Clinical Policy: Semaglutide (Wegovy)

Reference Number: NH.PMN.295
Effective Date: 06.24
Last Review Date: 04.26
Line of Business: 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 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.
- For the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known alcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults.
- 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. Cardiovascular Event Prevention (must meet all)**:**

1. Member has established cardiovascular disease (must submit clinical chart notes);
2. Member is at risk for major cardiovascular events (CV death, non-fatal myocardial infarction, or non-fatal stroke) (must submit clinical chart notes validating risk);
3. Member does NOT have a diagnosis of Type 1 or Type 2 Diabetes Mellitus;
4. Age ≥ 18 years;
5. BMI ≥ 25 kg/m^2;
6. Prescriber attestation that member is currently receiving cardiovascular standard of care management (*see Appendix D)*;
7. Wegovy is not prescribed concurrently with other semaglutide-containing products or any other GLP-1 receptor agonist(s);

8. Documentation supports member's participation in a physician-directed weight loss program that involves a reduced calorie diet, increased physical activity, and behavioral modification that meets both of the following (must submit clinical chart notes) (a and b):
    a. Been actively enrolled in a physician-directed weight loss program for at least 6 months;
    b. Will continue to be enrolled in a physician-directed weight loss program while concomitantly prescribed Wegovy;
9. Documentation of member's baseline body weight in kg;
10. 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

B. 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

C. Metabolic Dysfunction-Associated Steatohepatitis (must meet all)**:**

1. Diagnosis of MASH (formerly known as NASH) (must submit clinical chart notes);
2. Prescribed by or in consultation with a hepatologist or gastroenterologist;
3. Age ≥ 18 years;
4. MASH with stage F2 or F3 fibrosis is confirmed by one of the following (must submit clinical chart notes) (a or b):
    a. Liver biopsy within the last 3 years;
    b. Both of the following assessments within the last 6 months (i and ii; *see Appendix E for examples*):
        i. Serum-based assessment (e.g., fibrosis-4 [FIB-4], NAFLD fibrosis score [NFS], enhanced liver fibrosis test [ELF]);
        ii. Imaging-based assessment (e.g., vibration-controlled transient elastography [VCTE], magnetic resonance-based elastography [MRE], magnetic resonance imaging–proton density fat fraction [MRI-PDFF]);
5. Documentation supports member's participation in a physician-directed weight loss program that involves a reduced calorie diet, increased physical activity, and behavioral modification that meets both of the following (must submit clinical chart notes) (a and b):
    a. Been actively enrolled in a physician-directed weight loss program for at least 6 months;
    b. Will continue to be enrolled in a physician-directed weight loss program while concomitantly prescribed Wegovy;
6. Prescriber attestation that member is currently receiving standard of care management for concomitant related conditions, including T2DM, dyslipidemia, and hypertension;

7. Wegovy is not prescribed concurrently with Rezdiffra™;
8. Wegovy is not prescribed concurrently with other semaglutide-containing products or any other GLP-1 receptor agonist(s);
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

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 PDL, the no coverage criteria policy CP.PMN.255; or
    b. For drugs NOT on the PDL, the non-formulary policy: CP.PMN.16; 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: CP.PMN.53.

II. Continued Therapy

A. 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 (must submit clinical chart notes) (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 of member's current body weight in kg;
4. Prescriber attestation that member is currently receiving cardiovascular standard of care management (*see Appendix D);*
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 (must submit clinical chart notes);
7. Request meets both of the following (a and b):
    a. Dose does not exceed 2.4 mg once weekly;
    b. Member is able to tolerate a maintenance dose of > 1.7 mg once weekly after at least 17 weeks of Wegovy therapy.

Approval duration: 12 months

B. 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

C. Metabolic Dysfunction-Associated Steatohepatitis (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. After at least 12 months of therapy, member is responding positively to therapy as evidenced by, including but not limited, improvement in <u>any</u> of the following parameters (must submit clinical chart notes):
   a. Improvement in fibrosis ≥ 1-stage from baseline with no worsening of MASH (i.e., no worsening of hepatocellular ballooning, lobular inflammation, or steatosis);
   b. Resolution of MASH with no worsening of fibrosis;
   c. No increase in fibrosis stage and no worsening of MASH from baseline;
3. Prescriber attestation that member is currently receiving standard of care management for concomitant related conditions, including T2DM, dyslipidemia, and hypertension;
4. 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 (must submit clinical chart notes);
5. Wegovy is not prescribed concurrently with Rezdiffra;
6. Wegovy is not prescribed concurrently with other semaglutide-containing products or any other GLP-1 receptor agonist(s);
7. Request meets both of the following (a and b):
   a. Dose does not exceed 2.4 mg once weekly;
   b. Member is able to tolerate a maintenance dose of ≥ 1.7 mg once weekly after at least 17 weeks of Wegovy therapy.

Approval duration: 12 months

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 PDL, the no coverage criteria policy: CP.PMN.255; or
   b. For drugs NOT on the PDL, the non-formulary policy: CP.PMN.16; 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: CP.PMN.53.

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 – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACE: angiotensin-converting enzyme
ARB: angiotensin receptor blocker
BMI: body mass index
CVD: cardiovascular disease
DPP-4: dipeptidyl peptidase 4
ELF: enhanced liver fibrosis
FDA: Food and Drug Administration
FIB-4: fibrosis-4
GLP-1: glucagon-like peptide-1
MASH: metabolic dysfunction-associated steatohepatitis
MASLD: metabolic dysfunction–associated steatotic liver disease
MRE: magnetic resonance elastography
NASH: non-alcoholic steatohepatitis
NFS: NAFLD fibrosis score
PAD: peripheral arterial disease
PCSK9: proprotein convertase subtilisin/kexin type 9
SGLT2: sodium-glucose co-transporter
T2DM: type 2 diabetes mellitus
VCTE: vibration-controlled transient elastography

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Ozempic® (semaglutide)	0.25 mg to 2 mg SC once weekly, increased no more frequently than every 4 weeks For patients with type 2 diabetes and chronic kidney disease, the dosage should be increased to the maintenance dose of 1 mg once weekly after at least 4 weeks on the 0.5 mg dosage	2 mg/week
Rybelsus® (semaglutide)	Formulation R1:* Initial dose: 3 mg PO QD. After 30 days on the 3 mg dose, increase to 7 mg PO QD. May increase to 14 mg PO QD if needed after at least 30 days on the 7 mg dose Formulation R2:* Initial dose: 1.5 mg PO QD. After 30 days on the 1.5 mg dose, increase to 4 mg PO QD. May increase to 9 mg PO QD if needed after at least 30 days on the 4 mg dose **Formulations R1 and R2 are not substitutable on a mg per mg basis. Use either formulation, but do not use both formulations at the same time. Patients may switch between formulations after 30 days of treatment (i.e., after the*	Formulation R1: 14 mg/day Formulation R2: 9 mg /day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	initiation phase). When switching between the formulations, initiate the other formulation the day after discontinuing the previous formulation	
Trulicity® (dulaglutide)	0.75 mg to 1.5 mg SC once weekly May increase to 3 mg once weekly if needed after at least 4 weeks on 1.5 mg dose. May further increase to 4.5 mg once weekly if needed after at least 4 weeks on 3 mg dose.	4.5 mg/week
liraglutide (Victoza®)	Initial: 0.6 mg SC QD for 7 days Maintenance: 1.2 mg to 1.8 mg SC QD	1.8 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

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 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), 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.).

Appendix E: General Information – MASH

- In June 2023, the nomenclature describing NASH and nonalcoholic fatty liver disease (NAFLD) was changed by an international liver disease societies consensus to MASH and metabolic dysfunction-associated steatotic liver disease (MASLD), respectively.

- MASH is defined by the presence of ≥ 5% hepatic steatosis with inflammation and hepatocyte injury (hepatocyte ballooning), with or without evidence of liver fibrosis.
- Standard of care management for concomitant related conditions:
  - T2DM management may include metformin, GLP-1 receptor agonist, SGLT2 inhibitor, sulfonylurea, dipeptidyl peptidase 4 (DPP-4) inhibitors, pioglitazone, or insulin.
  - 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.
- Examples of liver assessment scores combining serum-based and imaging-based tests to help identify MASH:
  - FAST score, as measured by FibroScan and serum aspartate aminotransferase (AST);
  - MAST score as measured by MRI-PDEF, MRE, and serum AST;
  - MEFIB score, as measured by FIB-4 and MRE.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CV event prevention, MASH	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. For MASH, the maintenance dosage is 2.4 mg once daily. If patients do not tolerate 2.4 mg once weekly, the dosage can be decreased to 1.7 mg once weekly. Consider reescalation to 2.4 mg once weekly. For CV event prevention, the maintenance dosage in adults is either 2.4 mg (recommended) or 1.7 mg once weekly. ** 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

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.; August 2025. Available at: www.wegovy.com. Accessed August 23, 2025.
   Cardiovascular Event Prevention
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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.
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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.
   MASH
9. Sanyal AJ, Newsome PN, Kliers I, et al. Phase 3 trial of semaglutide in metabolic dysfunction-associated steatohepatitis. N Engl J Med. 2025;292(21):2089-2099.
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11. American Diabetes Association Professional Practice Committee. 4. Comprehensive medical evaluation and assessment of comorbidities: Standards of Care in Diabetes-2024. Diabetes Care. 2024;47(Suppl 1):S52-S76.
12. Cusi K, Isaacs S, Barb D, et al. American Association of Clinical Endocrinology (AACE) clinical practice guideline for the diagnosis and management of nonalcoholic fatty liver disease in primary care and endocrinology clinical settings: co-sponsored by the American Association for the Study of Liver Diseases (AASLD). Endocr Pract. 2022;28(5):528-562.
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14. Rinella ME, Lazarus JV, Ratziu V, et al. A multisociety Delphi consensus statement on new fatty liver disease nomenclature. Ann Hepatol. 2024;29(1):101133. 8. Sterling RK, Duarte-Rojo A, Patel K, et al. AASLD Practice Guideline on imaging-based noninvasive liver disease assessment of hepatic fibrosis and steatosis. Hepatology. Published online March 15, 2024.

15. Younossi ZM, Zelber-Sagi S, Lazarus JV, et al. Global consensus recommendations for metabolic dysfunction-associated steatotic liver disease and steatohepatitis. Gastroenterology 2025;1-16.
16. Cusi K, Abdelmalek MF, Apovian CM, et al. Metabolic dysfunction-associated steatotic liver disease (MASLD) in people with diabetes: The need for screening and early intervention. A consensus report of the American Diabetes Association. Diabetes Care 2025;48:1057-1082.

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	06.01.24	06.24
Annual review, no significant changes	04.25	04.25
Adjusted to excluded benefit for weight management as of 1/1/26. Added new indication for MASH – criteria updated per FDA labeling: revised biopsy lookback period from 6 months to 3 years per AASLD guidance; for imaging-based biomarker examples, replaced Fibroscan with VCTE as FibroScan is an example of VCTE; moved MAST, FAST, and MEFIB examples of non-invasive diagnostic tests to Appendix E; for members with concurrent T2DM, for diet and exercise criterion, clarified that member continues diet and exercise with concomitant Wegovy; for continued therapy, moved location of criterion regarding tolerance to maintenance dose of ≥ 1.7 mg once weekly after at least 17 weeks of Wegovy therapy; references reviewed and updated.	10.25	10.25
Added “must submit clinical chart notes”. Adjusted cardiovascular event prevention criteria.	11.25	11.25
Annual review: No significant changes	04.26	04.26

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.