Original Effective Date: 05/09/2024
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Last P&T Approval/Version: 04/24/2024
Next Review Due By: 01/2025
Policy Number: C27635-A

Wegovy (semaglutide) MNR

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:
Reduce risk of major adverse cardiovascular events

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CARDIOVASCULAR RISK REDUCTION:
   1. Documented diagnosis of cardiovascular disease as evidenced by history of myocardial infarction, history of stroke (ischemic or hemorrhagic), or symptomatic peripheral arterial disease (intermittent claudication, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)

AND

2. Documentation member's BMI is 27 kg/m2 or greater
   AND
3. Prescriber attests or clinical reviewer has found member is currently receiving cardiovascular risk reduction standard of care (e.g., diet, physical activity, aspirin, lipid-lowering drug, antihypertensive)
   AND
4. Documentation member does NOT have a diagnosis of Type 1 or Type 2 diabetes
   AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [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.]

B. OVERWEIGHT/OBESITY:
MOLINA REVIEWER NOTE: PLEASE FIRST REFER TO STATE AND LINE OF BUSINESS EXPLANATION OF BENEFITS TO DETERMINE IF WEIGHT LOSS IS A COVERED BENEFIT.
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:

A. CARDIOVASCULAR RISK REDUCTION:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND

3. Prescriber attests or clinical reviewer has found member continues to receive cardiovascular risk reduction standard of care (e.g., diet, physical activity, aspirin, lipid-lowering drug, antihypertensive)
   AND
4. Documentation member does NOT have a diagnosis of Type 1 or Type 2 diabetes

B. OVERWEIGHT/OBESITY: N/A

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified cardiologist
MOLINA REVIEWER NOTE: Special consideration should be given if the requesting provider attests a specialist is unavailable in member's vicinity, if specialist appointments are not available timely, and/or the provider requesting is actively managing the member's cardiovascular regimen.
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
1.7mg or 2.4mg once weekly
NOTE: The 0.25 mg, 0.5 mg, and 1 mg once-weekly dosages are initiation and escalation dosages and are not approved as maintenance dosages.

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

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:
None

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).

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/0.75ML

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