Effective Date: 05/09/2024
Current Effective Date: 05/09/2024
Last P&T Approval/Version: 04/24/2024
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Policy Number: C27682-A

Wegovy (semaglutide) NC

PRODUCTS AFFECTED

Wegovy (semaglutide)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Overweight/obesity, History of heart attack, stroke, or peripheral artery disease

REQUIRED MEDICAL INFORMATION:
In states where weight loss drugs are a benefit exclusion, Wegovy (semaglutide) is considered a benefit exclusion for all indications, including but not limited to weight reduction and chronic weight management, weight reduction to lower risk for repeat cardiovascular event in individuals with history of prior heart attack or stroke, and so on.

Weight loss drugs are benefit exclusions as outlined in the Marketplace Evidence of Coverage.
MOLINA REVIEWER NOTE: For New Mexico Marketplace, please see Appendix.

Wegovy (semaglutide) is excluded from coverage for overweight/obesity per Social Security 1927 (d)(3)(A).
A State may exclude or otherwise restrict coverage of a covered outpatient drug if the drug is contained in the list:

- **Agents when used for anorexia, weight loss, or weight gain.**
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.

- Agents when used for the symptomatic relief of cough and colds.
- Agents when used to promote smoking cessation.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A), agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.
- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- Barbiturates.
- Benzodiazepines.
- Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
N/A

PRESCRIBER REQUIREMENTS:
N/A

AGE RESTRICTIONS:
N/A

QUANTITY:
N/A

PLACE OF ADMINISTRATION:
N/A

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Anti-Obesity GLP-1 Receptor Agonist

FDA-APPROVED USES:
Indicated in combination with a reduced calorie diet and increased physical activity:

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

Limitations of Use: Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
New Mexico (Source: New Mexico)
"Weight Loss Programs: Covered: Dietary evaluations and counseling for the medical management of morbid obesity and obesity. *Prescription drugs medically necessary for the treatment of obesity and morbid obesity are also covered.* See also, benefits described under Bariatric Surgery. Not Covered: The following are not covered: Treatments and medications for the purpose of weight reduction or control, except for medically necessary treatment of morbid obesity and obesity. Exercise equipment, videos, personal trainers, club members and weight reduction programs."
Phendimetrazine and phentermine are on formulary.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
The safety and efficacy of Wegovy (semaglutide) for secondary prevention of cardiovascular disease in those who are overweight/obese without diabetes was determined by a multi-national, multi-center, placebo-controlled, double-blind trial designed to determine the effect of Wegovy relative to placebo on major adverse cardiovascular events (MACE) when added to current standard of care, which included management of CV risk factors and individualized healthy lifestyle counseling (including diet and physical activity). The primary endpoint, MACE, was the time to first occurrence of a three-part composite outcome which included cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke. All patients were 45 years or older, with an initial BMI of 27 kg/m2 or greater and established cardiovascular disease (prior myocardial infarction, prior stroke, or peripheral arterial disease). Patients with a history of type 1 or type 2 diabetes were excluded. Concomitant CV therapies could be adjusted, at the discretion of the investigator, to ensure participants were treated according to the current standard of care for patients with established cardiovascular disease. In this trial, 17,604 patients were randomized to Wegovy or placebo. At baseline, cardiovascular disease and risk factors were managed with lipid lowering therapy (90%), platelet aggregation inhibitors (86%), angiotensin converting enzyme inhibitors or angiotensin II receptor blockers (74%), and beta blockers (70%). Wegovy was found to significantly reduce the risk for first occurrence of MACE compared to placebo with an estimated hazard ratio (95% CI) of 0.80 (0.72, 0.90). The primary endpoint occurred in 6.5% of patients treated with Wegovy vs 8.0% treated with placebo over an average treatment exposure period of 34 months (Number Needed to Treat (NNT) = 67).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Wegovy (semaglutide) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Wegovy (semaglutide) include: a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2), prior serious hypersensitivity reaction to semaglutide or to any excipients in Wegovy (serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with Wegovy), avoid in patients with a history of suicidal attempts or active suicidal ideation.

OTHER SPECIAL CONSIDERATIONS:
Wegovy (semaglutide) has a Black Box Warning for 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. Wegovy is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Wegovy and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Wegovy.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Wegovy SOAJ 0.25MG/0.5ML
Wegovy SOAJ 0.5MG/0.5ML
Wegovy SOAJ 1MG/0.5ML
Wegovy SOAJ 1.7MG/0.75ML
Wegovy SOAJ 2.4MG/0.75M

REFERENCES

1. Wegovy (semaglutide) injection, for subcutaneous use [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; March 2024.
2. Smith, S. C., Benjamin, E. J., Bonow, R. O., Braun, L. T., Creager, M. A., Franklin, B. A., … Taubert, K. A. (2011). AHA/ACCF Secondary Prevention and Risk Reduction Therapy for Patients With Coronary and Other Atherosclerotic Vascular Disease: 2011 Update. Journal of the American College of Cardiology, 58(23), 2432–2446. https://doi.org/10.1016/j.jacc.2011.10.824
3. A. Michael Lincoff, Kirstine Brown-Frandsen, Colhoun, H. M., Deanfield, J., Emerson, S. S., Sille Esbjerg, … Ryan, D. H. (2023). Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. The New England Journal of Medicine, 389(24). https://doi.org/10.1056/nejmoa2307563

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q2 2024