Clinical Policy: Semaglutide for Weight Loss (Wegovy)

Reference Number: CP.CPA.352
Effective Date: 09.01.21
Last Review Date: 08.21
Line of Business: Commercial

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 comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).

Limitation(s) of use:

- Wegovy contains semaglutide and should not be coadministered with other semaglutide-containing products or with 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.

It is the policy of health plans affiliated with Centene Corporation® 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 CP.CPA.09 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 Centene benefit 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 Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.CPA.09 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 – CP.CPA.09 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 carcinoma (MTC) or with multiple endocrine neoplasia syndrome type 2 (MEN 2).
  - A prior serious hypersensitivity reaction to semaglutide or to any of the excipients in Wegovy. Serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with semaglutide.
- Boxed warning(s): risk of thyroid C-cell tumors
  - In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Wegovy causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined

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.

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	2.4 mg/week

Indication	Dosing Regimen	Maximum Dose
	Wegovy to the maintenance 2.4 mg once-weekly. Discontinue Wegovy if the patient cannot tolerate the 2.4 mg dose.	

VI. Product Availability

Injection: pre-filled, single-dose pen that delivers doses of 0.25 mg, 0.5 mg, 1 mg, 1.7 mg or 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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions. Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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