Clinical Policy: Semaglutide (Wegovy)

Reference Number: NE.PMN.295
Effective Date: 07.01.2024
Last Review Date: 02.26
Line of Business: Nebraska Total Care Medicaid

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 injection 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.
- 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.

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.

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 Nebraska Total Care that Wegovy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Age is 45 years to 74 years;

2. The member does not have a diagnosis of type 1 or type 2 diabetes mellitus;
3. The member does not have HgA1c ≥ 6.5%
4. The member has one of the following (a or b):
   a. An initial BMI of ≥ 27 kg/m^2 and at least one weight-related comorbid condition (for example, hypertension, dyslipidemia, coronary artery disease, or sleep apnea)
   b. An initial BMI of ≥ 30 kg/m^2
5. Documentation supports member has completed participation in a weight loss program directed by a physician, nurse practitioner, or physician assistant, that involves a reduced calorie diet, increased physical activity, and behavioral modification for at least 6 months;
6. Member has demonstrated compliance with prescribed cardiovascular medications (*see Appendix D)*;
7. Member has at least one of the following established CVD (a, b, or c):
   a. History of myocardial infarction;
   b. History of stroke (ischemic or hemorrhagic stroke;
   c. Symptomatic peripheral arterial disease (PAD), as evidenced by one of the following (i, ii, or iii):
      i. Intermittent claudication with ankle -brachial index <0.85
      ii. Peripheral arterial revascularization procedure
      iii. Amputation due to atherosclerotic disease
8. Wegovy is not prescribed concurrently with other semaglutide-containing products or any other GLP-1 receptor agonist(s) or DPP-4 inhibitors
9. Member does not have any of the following:
   a. NYHA Class IV Heart failure
   b. ESRD or Dialysis
   c. History of chronic pancreatitis or presence of acute or chronic pancreatitis
   d. Personal or first-degree relative(s) history of multiple endocrine neoplasia type 2 or medullary thyroid carcinoma
   e. Known or suspected hypersensitivity to the product
   f. Pregnant, breastfeeding, or intends to become pregnant, or is of childbearing potential and not using a highly effective contraceptive method.

Approval duration: 6 months

B. Metabolic Dysfunction – Associated Steatohepatitis (MASH) (must meet all):

1. Diagnosis of MASH with moderate to advanced liver fibrosis and has a fibrosis stage of F2 or F3 as confirmed by ONE of the following (a, b, c, OR d):
   a. Liver stiffness measurement (LSM) by vibration-controlled transient elastography (VCTE) e.g., FibroScan within the past 6 months
   b. LSM by magnetic resonance elastography (MRE) within the past 6 months
   c. Non-invasive test (NIT) of Enhanced Liver Fibrosis (ELF) test within the past 6 months
   d. Liver biopsy within the past 12 months;
2. Request is for Wegovy injection;
3. Prescribed by or in consultation with a hepatologist, endocrinologist, or gastroenterologist;
4. Age ≥ 18 years;

5. Documentation supports member has completed participation in a weight loss program directed by a physician, nurse practitioner, or physician assistant, that involves a reduced calorie diet, increased physical activity, and behavioral modification for at least 6 months;
6. The member is currently on and will continue to follow ALL of the following (a, b, c and d):
    a. Behavioral modification
    b. Reduced calorie diet
    c. Increased physical activity
    d. Compliance with medical management for metabolic risk factors (i.e. hypertension, diabetes mellitus, dyslipidemia);
7. For members with concurrent type 2 diabetes mellitus, member has tried and failed Ozempic injection as evidenced by paid claims;
8. The member does not have any of the following (a, b. and c):
    a. Personal or family history of medullary thyroid carcinoma
    b. Personal history of multiple endocrine neoplasia type 2 (MEN2)
    c. Known or suspected hypersensitivity to the product;
9. Wegovy injection will not be prescribed or used in combination with any of the following (a, b and c):
    a. Resmetirom (Rezdiffra)
    b. GLP-1 receptor agonists (i.e. Trulicity, Ozempic, Victoza, Mounjaro, Rybelsus, exenatide)
    c. DPP-4 inhibitors (i.e. Januvia, Tradjenta, Onglyza).

Approval duration: 6 months

C. Weight Management

1. Use of Wegovy for the treatment of weight management is a benefit exclusion and will not be authorized.

Approval duration: Not applicable

D. 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, the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
    b. For drugs NOT on the formulary, the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; 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.PMN.53 for Medicaid.

II. Continued Therapy

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

1. The member has completed at least 3 months of therapy with the requested agent at a stable maintenance dose
2. Member is responding positively to therapy as evidenced by one of the following (a or b):
   a. If this is the first request renewal, 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 that member is actively enrolled in a weight loss program that involves a reduced calorie diet, increased physical activity, and behavioral modification adjunct to therapy
4. Member has demonstrated compliance with prescribed cardiovascular medications
5. The member does not have either of the following (a or b):
   a. A diagnosis of Type 1 or Type 2 diabetes mellitus
   b. HgA1c > 6.5%
6. Wegovy is not prescribed concurrently with other semaglutide-containing products or any other GLP-1 receptor agonist(s) or DPP-4 inhibitors;
7. Member does not have any of the following:
   a. NYHA Class IV Heart failure
   b. ESRD or Dialysis
   c. History of chronic pancreatitis or presence of acute or chronic pancreatitis
   d. Personal or first-degree relative(s) history of multiple endocrine neoplasia type 2 or medullary thyroid carcinoma
   e. Known or suspected hypersensitivity to the product
   f. Pregnant, breastfeeding, or intends to become pregnant, or is of childbearing potential and not using a highly effective contraceptive method

Approval duration: 12 months

B. Metabolic Dysfunction – Associated Steatohepatitis (MASH) (must meet all):

1. Request is for Wegovy Injection;
2. Member is on a stable maintenance dose;
3. The member has demonstrated a positive clinical response to therapy i.e., improvement in or stabilization of fibrosis;
4. The member has not progressed to cirrhosis;
5. The member is currently on and will continue to follow all of the following (a, b, c AND d):
   a. Behavioral modification
   b. Reduced calorie diet
   c. Increased physical activity
   d. Compliance with medical management for metabolic risk factors (i.e. hypertension, diabetes mellitus, dyslipidemia);
6. Prescribed by or in consultation with a hepatologist, endocrinologist, or gastroenterologist;
7. Wegovy injection will not be prescribed or used in combination with any of the following (a, b and c):
   a. Resmetirom (Rezdiffra)

b. GLP-1 receptor agonists (i.e. Trulicity, Ozempic, Victoza, Mounjaro, Rybelsus, exenatide)
c. DPP-4 inhibitors (i.e. Januvia, Tradjenta, Onglyza);

8. The member does not have any of the following (a, b, c and d):
   a. Personal or family history of medullary thyroid carcinoma
   b. Personal history of multiple endocrine neoplasia type 2 (MEN2)
   c. Known or suspected hypersensitivity to the product
   d. intolerance to the maintenance dose per labeling.

Approval duration: 12 months

C. Weight Management

1. Use of Wegovy for the treatment of weight management is a benefit exclusion and will not be authorized.

Approval duration: Not applicable

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 policies – HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

V. 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

- 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), angiotensin converting enzyme 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.).

VI. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CV event prevention	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. 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*	2.4 mg/week

VII. Product Availability

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

VIII. References

1. Wegovy Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; March 2024. Available at: www.wegovy.com. Accessed February 3, 2026
2. 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 April 10, 2025.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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
Policy created	05.24
Annual review: no significant changes; spelling errors corrected, references reviewed and updated.	05.25
Annual review; added criteria for new and continued therapy for the new indication for MASH; Added requirement that Wegovy cannot be used in combination with DPP-4 for MACE indication on initial and continued therapy; updated references.	02.26

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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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.