovascular risk (e.g., coronary artery/heart disease, hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
2. Age ≥ 18 years;
3. Wegovy is not prescribed concurrently with other semaglutide-containing products or any other GLP-1 receptor agonist(s);
4. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy;
5. Dose does not exceed the following:
   a. Week 1 through 4: 0.25 mg once weekly;
   b. Week 5 through 8: 0.5 mg once weekly;
   c. Week 9 through 12: 1 mg once weekly;
   d. Week 13 through 16: 1.7 mg once weekly.

Approval duration: 16 weeks

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Weight Management (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. BMI ≥ 25 kg/m^2;
3. Member is responding positively to therapy as evidenced by one of the following (a or b):
   a. If this is the first renewal request, member has lost ≥ 5% of baseline body weight;
   b. If this is a second or subsequent renewal request, member has lost weight and/or maintained weight loss on therapy;
4. Wegovy is not prescribed concurrently with other semaglutide-containing products or any other GLP-1 receptor agonist(s);
5. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy;
6. Request meets both of the following (a and b):
   a. Dose does not exceed 2.4 mg once weekly;
   b. After the initial dose escalation period (*see Section V*), one of the following (i or ii):
      i. Maintenance dose is at least 2.4 mg;
      ii. A temporary dose reduction to 1.7 mg is needed for a maximum of 4 weeks.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BMI: body mass index
FDA: Food and Drug Administration
GLP-1: glucagon-like peptide-1

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): personal or family history of medullary thyroid cancer (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN 2), known hypersensitivity to semaglutide or any of the excipients in Wegovy
- Boxed warning(s): risk of thyroid C-cell tumors

Appendix D: General Information
- BMI = 703 x [weight (lbs)/height (inches)^2]

- Examples of coronary artery/heart disease include coronary artery bypass graft, angina, and history of myocardial infarction or stroke.
- Per PI, the primary efficacy parameters for studies 1, 2 and 3 were the mean percent change in body weight and the proportion of patients achieving greater than or equal to 5% weight loss from baseline to week 68. After 68 weeks, treatment with semaglutide resulted in a statistically significant reduction in body weight compared with placebo. Greater proportions of patients treated with semaglutide achieved 5%, 10%, and 15% weight loss than those treated with placebo.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Weight management	Dose escalation schedule: • Week 1 through 4: 0.25 mg • Week 5 through 8: 0.5 mg • Week 9 through 12: 1 mg • Week 13 through 16: 1.7 mg • Week 17 and onward: 2.4 mg If patients do not tolerate a dose during dose escalation, consider delaying dose escalation for 4 weeks. If patients do not tolerate the maintenance 2.4 mg once-weekly dose, the dose can be temporarily decreased to 1.7 mg once-weekly, for a maximum of 4 weeks. After 4 weeks, increase Wegovy to the maintenance 2.4 mg once-weekly. Discontinue Wegovy if the patient cannot tolerate the 2.4 mg dose.	2.4 mg/week

VI. Product Availability

Pre-filled, single-dose pen: 0.25 mg, 0.5 mg, 1 mg, 1.7 mg, 2.4 mg

VII. References

1. Wegovy Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; June 2021. Available at: www.wegovy.com. Accessed June 14, 2021.
2. Jensen MD, Ryan DH, Apovian CM, 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.
3. 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): 42-362.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	06.15.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.