Clinical Policy: Semaglutide (Wegovy)

Reference Number: CP.CPA.352
Effective Date: 09.01.21
Last Review Date: 08.24
Line of Business: Commercial

Coding Implications
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 in combination with a reduced-calorie diet and increased physical activity:

- To reduce the risk of major cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (CVD) and either obesity or overweight.
- To reduce excess body weight and maintain weight reduction long term in:
  - Adult and pediatric patients aged 12 years and older with obesity;
  - Adults with overweight in the presence of at least one weight-related comorbid condition.

Limitation(s) of use: Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended.

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, b, or c):
   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);
   c. If age is between 12 and 17 years: BMI ≥ 95th percentile standardized for age and sex (*see Appendix D*);
2. Age ≥ 12 years;
3. Wegovy is not prescribed concurrently with other semaglutide-containing products or any other GLP-1 receptor agonist(s);
4. Documentation supports member's participation in a Health Net approved weight loss program (e.g., Weight Watchers) or other weight loss programs recommended by the

prescriber that involves a reduced calorie diet, increased physical activity, and behavioral modification that meets both of the following (a and b):
   a. Been actively enrolled in a Health Net approved weight loss program (e.g., Weight Watchers) or other weight loss programs recommended by the prescriber for at least 6 months;
   b. Will continue to be actively enrolled in a weight loss program while concomitantly prescribed Wegovy;
5. Documentation of member's baseline body weight in kg;
6. 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. Cardiovascular Event Prevention (must meet all):
1. Member has at least one of the following established CVD (a, b, or c):
   a. History of myocardial infarction;
   b. History of stroke;
   c. Symptomatic peripheral arterial disease (PAD) (*see Appendix E*);
2. Age ≥ 18 years;
3. BMI ≥ 27 kg/m^2;
4. Prescriber attestation that member is currently receiving cardiovascular standard of care management (*see Appendix E*);
5. For members with concurrent type 2 diabetes mellitus, both of the following (a and b):
   a. Failure of ≥ 3 consecutive months of Ozempic®, Trulicity®, and Victoza®, unless clinically significant adverse effects are experienced or all are contraindicated;*
   **Prior authorization may be required*
   b. If member is currently receiving a GLP-1 receptor agonist and is requesting to switch to Wegovy therapy, medical justification* supports necessity for Wegovy;
   **Intolerance due to common adverse effects of the GLP-1 receptor agonist class such as gastrointestinal symptoms is not considered acceptable medical justification*
6. Wegovy is not prescribed concurrently with other semaglutide-containing products or any other GLP-1 receptor agonist(s);
7. Documentation supports member's participation in a Health Net approved weight loss program (e.g., Weight Watchers) or other weight loss programs recommended by the prescriber that involves a reduced calorie diet, increased physical activity, and behavioral modification that meets both of the following (a and b):
   a. Been actively enrolled in a Health Net approved weight loss program (e.g., Weight Watchers) or other weight loss programs recommended by the prescriber for at least 6 months;
   b. Will continue to be actively enrolled in a weight loss program while concomitantly prescribed Wegovy;
8. Documentation of member's baseline body weight in kg;

9. 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;
   e. Week 17 and onward: 2.4 mg once weekly.

Approval duration: 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. 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 (adults) or baseline BMI (pediatrics);
   b. If this is a second or subsequent renewal request, member has lost weight and/or maintained weight loss on therapy;
3. Documentation of member's current body weight in kg;
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 physician-directed weight loss program that involves a reduced calorie diet, increased physical activity, and behavioral modification 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*), maintenance dose is ≥ 1.7 mg once weekly.

Approval duration: 6 months or to the member's renewal date, whichever is longer

B. Cardiovascular Event Prevention (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. 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;
3. Documentation of member's current body weight in kg;
4. Prescriber attestation that member is currently receiving cardiovascular standard of care management (*see Appendix E);*
5. Wegovy is not prescribed concurrently with other semaglutide-containing products or any other GLP-1 receptor agonist(s);
6. Documentation that member is actively enrolled in a physician-directed program that involves a reduced calorie diet, increased physical activity, and behavioral modification adjunct to therapy;
7. 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),* maintenance dose is ≥ 1.7 mg once weekly.

Approval duration: 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

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
CVD: cardiovascular disease
FDA: Food and Drug Administration
GLP-1: glucagon-like peptide-1
PAD: peripheral arterial disease

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), known hypersensitivity reaction to semaglutide or to any of the excipients in Wegovy
- Boxed warning(s): risk of thyroid C-cell tumors

Appendix D: General Information – Weight Management

- 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.
- The Endocrine Society practice guideline on pharmacological management of obesity states that a weight loss < 5% after 3 months of therapy indicates the weight loss medication is ineffective. In such cases, the Endocrine Society recommends that the medication be discontinued and alternative medications be considered.
- BMI cut-offs (95th percentile) for obesity by age and sex for pediatric patients aged ≥ 12 years:

	95th Percentile BMI Value	
Age (in years)	**Male**	**Female**
12	24.2	25.2
12.5	24.7	25.7
13	25.1	26.3
13.5	25.6	26.8
14	26.0	27.2
14.5	26.4	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.5	28.9
16.5	27.9	29.3
17	28.2	29.6
17.5	28.6	30.0

Appendix E: General Information – Cardiovascular Event Prevention

- In the SELECT trial, symptomatic PAD was defined as intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease.
- Cardiovascular standard of care management:
  - Dyslipidemia management may include a statin, ezetimibe, fibrate, omega-3 fatty acids, or proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors.
  - Hypertension management may include an angiotensin-converting enzyme (ACE) inhibitor, angiotensin receptor blocker (ARB), calcium channel blocker, or a thiazide diuretic.
  - Non-acute management of myocardial infarction may include beta-blockers, long-term dual antiplatelet therapy with aspirin and a $P2Y_{12}$ receptor blocker, statins (high-intensity), ACE inhibitors, aldosterone antagonist, and/or nitroglycerin.
  - Secondary prevention therapies for ischemic stroke may include antithrombotic therapy, antihypertensive therapy, and/or statins.
  - Secondary prevention therapies for PAD may include antiplatelet therapy, antithrombotic therapy, lipid-lowering therapy (e.g., statins), antihypertensive therapy, and/or glycemic control therapy (e.g., metformin, sulfonylurea, GLP-1 receptor agonists, sodium-glucose cotransporter-2 [SGLT2] inhibitors, etc.).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Weight management, CV event prevention	<u>Adults</u> SC once weekly following 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*: 1.7 mg or 2.4 mg If patients do not tolerate a dose during dose escalation, consider delaying dose escalation for 4 weeks. The maintenance dosage in adults is either 2.4 mg (recommended) or 1.7 mg once weekly. <u>Pediatric patients aged ≥ 12 years old</u> SC once weekly following 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	2.4 mg/week

Indication	Dosing Regimen	Maximum Dose
	If patients do not tolerate a dose during dose escalation, consider delaying dose escalation for 4 weeks. If patients do not tolerate the 2.4 mg once-weekly maintenance dose, the maintenance dose may be reduced to 1.7 mg once weekly. Discontinue Wegovy if the patient cannot tolerate the 1.7 mg dose. ** 0.25 mg. 0.5 mg, and 1 mg once-weekly dosages are initiation and escalation dosages and are not approved as maintenance dosages*	

VI. Product Availability

Pre-filled, single-dose pens: 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.; March 2024. Available at: www.wegovy.com. Accessed May 10, 2024.

Weight Management

2. Hampl SE, Hassink SG, Skinner AC, et al. Clinical practice guideline for the evaluation and treatment of children and adolescents with obesity [published online ahead of print, 2023 Jan 9]. Pediatrics. 2023;e2022060640.
3. Weghuber D, Barrett T, Barrientos-Pérez M, et al. Once-weekly semaglutide in adolescents with obesity. N Engl J Med. 2022;387(24):2245-2257.
4. 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.
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): 42-362.

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6. ClinicalTrails.Gov Semaglutide effects on heart disease and stroke in patients with overweight or obesity (SELECT). Available at: https://classic.clinicaltrials.gov/ct2/show/NCT03574597. Accessed May 10, 2024
7. Lincoff AM, Brown-Frandsen K, Colhoun HM, et al. Semaglutide and cardiovascular outcomes in obesity without diabetes. N Engl J Med. December 2023; 389(24): 2221-2232.
8. Ryan DH, Lingvay I, Colhoun HM, et al. Semaglutide effects on cardiovascular outcomes in people with overweight or obesity (SELECT) rationale and design. American Heart Journal 2022;229:80-80.
9. Lingvay I, Brown-Frandsen K, Colhoun HM et al. Semaglutide for cardiovascular event reduction in people with overweight or obesity: SELECT study baseline characteristics. Obesity 2023;31:111-122.

10. Gulati M, Levy PD, Mukherjee D, et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the evaluation and diagnosis of chest pain: Executive summary: A report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. Circulation 2021;144(22):e336-e367.
11. Kleindorfer DO, Chaturvedi S, Cockroft KM, et al. 2021 Guideline for the prevention of stroke in patients with stroke and transient ischemic attack: A guideline from the American Heart Association/American Stroke Association. Stroke 2021;52(7):e364-e467.
12. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the management of patients with lower extremity peripheral artery disease: Executive summary: A report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines. Circulation 2017;135(12):e686-e725.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	06.15.21	08.21
3Q 2022 annual review: no significant changes; references reviewed and updated.	03.30.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.29.22	
RT4: updated indication with pediatric expansion of age ≥ 12 years; removed continued therapy criterion of BMI ≥ 25 kg/m^2; specified continuation therapy positive response criterion of ≥ 5% loss of baseline body weight for adults and BMI for pediatric members.	02.14.23	05.23
3Q 2023 annual review: no significant changes; added HCPCS code; references reviewed and updated.	04.25.23	08.23
Per updated prescribing information, updated dosing to allow and require ≥ 1.7 mg once weekly maintenance dose.	09.05.23	
For documentation of weight loss program, added members has been actively enrolled for at least 6 months, added a weight loss program that also involves behavioral modification, clarified weight loss program to be either a Health Net approved weight loss program or a weight loss program recommended by the prescriber.	12.12.23	02.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
RT2: criteria updated with newly approved indication per FDA labeling for cardiovascular event prevention: updated limitations of use per PI; revised age to ≥ 18 years; added criteria for members with concurrent T2DM, failure of Ozempic, Trulicity and Victoza and provider documentation for medical necessity if currently receiving a GLP-1 receptor agonist; added requirement for documentation of a provider-directed program with a reduced calorie diet and increased physical activity adjunct to therapy; added requirement for documentation of baseline body weight in kg and current body weight in kg to initial and continued criteria, respectively; revised continuation therapy positive response criterion to member has lost ≥ 5% of body weight if first renewal request and member has lost and/or maintained weight loss on therapy if second or subsequent renewal request; revised approval duration from "6 months" to "6 months or to the member's renewal date, whichever is longer"; references reviewed and updated.	04.09.24	05.24
3Q 2024 annual review: no significant changes; references reviewed and updated.	05.10.24	08.24

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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