

Semaglutide (WEGOVY) in Metabolic Dysfunction-Associated Steatohepatitis (MASH) Criteria for Use January 2026

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for semaglutide (WEGOVY) in MASH.

- Child-Pugh score ≥ 7 (Note: Bilirubin can be adjusted for patients with Gilbert syndrome, and score adjusted for patients taking anticoagulants.)
- Decompensated liver cirrhosis as manifested by complications of cirrhosis (e.g., noncardiac ascites, variceal hemorrhage, hepatic encephalopathy, spontaneous bacterial peritonitis, etc.)¹
- In most recent assessment, FibroScan LSM greater than 18 kPa or vibration-controlled transient elastography (VCTE) consistent with cirrhosis, MRE > 5.0 kPa, FIB-4 > 2.67 (unless LSM < 18 kPa),² or liver biopsy indicating cirrhosis (METAVIR stage F4)
- Hepatocellular carcinoma currently not actively managed by hepatology (or multidisciplinary team)
- Uncontrolled liver disease associated with condition other than metabolic dysfunction³
- Heavy ingestion of alcohol for greater than 3 consecutive months within the previous 1 year with heavy alcohol ingestion defined as ≥ 4 alcoholic drinks per day for men and ≥ 3 alcoholic drinks per day for women⁴
- Personal or first-degree family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2
- Severe gastrointestinal dysmotility, including gastroparesis
- History or presence of pancreatitis (does not pertain to patients for whom the cause of pancreatitis is known and no longer presents a risk)⁵
- Type 1 diabetes⁶
- Known PDR, severe NPDR, clinically significant ME, or DME unless risks/benefits have been discussed with the patient and is documented in the EHR with monitoring plans and follow-up with an eye specialist who is informed at the time of the initiation.⁷
- Known pregnancy⁸
- Lactating⁹

DME=diabetic macular edema; EHR=electronic health record; FIB-4, Fibrosis-4 index; LSM, liver stiffness measurement on liver elastography/FibroScan; ME=macular edema; MRE, magnetic resonance elastography; NPDR=nonproliferative diabetic retinopathy; PDR=proliferative diabetic retinopathy

- 1 Patients currently on semaglutide for another indication (e.g., diabetes or obesity) who are diagnosed with cirrhosis or portal hypertension may continue to use semaglutide. Patients on semaglutide for diabetes who are diagnosed with compensated cirrhosis may continue semaglutide if LSM is < 18 kPa or ELF < 10.5 or platelets > 130.
- 2 Use FIB-4 with caution in patients aged > 65 years because of lower reliability.
- 3 E.g., biliary obstruction, viral hepatitis, autoimmune hepatitis, hereditary liver disease, drug-induced liver disease, etc.
- 4 One alcoholic drink = 355 mL (12 fl oz) of 5% alcohol by volume (ABV) beer; 148 mL (5 fl oz) of 12% ABV wine; 44 mL (1.5 fl oz) of 40% ABV distilled spirits.
- 5 Risk factors for pancreatitis include triglyceride level > 1000 mg/dL, known gallstones with intact gallbladder, high alcohol intake
- 6 History or presence of type 1 diabetes was an exclusion criterion in the semaglutide in MASH ESSENCE trial. If the patient is followed by a diabetes specialist, semaglutide can be considered for MASH management under careful supervision in patients with type 1 diabetes.
- 7 Before considering treatment with semaglutide in patients with diabetes, the provider should have the results of a diabetic eye exam on file within the past 12 months (or 24 months if no evidence of retinopathy). Patients with a history of diabetic retinopathy should have planned follow-up with the eye provider to monitor for progression. Ophthalmology consult should be obtained any time there are concerns related to use in patients with diabetic retinopathy.
- 8 Weight loss offers no potential benefit to a pregnant female and may result in fetal harm. Refer to product information.
- 9 Breastfeeding females were excluded from the ESSENCE clinical trial. Consider risks vs benefits in the female and the infant being fed breastmilk.

Inclusion Criteria

ALL of the following must be selected to meet criteria for semaglutide (WEGOVY) in metabolic dysfunction-associated steatohepatitis (MASH).

- Initiated by a VA/VA Community Care gastroenterologist/hepatologist or locally designated expert.
 - Documented plan on addressing and monitoring appropriate lifestyle interventions.^{10,11}
 - Documented plan to change medications that can cause or exacerbate steatohepatitis to alternative agents as applicable and clinically appropriate.¹²
- 10 Lifestyle counseling is an essential component of overall MASH management and includes recommendations on nutrition, exercise, and weight loss. Lifestyle counseling can be done, if feasible, by providers or as part of a comprehensive lifestyle intervention (CLI). <https://dvagov.sharepoint.com/sites/vhamove/Shared%20Documents/NCP-MOVE-CLI-Definition.pdf> .
 - 11 In patients with metabolic dysfunction-associated steatotic liver disease (MASLD) and overweight/obesity, weight loss $\geq 5\%$ of total body weight can improve hepatic steatosis, $\geq 7\%$ can improve liver inflammation/resolve MASH, and $\geq 10\%$ can improve or stabilize hepatic fibrosis. In patients with normal-weight/lean MASLD (body mass index [BMI] < 25 kg/m² in non-Asians or BMI < 23 kg/m² in Asians), moderate weight loss of 3%–5% can improve liver histology. [PMIDs: 33307021, 30142427, 35842345]
 - 12 Examples of drugs implicated in the development or exacerbation of steatohepatitis, MASLD, or MASH: amiodarone, androgenic steroids, atypical antipsychotics (e.g., clozapine, olanzapine), estrogens, glucocorticoids, irinotecan, methotrexate, nucleoside reverse transcriptase inhibitors, selective serotonin receptor inhibitor antidepressants, tamoxifen, valproic acid, etc.

Additional Inclusion Criteria

Select if applicable.

- For patients who are overweight or obese: Documented **MASH with moderate to advanced fibrosis consistent with stage F2 or F3** diagnosed in the past 6 months on noninvasive tests (or past 36 months on liver biopsy).¹³
- For lean patients with suspected MASH: Documented **MASH with moderate to advanced fibrosis consistent with stage F2 or F3** diagnosed on liver biopsy in the past 36 months (exclude non-MASH liver diagnoses).
- For patients on semaglutide for MASH only: Initiated by a VA/VA Community Care gastroenterologist or hepatologist OR a locally designated expert in the management of MASH.
- For females who can become pregnant: Pregnancy should be excluded prior to receiving semaglutide (WEGOVY) and patient counseled on contraceptives and potential risks vs benefits of treatment if she were to become pregnant.
- For females who are breastfeeding/providing breastmilk to an infant: Counseling provided on potential risks vs benefits of treatment.

- 13 Noninvasive diagnostic tests for MASH with stage F2–F3 fibrosis (e.g., elastography) without requirement for liver biopsy may be used: Enhanced Liver Fibrosis (ELF) score 9.2–10.5; LSM 8.0–18.0 kPa; and MRE 3.1–4.4 kPa. Some patients with BMI > 25 kg/m² and components of the metabolic syndrome may be misdiagnosed as having moderate to advanced (F2–F3) MASH (false positive) using noninvasive tests but these patients may still benefit from the weight loss and cardiometabolic effects of semaglutide therapy. Weight loss with semaglutide should occur at a slow rate such as 5% within 6 months and cumulative 10% or more within 18 months.

Other Justification

Original: January 2026.

Contact: Francine Goodman, National Program Manager, VA Pharmacy Benefits Management Services – Formulary Management (12PBM)
