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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, Metabolic dysfunction-associated steatohepatitis (MASH)

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. METABOLIC DYSFUNCTION-ASSOCIATED STEATOHEPATITIS (MASH):
1. Documented diagnosis of metabolic dysfunction-associated steatohepatitis (MASH)
AND
2. Documentation diagnosis was confirmed by ONE of the following [DOCUMENTATION REQUIRED]:
   a) Liver biopsy
   OR
   b) Imaging (FibroScan, magnetic resonance elastography [MRE]), biomarker testing (FIB-4, NFS, ELF), or relevant scoring tool (FAST, MAST, MEFIB) [See Appendix]
AND
3. Documentation member has moderate to advanced liver fibrosis stage F2 or F3
NOTE: Wegovy is not indicated for stage 4, severe, cirrhotic liver fibrosis
AND
4. Documentation that member is receiving standard of care for metabolic risk factors as applicable (e.g., hypertension, type 2 diabetes, dyslipidemia)
AND
5. Appropriate lifestyle modifications have been implemented, including adherence to healthy diet to promote weight loss, regular physical activity, and avoidance of alcohol that will continue during treatment, supported by documentation of counseling in chart notes
AND
6. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., steatosis, fibrosis, etc.) [DOCUMENTATION REQUIRED]
AND
7. FOR MEMBERS WITH TYPE 2 DIABETES: Documented trial and inadequate response to ALL formulary GLP1 or GLP1/GIP agents indicated for diabetes. Inadequate response is defined as not achieving expected A1c lowering goal while adherent to therapy and not achieving member individualized goals for therapy (e.g., A1c, weight management, maintaining blood glucose within the target range, preventing or reducing hospitalization due to hyper-or hypo-glycemic events, etc.).
AND
8. 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.]

C. 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. METABOLIC DYSFUNCTION-ASSOCIATED STEATOHEPATITIS (MASH):
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. Documentation member has NOT progressed to liver fibrosis stage 4 (F4)

AND

4. Documentation of positive clinical response as demonstrated by low disease activity, stabilization, and/or improvements in the condition's signs and symptoms (e.g., improved steatosis, improved fibrosis, improvement in fibrosis score, lack of disease progression, etc.) [DOCUMENTATION REQUIRED]
   AND
5. Appropriate lifestyle modifications have been implemented, including adherence to healthy diet to promote weight loss, regular physical activity, and avoidance of alcohol that will continue during treatment, supported by documentation of counseling in chart notes

C. OVERWEIGHT/OBESITY: N/A

DURATION OF APPROVAL:
Cardiovascular Risk Reduction: Initial authorization: 6 months, Continuation of Therapy: 12 months
MASH: Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Cardiovascular Risk Reduction: Prescribed by or in consultation with a board-certified cardiologist
MASH: Prescribed by or in consultation with a board-certified gastroenterologist or hepatologist
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 or metabolic 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.

Maximum Quantity Limits - For MASH, the maintenance dose is 2.4 mg once weekly. If 2.4 mg once weekly is not tolerated, the dosage can be decreased to 1.7 mg once weekly. For other indication, the maintenance dosage is either 2.4 mg (recommended) or 1.7 mg once weekly.

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

Drug and Biologic Coverage Criteria

- 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
- 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
  The indication for MASH is approved under accelerated approval based on improvement of MASH and fibrosis. Continued approval for this indication may be contingent upon the verification and description of clinical benefit in a confirmatory trial.

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:

AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease 2023 https://journals.lww.com/hep/Fulltext/2023/05000/AASLD_Practice_Guidance_on_the_clinical_assessment.31.aspx

Table 5 Parameters for the noninvasive assessment of NAFLD according to clinical context of use

	Cut point		
Modality type	**Likely**	**Unlikely**	**Strengths/limitations, references/caveats**
Identification of hepatic steatosis			
Imaging			
Ultrasound	"Detected"	NA	Semiquantitative assessment: mild/moderate/severe; low sensitivity with less severe steatosis[322]; steatosis can have similar echo characteristics as advanced fibrosis
FibroScan: CAP	≥288 dB/min		Limited accuracy for quantification[323]
MRI-PDFF	≥5%	<5%	Most sensitive across spectrum of steatosis; accurate to assess dynamic change[324]
Identification of "at-risk" NASH			
FAST	≥0.67	<0.35	≤0.35 (sensitivity 90%), ≥0.67 (specificity 90%); in validation cohorts, the PPV of FAST ranged between 0.33 and 0.81[28,325]
MAST	≥0.242	≤0.165	0.242 (specificity 90%),[326] 0.165 (sensitivity 90%)[326]
MEFIB	FIB-4 ≥1.6 plus MRE ≥3.3 kPa	FIB-4 <1.6 plus MRE <3.3 kPa	Sequential approach identifies patients with at least stage 2 fibrosis with >90% PPV[327]
cT1	≥875 ms	<825 ms	Requires further validation[328]
Detection of advanced fibrosis			
Serum			
FIB-4	≥2.67	<1.3	No added cost[117,329,330]; not accurate in age <35 y and lower rule-out threshold among high-risk individuals who have high pretest probability
NFS	≥0.672	<−1.44	No added cost; not accurate in age <35 y, people with obesity and/or type 2 diabetes[117,329,330]
ELF	≥9.8	<7.7	Blood test sent to a reference laboratory[331]; cost
FIBROSpect II	≥17	<17	Blood test sent to a reference laboratory[332]; cost
Imaging			
VCTE	≥12 kPa	<8 kPa	Point of care[4]
ARFI	≥1.34	<1.3	Cut points not well validated[333]
SWE	≥12 kPa	<8 kPa	Cut points not well validated[488]
MRE	≥3.63 kPa	<2.55 kPa	MRE LSM ≥3.63 kPa (associated with advanced fibrosis, AUROC of 0.93)[334]
Diagnosis of cirrhosis (rule-in or rule-out)	Rule-in	Rule-out	
CPR			
FIB-4	≥3.48	<1.67	90% specificity cut point for ruling-in and 90% sensitivity for ruling out cirrhosis, respectively[4,335]
ELF	≥11.3	<7.7	ELF ≥11.3 is associated with increased risk of hepatic decompensation among patients with cirrhosis[331]
Imaging			
VCTE	≥20 kPa	<8 kPa	LSM by VCTE ≥20 kPa is associated with cirrhosis, but for ruling out, cirrhosis optimal cut point is <8 kPa[4]
MRE	≥5 kPa	<3 kPa	LSM by MRE ≥5 kPa has a very good (approaches 95%) specificity for diagnosis of cirrhosis and is also associated with increased risk of incident hepatic decompensation[334,336]

Please note that "at-risk" NASH is defined as NAS with stage ≥ 2 fibrosis Abbreviations: AUROC, area under the receiver operating characteristic curve; CAP, controlled attenuation parameter; CPR, clinical prediction rule; cT1, corrected T1; ELF, Enhanced Liver Fibrosis; FAST, FibroScan assessed liver stiffness measurement in kPa, CAP, and serum aspartate aminotransferase; FIB-4, fibrosis-4 index; LSM, liver stiffness measurement; MAST: score from MRI-PDFF, MRE, and serum aspartate aminotransferase; MEFIB, FIB-4 ≥1.6 plus MRE ≥3.3 kPa; MRE, magnetic resonance elastography; MRI- PDFF, magnetic resonance imaging–proton density fat fraction; NFS, NAFLD Fibrosis Score; PPV, positive predictive value; SWE, shear wave elastography; VCTE, vibration-controlled elastography.

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

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

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; August 2025.
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
4. Rinella, M. E., Neuschwander-Tetri, B. A., Siddiqui, M. S., Abdelmalek, M. F., Caldwell, S., Barb, D., … Loomba, R. (2023). AASLD Practice Guidance on the Clinical Assessment and Management of Nonalcoholic Fatty Liver Disease. Hepatology, 77(5), 10.1097/HEP.0000000000000323. https://doi.org/10.1097/HEP.0000000000000323
5. Kanwal, F., Shubrook, J. H., Adams, L. A., Pfotenhauer, K., Wai-Sun Wong, V., Wright, E., … Cusi, K. (2021). Clinical Care Pathway for the Risk Stratification and Management of Patients With Nonalcoholic Fatty Liver Disease. Gastroenterology, 161(5), 1657–1669. https://doi.org/10.1053/j.gastro.2021.07.049
6. Cusi, K., Isaacs, S., Barb, D., Basu, R., Caprio, S., Garvey, W. T., … Younossi, Z. (2022). American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings. Endocrine Practice, 28(5), 528–562. https://doi.org/10.1016/j.eprac.2022.03.010
7. American Association for the Study of Liver Diseases. (n.d.). New MASLD Nomenclature | AASLD. Retrieved from www.aasld.org website: https://www.aasld.org/new-masld-nomenclature [Accessed 20 August 2025]

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements FDA-Approved Uses Appendix Background References	Q4 2025
REVISION- Notable revisions: References	Q1 2025
NEW CRITERIA CREATION	Q2 2024