



Drug Coverage Policy

Effective Date03/15/2026
Coverage Policy Number.....IP0781
Policy Title.....Metabolic Dysfunction-
Associated Steatohepatitis – Wegovy

Hepatology – Metabolic Dysfunction- Associated Steatohepatitis – Wegovy Benefit Exclusion Overrides Policy for Individual and Family Plans

- Wegovy® (semaglutide subcutaneous injection – Novo Nordisk)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used

as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

Wegovy is a glucagon-like peptide-1 (GLP-1) receptor indicated in combination with a reduced-calorie diet and increased physical activity:¹

- To **reduce excess body weight and maintain weight reduction long term** in:
 - Adults with overweight in the presence of at least one weight-related comorbid condition.
 - Adults with obesity.
 - Pediatric patients ≥ 12 years of age with obesity.
- To **reduce the risk of major adverse cardiovascular (CV) events** (CV death, non-fatal myocardial infarction {MI}, or non-fatal stroke) in adults with established CV disease and either **obesity or overweight**.
- For the treatment of **non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH)**, formerly known as non-alcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults.

Clinical Efficacy

MASH

The ESSENCE trial (Part 1, n = 800), a two-part, ongoing, Phase III, multicenter, double-blind, parallel-group trial randomized adults with MASH and stage F2 to F3 fibrosis to Wegovy or placebo, both in addition to standard of care (optimization of treatment for type 2 diabetes, dyslipidemia, and CV risk management).^{2,3} Results from Part 1 have been published. Eligible patients were ≥ 18 years of age with histological presence of steatohepatitis with stage F2 to F3 fibrosis from a baseline liver biopsy. Patients with an average alcohol consumption of ≥ 20 grams/day for women or ≥ 30 grams/day for men or alcohol dependence were excluded. Rezdiffra™ (resmetirom tablets) was not approved at the time the trial commenced; therefore, no patients were taking Rezdiffra in Part 1 of this trial. Concomitant use of any other GLP-1 or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) agonist was not allowed. The two primary histologic endpoints were: 1) Resolution of steatohepatitis and no worsening of liver fibrosis; and 2) Improvement in liver fibrosis and no worsening of steatohepatitis. In Part 2 of the trial, the primary endpoint will be cirrhosis-free survival at Week 240 (ongoing). Overall, 56% of patients had type 2 diabetes. The mean body mass index (BMI) was 34.6 kg/m². Most patients fulfilled four (27.8%) or five (43.3%) of five metabolic dysfunction-associated metabolic liver disease (MASLD) cardiometabolic criteria (i.e., BMI ≥ 25 kg/m² [≥ 23 kg/m² Asia] or waist circumference > 94 cm [male] or > 80 cm [female] or ethnicity adjusted equivalent; fasting serum glucose ≥ 100 mg/dL or 2-hour post-prandial glucose ≥ 140 mg/dL or type 2 diabetes or treatment for type 2 diabetes; blood pressure $\geq 130/85$ mmHg or specific antihypertensive drug treatment; plasma high-density lipoprotein cholesterol ≤ 40 mg/dL [male] and ≤ 50 mg/dL [female] or lipid-lowering treatment). Most patients had stage F3 fibrosis (68.8%); 31.3% of patients had stage F2 fibrosis.

Results. At the interim analysis (the first 800 patients enrolled in the trial), the between-group differences for both primary endpoints were significant for Wegovy vs. placebo.³ Wegovy demonstrated a significant improvement in liver fibrosis with no worsening of steatohepatitis, as well as resolution of steatohepatitis with no worsening of liver fibrosis. Confirmatory secondary

endpoints also generally favored Wegovy (e.g., resolution of steatohepatitis with improvement in liver fibrosis, weight change). Part 2 of the trial is ongoing and expected to read out in 2029.

Guidelines

The American Association for the Study of Liver Diseases Practice Guidance on the Clinical Management of non-alcoholic fatty liver disease (2023) was updated in October 2024 to address the approval of Rezdiffra and in November 2025 to address the approval of Wegovy for MASH.^{4,5} Best practices in the management of MASH include comprehensive lifestyle modification (nutrition, exercise, behavioral modification), and optimal control of comorbid metabolic conditions.^{4,5} MASH can only be definitively diagnosed by histologic exam (biopsy); however, in practice, patient selection is based on evidence of steatosis and fibrosis as determined by non-invasive tests in patients with cardiometabolic risk factors without other causes of steatosis, notably, alcohol consumption of > 20 g/day for women and > 30 g/day for men. Specifically, fibrosis can be estimated using imaging and/or blood-based non-invasive tests with reasonable to high accuracy.⁵ There are no FDA-approved non-invasive tests to diagnose MASH with stage F2 to F3 fibrosis or to monitor the response to pharmacotherapy.⁴ Although liver biopsy is not typically recommended for fibrosis staging in current clinical practice, histologic exam remains the gold standard to quantify fibrosis if performed previously (historical biopsy obtained reasonably recently, e.g., within 3 years).⁴ Since non-invasive tests are more readily available than liver biopsy, it is recommended that more current data (e.g., within 6 to 12 months) be utilized to determine patients who are appropriate candidates for treatment. Three non-invasive tests are supported in the 2025 guidance: vibration-controlled transient elastography (VCTE), magnetic resonance elastography (MRE), and the blood-based biomarker Enhanced Liver Fibrosis™ (ELF) score.⁵ For the blood-based ELF score, a cutoff of 9.2 provides optimal sensitivity and specificity for detecting ≥ F2 fibrosis. To guide the selection of appropriate candidates for treatment with MASH therapy, the ELF score range of 9.2 to 10.5 is recommended. In the ESSENCE trial, this range identified approximately 50% of patients with F2 or F3 fibrosis. While the range serves as guidance, in those with values outside of the upper range, exclusion of cirrhosis and portal hypertension should be considered using another non-invasive test such as VCTE or MRE. Wegovy is not indicated in patients with cirrhotic (F4) MASH.

Coverage Policy

POLICY STATEMENT

This Benefit Exclusion Overrides policy has been developed to authorize coverage of the targeted drug(s) for approved metabolic dysfunction-associated steatohepatitis (MASH)/non-alcoholic steatohepatitis (NASH). This Benefit Exclusion Overrides policy is not applicable if clients have weight loss as a covered benefit. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: males are defined as individuals with the biological traits of a male, regardless of the individual's gender identity or gender expression; females are defined as individuals with the biological traits of a female, regardless of the individual's gender identity or gender expression. Because of the specialized skills required for evaluation and diagnosis of patients treated with Wegovy for MASH/NASH as well as the monitoring required for adverse events and long-term efficacy, approval requires Wegovy for MASH/NASH to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below.

Documentation: Documentation is required for use of Wegovy for MASH/NASH as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart

notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.

Wegovy is considered medically necessary when the following are met:

FDA-Approved Indication

1. Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH). Approve for 1 year if the patient meets the ONE of the following (A or B):

- A) Initial Therapy:** Approve if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):
- i.** Patient is ≥ 18 years of age; AND
 - ii.** Patient does not have cirrhosis (F4); AND
 - iii.** Patient has stage F2 or F3 fibrosis prior to initiating treatment with Rezdifra or Wegovy **[documentation required]** identified by ONE of the following (a, b, c, or d):
 - a)** Liver biopsy performed within the 3 years preceding treatment with Rezdifra or Wegovy **[documentation required]**; OR
 - b)** Vibration-controlled transient elastography (VCTE) performed within the 6 months preceding treatment with Rezdifra or Wegovy **[documentation required]**; OR
 - c)** Magnetic resonance elastography (MRE) performed within the 6 months preceding treatment with Rezdifra or Wegovy **[documentation required]**; OR
 - d)** Enhanced Liver Fibrosis™ (ELF) test performed within the 6 months preceding treatment with Rezdifra or Wegovy **[documentation required]** with a score of ≥ 9.2 to ≤ 10.5 **[documentation required]**; AND
 - iv.** According to the prescriber, the patient has ONE or more of the following metabolic risk factors that are managed according to standard of care (a, b, c, d, e):
 - a)** Central obesity;
 - b)** Hypertriglyceridemia;
 - c)** Reduced high-density lipoprotein cholesterol;
 - d)** Hypertension;
 - e)** Elevated fasting plasma glucose indicative of diabetes or pre-diabetes; AND
 - v.** According to the prescriber, patient meets ONE of the following (a or b):
 - a)** Female* patient: Alcohol consumption is < 20 grams/day; OR
Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.
 - b)** Male* patient: Alcohol consumption < 30 grams/day; AND
Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.
 - vi.** The medication will be used in combination with appropriate diet and exercise therapy; AND
 - vii.** The medication is prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist; OR
- B) Patient is Currently Receiving Wegovy:** Approve if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
- Note: A patient who has received < 1 year of therapy or who is restarting therapy should be considered under criterion A (Initial Therapy).

- i. Patient has completed ≥ 1 year of therapy with Wegovy AND according to the prescriber, the patient has not had worsening of fibrosis or MASH/NASH; AND
Note: This applies to a patient starting their second (or more) year of therapy with Wegovy (i.e., the patient has already completed 1 year or more of therapy with Wegovy).
- ii. According to the prescriber, patient does not have cirrhosis (F4); AND
- iii. According to the prescriber, metabolic risk factors are managed according to standard of care; AND
- iv. According to the prescriber, patient meets ONE of the following (a or b):
 - a) Female* patient: Alcohol consumption is < 20 grams/day; OR
Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.
 - b) Male* patient: Alcohol consumption < 30 grams/day; AND
Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.
- v. The medication will be used in combination with appropriate diet and exercise therapy; AND
- vi. The medication is prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist.

*Refer to the Policy Statement

Conditions Not Covered

Wegovy for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Weight Loss.** Coverage is determined by the member's prescription benefit coverage of weight loss drugs.
2. **Concomitant Use with Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonists.** Coadministration of Wegovy with other semaglutide-containing products or with any other GLP-1 agonists is not recommended.¹ Note: Examples of other GLP-1 agonists include but are not limited to exenatide subcutaneous (SC) injection, Ozempic (semaglutide SC injection), Rybelsus (semaglutide tablets), Saxenda (liraglutide subcutaneous injection), Trulicity (dulaglutide SC injection), and liraglutide SC injection (Victoza, generic). An example of a GLP-1/GIP agonist is Mounjaro (tirzepatide SC injection).

References

1. Wegovy® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; August 2025.
2. Newsome PN, Sanyal AJ, Engerbretsen KA, et al. Semaglutide 2.4 mg in participants with metabolic dysfunction-associated steatohepatitis: baseline characteristics and design of the phase 3 ESSENCE trial. *Aliment Pharmacol Ther.* 2024;60(11-12):1525-1533.
3. Sanyal AJ, Newsome PN, Kliers I, et al. Phase 3 trial of semaglutide in metabolic dysfunction-associated steatohepatitis. *N Engl J Med.* 2025;392(21):2089-2099.

4. Chen VL, Morgan TR, Rotman Y, et al. Resmetirom therapy for metabolic dysfunction-associated steatotic liver disease: October 2024 updates to AASLD Practice Guidance. *Hepatology*. 2025;81(1):312-320.
5. Bansal MB, Patton H, Morgan TR, et al. Semaglutide therapy for metabolic dysfunction-associated steatohepatitis: November 2025 updates to AASLD practice guidance. *Hepatology*. 2025 Nov 7. [Online ahead of print].

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	03/15/2026

The policy effective date is in force until updated or retired.

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