LOUISIANA BLUE

Wegovy™ (semaglutide)

Policy # 00886
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease and Overweight or Obesity

Based on review of available data, the Company may consider Wegovy™‡ (semaglutide) injection or tablets 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 be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for Wegovy (semaglutide) injection or tablets 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 will be considered when ALL of the following criteria are met:

Initial Authorization (6 months):

- Patient is 45 years of age or older; AND
  *(Note: Age greater than or equal to 45 is an additional Company requirement for coverage eligibility. Age 18 to 44 will be denied as not medically necessary** and age less than 18 will be denied as investigational.)*
- Patient has a body mass index (BMI) greater than or equal to 27 kg/m^2; AND
  *(Note: BMI greater than or equal to 27 kg/m^2 is an additional Company requirement for coverage eligibility. BMI greater than or equal to 25 and less than 27 kg/m^2 will be denied as not medically necessary** and BMI less than 25 will be denied as investigational.)*
- Patient has documentation of established cardiovascular disease, as evidenced by at least ONE of the following:
  - Prior myocardial infarction (MI); OR
  - Prior stroke (ischemic or hemorrhagic) or documented history of a transient ischemic attack (TIA); OR

  - Angina pectoris with significant atherosclerosis (greater than or equal to 50% stenosis); OR
  - Prior percutaneous transluminal angioplasty (PTCA) or coronary artery bypass graft (CABG); OR
  - Symptomatic carotid stenosis (greater than or equal to 50% stenosis); OR
  - Prior carotid endarterectomy or carotid artery angioplasty and stenting; OR Aortic aneurysm secondary to atherosclerosis or history of aortic aneurysm repair; OR
  - Symptomatic peripheral arterial disease (PAD), as evidenced by ONE of the following:
    - Intermittent claudication with ABI less than 0.85 (at rest); OR
    - Peripheral arterial revascularization procedure; OR
    - Amputation due to atherosclerotic disease; AND

  *(Note: This specific patient selection criterion will be considered not covered** if not met.)*
  *(Note: If member contract INCLUDES coverage of medications for obesity, weight loss, weight management, or weight maintenance, this specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient will use the requested medication in combination with guideline-directed pharmacotherapy for cardiovascular disease (CVD), such as an antiplatelet agent (e.g., aspirin or P2Y12 inhibitor), lipid-lowering drug (e.g., statin, ezetimibe, fibrate, and/or PCSK-9 inhibitor), and antihypertensive therapy (e.g., beta blocker, ACE-I, ARB); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has not been diagnosed with Type I or Type II Diabetes Mellitus (DM), AND patient does not have a hemoglobin A1c greater than or equal to 6.5%; AND
- Patient has not been diagnosed with New York Heart Association (NYHA) Class IV heart failure, chronic pancreatitis, or acute pancreatitis within the last 180 days; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient does not have a personal history of, or first-degree relative with, multiple medullary thyroid carcinoma or personal history of Multiple Endocrine Neoplasia type 2 (MEN 2); AND
- The requested medication will be used concomitantly with behavioral modification and a reduced-calorie diet; AND
- For Wegovy injection requests: Patient will not use the requested medication in combination with other Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Agonists. Examples may include, but are not limited to, exenatide injection, Ozempic®‡ (semaglutide), Rybelsus®‡ (semaglutide), Wegovy (semaglutide) tablet, liraglutide injection (Saxenda®‡, generics), Trulicity®‡ (dulaglutide), liraglutide (Victoza®‡, generics), Zepbound™‡ (tirzepatide), and Mounjaro™‡ (tirzepatide).

- For Wegovy tablet requests: Patient will not use the requested medication in combination with other Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Agonists. Examples may include, but are not limited to, exenatide injection, Ozempic®‡ (semaglutide), Rybelsus®‡ (semaglutide), Wegovy (semaglutide) injection, liraglutide injection (Saxenda®‡, generics), Trulicity®‡ (dulaglutide), liraglutide (Victoza®‡, generics), Zepbound™‡ (tirzepatide), and Mounjaro™‡ (tirzepatide).

Continuation:

- Patient has received an initial authorization for Wegovy injection or tablets; AND
- The requested medication will be used concomitantly with behavioral modification and a reduced-calorie diet; AND
- Patient has established cardiovascular disease, as evidenced by at least ONE of the following:
  - Prior MI; OR
  - Prior stroke (ischemic or hemorrhagic) or documented history of a transient ischemic attack (TIA); OR
  - Angina pectoris with significant atherosclerosis (greater than or equal to 50% stenosis); OR
  - Prior percutaneous transluminal angioplasty (PTCA) or coronary artery bypass graft (CABG); OR
  - Symptomatic carotid stenosis (greater than or equal to 50% stenosis); OR
  - Prior carotid endarterectomy or carotid artery angioplasty and stenting; OR
  - Aortic aneurysm secondary to atherosclerosis or history of aortic aneurysm repair; OR
  - Symptomatic peripheral arterial disease (PAD), as evidenced by ONE of the following:
    - Intermittent claudication with ABI less than 0.85 (at rest); OR
    - Peripheral arterial revascularization procedure; OR
    - Amputation due to atherosclerotic disease; AND

  *(Note: This specific patient selection criterion will be considered not covered** if not met.)*
  *(Note: If member contract INCLUDES coverage of medications for obesity, weight loss, weight management, or weight maintenance, this specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient had a BMI greater than or equal to 27 kg/m^2 prior to initiation of therapy with Wegovy tablets or injection; AND
  *(Note: BMI greater than or equal to 27 kg/m^2 is an additional Company requirement for coverage eligibility. BMI greater than or equal 25 and less than 27 kg/m^2 will be denied as not medically necessary** and BMI less than 25 will be denied as investigational.)*
- Patient has not developed Type II DM since the previous authorization; AND
- Patient has not been diagnosed with NYHA Class IV heart failure, chronic pancreatitis, or acute pancreatitis within the last 180 days; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Patient will continue guideline-directed pharmacotherapy for CVD, such as an antiplatelet agent (e.g., aspirin or P2Y12 inhibitor), lipid-lowering drug (e.g., statin, ezetimibe, fibrate, and/or a PCSK-9 inhibitor), and antihypertensive therapy (e.g., beta blocker, ACE-I, ARB) with the requested medication; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- For Wegovy injection requests:
  - Patient is tolerating a Wegovy injection maintenance dose of 2.4 mg once weekly; AND
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
  - Patient will not use the requested medication in combination with other Glucagon Like Peptide-1 (GLP-1) Agonists or GLP-1/Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Agonists. Examples may include, but are not limited to, exenatide injection, Ozempic (semaglutide), Rybelsus (semaglutide), Wegovy (semaglutide) tablet, liraglutide injection (Saxenda, generics), Trulicity (dulaglutide), liraglutide (Victoza, generics), Zepbound (tirzepatide), and Mounjaro (tirzepatide); OR
- For Wegovy tablet requests:
  - Patient is tolerating a Wegovy tablet maintenance dose of 25 mg once daily; AND
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
  - Patient will not use the requested medication in combination with other Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Agonists. Examples may include, but are not limited to, exenatide injection, Ozempic (semaglutide), Rybelsus (semaglutide), Wegovy (semaglutide) injection, liraglutide injection (Saxenda, generics), Trulicity (dulaglutide), liraglutide (Victoza, generics), Zepbound (tirzepatide), and Mounjaro (tirzepatide).

Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH)

Based on review of available data, the Company may consider Wegovy (semaglutide) injection for the treatment of non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as non-alcoholic steatohepatitis (NASH) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for Wegovy (semaglutide) injection for the treatment of non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as non-alcoholic steatohepatitis (NASH) will be considered when ALL of the following criteria are met:

Initial Authorization:

- Patient has confirmed and documented diagnosis of 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); AND
  *(Note: This specific patient selection criterion will be considered not covered** if not met.)*

*(Note: If member contract INCLUDES coverage of medications for obesity, weight loss, weight management, or weight maintenance, this specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as investigational** if not met.)*

- Steatohepatitis and moderate to advanced liver fibrosis (stage F2 to F3 fibrosis) was confirmed by documentation of one of the following:
    - Liver biopsy within the last year; OR
    - One of the following imaging-based assessments within the last 6 months:
        - Vibration-controlled elastography (e.g. FibroScan)
        - Transient elastography
        - Shear wave elastography
        - Magnetic resonance elastography; AND

      *(Note that the 6 month and one year timeframe is an additional company requirement and will be denied as not medically necessary** if not met.)*

  *(Note: This specific patient selection criterion will be considered not covered** if not met.)*
  *(Note: If member contract INCLUDES coverage of medications for obesity, weight loss, weight management, or weight maintenance, this specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as investigational** if not met.)*
- Patient is 18 years of age or older; AND
- If patient had a liver biopsy, documentation is provided of a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS) greater than or equal to 4, and there is a score greater than 1 in ALL of the following:
    - Steatosis; AND
    - Hepatocyte ballooning; AND
    - Lobular inflammation; AND

  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient does NOT have cirrhosis (F4) or hepatic decompensation; AND
  *(Note: This specific patient selection criterion will be considered not covered** if not met.)*
  *(Note: If member contract INCLUDES coverage of medications for obesity, weight loss, weight management, or weight maintenance, this specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as investigational** if not met.)*
- Patient has not been diagnosed with Type I Diabetes Mellitus (DM), AND
- Patient has not been diagnosed with acute pancreatitis within the last 180 days; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has no history or current evidence of chronic pancreatitis; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient does NOT have documented causes of chronic liver disease other than metabolic dysfunction-associated steatotic liver disease (MASLD), formerly known as NAFLD; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Patient has no history or current evidence of hepatocellular carcinoma; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient does not have a personal history of, or first-degree relative with, medullary thyroid carcinoma or a personal history of Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); AND
- Patient will NOT use the requested medication in combination with other GlucagonLike Peptide-1 (GLP-1) Agonists or GLP-1/Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Agonists. Examples may include, but are not limited to, exenatide injection, Ozempic (semaglutide), Rybelsus (semaglutide), Wegovy (semaglutide) tablet, liraglutide injection (Saxenda, generics), Trulicity (dulaglutide), liraglutide (Victoza, generics), Zepbound (tirzepatide), and Mounjaro (tirzepatide); AND
- Patient does not have excessive alcohol use within the past 3 months defined as more than 20 g per day for women and more than 30 g per day for men. (Note that 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.); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient's concomitant related conditions including dyslipidemia, type II diabetes, and hypertension are managed according to standard of care; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Requested medication will be used in conjunction with lifestyle interventions, including diet and exercise; AND
- Patient will not use in combination with Rezdiffra™‡ (resmetirom tablets)

Continuation:

- Patient has an initial authorization for the requested medication; AND
- Patient has documentation of a diagnosis of MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis); AND
  *(Note: This specific patient selection criterion will be considered not covered** if not met.)*
  *(Note: If member contract INCLUDES coverage of medications for obesity, weight loss, weight management, or weight maintenance, this specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as investigational** if not met.)*
- Patient has been adherent to treatment with the requested medication; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient is experiencing a positive clinical response to Wegovy, as evidenced by documentation of stabilization, and/or improvement in fibrosis and/or MASH (e.g., improved steatosis, improved fibrosis, improvement in fibrosis score, lack of disease progression, etc.); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Patient has not progressed to stage F4 (cirrhosis); AND
  *(Note: This specific patient selection criterion will be considered not covered** if not met.)*
  *(Note: If member contract INCLUDES coverage of medications for obesity, weight loss, weight management, or weight maintenance, this specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as investigational** if not met.)*
- Patient's concomitant related conditions including dyslipidemia, type II diabetes, and hypertension are managed according to standard of care; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient will NOT use the requested medication in combination with other GlucagonLike Peptide-1 (GLP-1) Agonists or GLP-1/Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Agonists. Examples may include, but are not limited to, exenatide injection, Ozempic (semaglutide), Rybelsus (semaglutide), Wegovy (semaglutide) tablet, liraglutide injection (Saxenda, generics), Trulicity (dulaglutide), liraglutide (Victoza, generics), Zepbound (tirzepatide), and Mounjaro (tirzepatide); AND
- Patient does not have excessive alcohol use within the past 3 months defined as more than 20 g per day for women and more than 30 g per day for men. (Note that 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.); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient is tolerating a maintenance dose of 2.4 mg once weekly; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient will not use in combination with Rezdiffra (resmetirom tablets).

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection and tablet to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults without established cardiovascular disease (as noted in the patient selection criteria) for members whose contract INCLUDES coverage of medications for obesity, weight loss, weight management, or weight maintenance to be **not medically necessary.****

Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection and tablet when ANY of the following criteria listed below are NOT met to be **not medically necessary:****

Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease and Overweight or Obesity:

- **For Initial Requests**
  - Patient is greater than or equal to 45 years of age or older. Requests for patients 18 to 44 years of age will be denied as not medically necessary

  - Patient has a BMI greater than or equal to 27 kg/m^2. When BMI is 25 to 26.9 kg/m^2, request will be denied as not medically necessary
  - Patient will use the requested medication in combination with guideline-directed pharmacotherapy for CVD, such as an antiplatelet agent (e.g., aspirin or P2Y12 inhibitor), lipid-lowering drug (e.g., statin, ezetimibe, fibrate, and/or PCSK-9 inhibitor), and antihypertensive therapy (e.g., beta blocker, ACE-I, ARB)
  - Patient has not been diagnosed with New York Heart Association (NYHA) Class IV heart failure, chronic pancreatitis, or acute pancreatitis within the last 180 days
- **For Continuation Requests**
  - Patient had a BMI greater than or equal to 27 kg/m^2 prior to initiation of therapy with Wegovy. When BMI is 25 to 26.9 kg/m^2, request will be denied as not medically necessary
  - Patient will use the requested medication in combination with guideline-directed pharmacotherapy for CVD, such as an antiplatelet agent (e.g., aspirin or P2Y12 inhibitor), lipid-lowering drug (e.g., statin, ezetimibe, fibrate, and/or PCSK-9 inhibitor), and antihypertensive therapy (e.g., beta blocker, ACE-I, ARB)
  - Patient has not been diagnosed with New York Heart Association (NYHA) Class IV heart failure, chronic pancreatitis, or acute pancreatitis within the last 180 days
  - For Wegovy injection, patient is tolerating a Wegovy maintenance dose of 2.4 mg once weekly
  - For Wegovy tablet, patient is tolerating a Wegovy maintenance dose of 25 mg once daily

Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection when ANY of the following criteria listed below are NOT met to be **not medically necessary:****

Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH):

- **For Initial requests**
  - Liver biopsy has been obtained within the last year or imaging based assessment has been obtained within the past 6 months
  - If patient had a liver biopsy, NAFLD Activity Score is ≥ 4, and there is a score > 1 in steatosis, hepatocyte ballooning, and lobular inflammation
  - Patient has not been diagnosed with acute pancreatitis within the last 180 days
  - Patient has no history or current evidence of chronic pancreatitis
  - Patient does NOT have documented causes of chronic liver disease other than MASLD
  - Patient has no history or current evidence of hepatocellular carcinoma
  - Patient does not have excessive alcohol use within the past 3 months defined as more than 20 g per day for women and more than 30 g per day for men
  - Patient's concomitant related conditions including dyslipidemia, type II diabetes, and hypertension are managed according to standard of care

- **For Continuation requests**
  - Patient has been adherent to treatment with the requested medication
  - Patient is experiencing a positive clinical response to Wegovy
  - Patient does not have excessive alcohol use within the past 3 months defined as more than 20 g per day for women and more than 30 g per day for men
  - Patient's concomitant related conditions including dyslipidemia, type II diabetes, and hypertension are managed according to standard of care
  - Patient is tolerating a maintenance dose of 2.4 mg once weekly

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease and Overweight or Obesity:

- Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection and tablet when the patient is 17 years of age or younger to be **investigational**.*****

- Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection and tablet when BMI is less than 25 kg/m^2 to be **investigational**.*****

- Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection and tablet when the patient has Type I or Type II DM AND when Hemoglobin A1c is greater than or equal to 6.5% to be **investigational**.*****

- Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection and tablet when the patient has a personal history of, or first-degree relative with, medullary thyroid carcinoma or a personal history of MEN 2 to be **investigational**.*****

- Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection and tablet when the requested medication will not be used concomitantly with behavioral modification and a reduced-calorie diet to be **investigational**.*****

- Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection and tablet when the requested medication will be used in combination with other GLP-1 Agonists or GLP-1/GIP Receptor Agonists to be **investigational.***

- Based on review of available data, the Company considers the continued use of Wegovy (semaglutide) injection and tablet when BMI was less than 25 kg/m^2 prior to the initiation of therapy with Wegovy to be **investigational**.*****

Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH):

- Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection when the patient is 17 years of age or younger to be **investigational**.*
- Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection when the patient has been diagnosed with Type I Diabetes Mellitus (DM) to be **investigational**.*
- Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection when the patient has a personal history of, or first-degree relative with, medullary thyroid carcinoma or a personal history of MEN 2 to be **investigational**.*
- Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection when the requested medication will be used in combination with other GLP-1 Agonists or GLP-1/GIP Receptor Agonists to be **investigational**.*
- Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection when the requested medication will not be used concomitantly with behavioral modification and a reduced-calorie diet to be **investigational**.
- Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection in combination with Rezdiffra (resmetirom tablets) to be **investigational**.*

Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection for members whose contract **INCLUDES** coverage of medications for obesity, weight loss, weight management, or weight maintenance when the patient does not have confirmed and documented diagnosis of MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) (as noted in the patient selection criteria) to be **investigational.***

Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection for members whose contract **INCLUDES** coverage of medications for obesity, weight loss, weight management, or weight maintenance when the patient has cirrhosis (F4) or hepatic decompensation to be **investigational.***

When Services Are Not Covered

Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection and tablet to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults without established cardiovascular disease (as noted in the patient selection criteria) for members whose contract **EXCLUDES** coverage of medications for obesity, weight loss, weight management, or weight maintenance to be **not covered.****

Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection and tablet to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients aged 12 years and older with obesity and adults with overweight in the presence of at least one weight-related comorbid condition for members whose contract **EXCLUDES** coverage of medications for obesity, weight loss, weight management, or weight maintenance to be **not covered.****

Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection 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 without confirmed and documented diagnosis of MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) (as noted in the patient selection criteria) for members whose contract **EXCLUDES** coverage of medications for obesity, weight loss, weight management, or weight maintenance to be **not covered.****

Based on review of available data, the Company considers the use of Wegovy (semaglutide) injection when the patient has cirrhosis (F4) or hepatic decompensation for members whose contract **EXCLUDES** coverage of medications for obesity, weight loss, weight management, or weight maintenance to be **not covered.****

Based on review of available data, the Company considers the use of Wegovy (semaglutide) tablets 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) to be **not covered.****

Note: Coverage of medications for obesity, weight loss, weight management, or weight maintenance is considered an exclusion in most member contracts.

Background/Overview

Wegovy (semaglutide) injection and tablets are indicated in combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adult and pediatric patients aged 12 years and older with obesity and adults with overweight in the presence of at least one weight-related comorbid condition and 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 (CVD) and either obesity or overweight. Wegovy injection is also indicated in combination with a reduced calorie diet and increased physical activity 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. Although Wegovy tablets are indicated for cardiovascular (CV) risk reduction in adults with established CVD and overweight or obesity, the tablet formulation lacks a dedicated CV outcomes trial; instead, support for this indication is based on pharmacokinetic modeling showing that, in adults with overweight or obesity without type 2 diabetes, once-daily Wegovy 25 mg tablets are predicted to achieve semaglutide concentrations comparable to those observed with Wegovy 2.4 mg subcutaneous injection.

Semaglutide is an incretin mimetic agent that selectively binds to and activates the human GLP-1 receptor. GLP-1 is a physiological regulator of appetite and caloric intake as GLP-1 receptors are present in several areas of the brain involved in appetite regulation. GLP-1 receptors are also expressed in other organs, including the pancreas, gastrointestinal (GI) tract, heart, kidney, lung, and thyroid. Wegovy (semaglutide) shares the same chemical entity, semaglutide, as Ozempic (semaglutide SC injection) and Rybelsus (oral semaglutide) which reduce blood glucose by stimulating insulin secretion and suppressing glucagon secretion in a glucose-dependent manner, thereby slowing gastric emptying. Ozempic and Rybelsus are FDA approved to treat type 2 diabetes mellitus in adults while Wegovy is an anti-obesity medication (AOM) without an indication or dosing regimen for diabetes. Wegovy is indicated at a higher dose than Ozempic, and the products are not interchangeable. According to Wegovy's prescribing information, concomitant use with other semaglutide-containing products or with any GLP-1 receptor agonist is not recommended Wegovy injection is available as single-dose pre-filled pens delivering 0.25 mg, 0.5 mg, 1 mg, 1.7 mg, or 2.4 mg of semaglutide. Wegovy injection is initiated at 0.25 mg once weekly for 4 weeks and then titrated every 4 weeks according to the labeled dosage-escalation schedule to reach the maintenance dosage; the usual recommended maintenance dosage is 2.4 mg once weekly. Wegovy tablets are available in 1.5 mg, 4 mg, 9 mg, and 25 mg strengths. Wegovy tablets are titrated to a recommended maintenance dosage of 25 mg orally once daily, with titration to maintenance occurring over a minimum of 90 days (a longer titration period may be warranted based on tolerability). Unlike the injection, Wegovy tablets strict administration requirements and must be taken in the morning on an empty stomach with water only (4 ounces or less). Patients should avoid food, beverages, or other medications for at least 30 minutes after the dose. Failure to follow the administration instructions may reduce the bioavailability of Wegovy tablets and may diminish treatment efficacy. Wegovy carries a black box warning for an increased risk of thyroid c-cell tumors and is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2.

Cardiovascular Disease
Cardiovascular disease is the leading cause of global mortality and a major cause of morbidity. Atherosclerotic cardiovascular disease (ASCVD) is a subset of cardiovascular disease caused by atherosclerosis. It encompasses four major clinical areas: coronary heart disease, manifested by fatal or nonfatal MI and angina pectoris; cerebrovascular disease, manifested by ischemic stroke and transient ischemic attack; peripheral artery disease, manifested by intermittent claudication and critical limb ischemia; and aortic atherosclerosis, including thoracic or abdominal aortic aneurysm. Patients with established CVD are at high-risk for subsequent CV events such as MI, stroke, and death. Treatment guidelines for the secondary prevention of CVD recommend therapeutic lifestyle changes, adjunctive drug therapies, and management of other disease states, such as dyslipidemia, hypertension, and diabetes. Lifestyle modifications which have shown to have beneficial effects on CVD morbidity and mortality include avoidance/cessation of smoking, increasing levels of daily physical activity, and following a healthy diet. Patients with CVD should have a measurement of waist circumference and evaluation of BMI. If weight reduction is indicated, obesity treatment guidelines recommend multiple strategies for weight loss, including diet, increased physical activity, and possible pharmacologic therapy. All patients with established CVD should also receive aspirin and statin therapy, unless contraindicated. Other adjuvant therapies which may be of benefit in some

patients include anticoagulants, beta blockers, angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), P2Y12 receptor blockers, colchicine, mineralocorticoid receptor antagonists, certain sodium-glucose co-transporter 2 (SGLT2) inhibitors, and COVID-19 and influenza vaccinations.

MASH
Metabolic dysfunction-associated steatotic liver disease (MASLD), formerly known as nonalcoholic fatty liver disease (NAFLD), is the most common chronic liver condition in the United States. It is characterized by pathophysiological fatty changes in the liver that are unrelated to alcohol intake and is strongly associated with insulin resistance, obesity, weight gain, and type 2 diabetes. Most individuals with MASLD are asymptomatic and are often diagnosed incidentally, either through imaging studies such as ultrasound performed for unrelated reasons or during evaluation for abnormal liver enzymes identified on routine blood tests. Metabolic dysfunction-associated steatohepatitis (MASH), formerly known as non-alcoholic steatohepatitis (NASH), represents a more severe subset of MASLD. MASH is defined by the presence of greater than or equal to 5% hepatic steatosis along with hepatocellular damage and inflammation. This progressive liver disease can advance to significant liver fibrosis, cirrhosis, and hepatocellular carcinoma (HCC), contributing to substantial morbidity and mortality. In the United States, MASH is among the leading causes of HCC and is the second most common indication for liver transplantation, following hepatitis C. Once MASH progresses to clinically meaningful fibrosis, specifically fibrosis stages F2 and F3, the risk of adverse clinical outcomes increases. It is estimated that approximately 25% of the U.S. population is affected by MASLD, while 1.5% to 6.5% are affected by MASH. The risk of developing MASH is two- to three-fold higher in individuals with obesity (25% to 30%) and/or type 2 diabetes (30% to 40%). Weight loss of 10% or more has been shown to result in resolution of MASH in the majority of patients and is associated with improvements in fibrosis and portal inflammation.

The American Association for the Study of Liver Diseases (AASLD) updated its Practice Guidance on the Clinical Management of NAFLD in October 2024 to reflect evolving diagnostic and therapeutic approaches, including the approval of pharmacologic agents for the treatment of NAFLD/MASLD. The guidance also includes recommendations regarding other therapies, such as GLP-1 receptor agonists. Regardless of pharmacologic treatment, the management of NAFLD/MASLD should include comprehensive lifestyle modification, encompassing nutrition, exercise, and behavioral interventions, as well as optimal control of comorbid metabolic conditions. Given the high prevalence of cardiovascular comorbidities in individuals with NAFLD/MASLD, cardiovascular risk management is a critical component of care. Although MASH can only be definitively diagnosed via histologic examination (i.e., liver biopsy), in clinical practice, patient selection for treatment is typically based on evidence of hepatic steatosis and fibrosis as determined by non-invasive liver testing (NITs) in individuals with cardiometabolic risk factors and no other identifiable causes of steatosis. Notably, alcohol consumption exceeding 20 g/day for women and 30 g/day for men should be excluded. Currently, there are no FDA-approved noninvasive tests to definitively diagnose MASH with stage F2 to F3 fibrosis or to monitor response to pharmacotherapy. Imaging-based assessments, such as liver stiffness measurement via vibration-controlled transient elastography (VCTE) and magnetic resonance elastography (MRE), generally offer better accuracy in assessing fibrosis compared to blood-based tests (e.g., Fibrosis-4 Index [FIB-4], enhanced liver

fibrosis [ELF]). For quantifying hepatic steatosis, magnetic resonance spectroscopy and magnetic resonance imaging proton density fat fraction (MRI-PDFF) are considered the most accurate modalities, followed by VCTE-controlled attenuation parameter scores and grayscale ultrasound. For the purpose of selecting patients for treatment, non-quantitative imaging evidence of hepatic steatosis (e.g., ultrasonographic findings) in individuals with at least one cardiometabolic risk factor and F2 or F3 fibrosis may be considered sufficient. While liver biopsy is not typically recommended for fibrosis staging in current clinical practice, histologic examination remains the gold standard and may be used if a reasonably recent biopsy (e.g. within the past 3 years) is available. Given the broader availability of NITs compared to liver biopsy, it is recommended that more current data (e.g., within the past 6 to 12 months) be used to determine appropriate candidates for treatment.

Obesity
Obesity is a serious and costly chronic disease which is increasing in prevalence. The Centers for Disease Control and Prevention (CDC) estimates that more than 2 out of 5 U.S. adults have obesity and define overweight/obesity as "weight that is considered higher than what is considered healthy for a given height." The World Health Organization (WHO) defines obesity as "excess or abnormal fat accumulation that presents a risk to health." In epidemiological studies, BMI is typically used to define excess weight to estimate relative risk of disease and has been found to correlate with both morbidity and mortality. Using BMI as the primary screening tool for obesity and overweight is consistent with guidelines and recommendations developed by many organizations (e.g., CDC, U.S. Preventive Services Task Force (USPTF), American Heart Association (AHA), American College of Cardiology (ACC), American Association of Clinical Endocrinologists/American College of Endocrinology (AACE/ACE), and the National Institute for Health Care and Excellence (NICE), and WHO). BMI provides a better estimate of total body fat than body weight alone, and BMI classifications of excess weight generally correlate individual adiposity and the associated risk of developing comorbidities, such as diabetes and CVD. It is important to note, however, that BMI does have some limitations in measuring total body fat. For example, BMI overestimates body fat in individuals who are very muscular and can underestimate body fat in individuals who have lost muscle mass (e.g., the elderly). Also, the relationship between BMI and disease risk varies among individuals and among different populations and ethnicities. For example, studies have shown that BMI cutoffs underestimate the risks associated with obesity, such as diabetes, in Asian populations. The BMI associated with adverse obesity-related health outcomes is lower for populations of South Asian descent and higher for those of African ethnicity/Black race, as compared to White populations. However, in all population groups, the relative risk for cardiovascular disease increases in correlation with increasing BMI.

Classification of Overweight and Obesity
The National Institutes of Health (NIH) and WHO have adopted BMI classifications based upon risk of CV disease for White, Hispanic, and Black individuals, as shown in Table 1. NIH/WHO guidelines provide lower BMI cutoffs for overweight and obese Asian individuals and define overweight as a BMI of greater than or equal to 23 to 24.9 kg/m^2 and obesity as a BMI of 25 kg/m^2 or greater in these populations. The CDC also recommends BMI as an easy, inexpensive screening method for classifying weight status for adults 20 years of age and older. The CDC recommends further assessments, such as skinfold thickness measurements and evaluation of diet, physical

activity, and family history, for determining health risks related to body fatness or health of an individual. Classifications per the CDC are included in Table 2. For adults aged 18 years or older, the U.S. Preventative Services Task Force (USPSTF) defines overweight as a BMI of 25 to 29.9 kg/m^2 and obesity as a BMI of 30 kg/m^2 or higher.

Table 1: BMI Classifications adopted by the National Institutes of Health (NIH) and World Health Organization (WHO) for White, Hispanic, and Black Adults.

Weight Status	**BMI**
Underweight	BMI < 18.5 kg/m^2
Normal Weight	BMI ≥ 18.5 to 24.9 kg/m^2
Overweight*	BMI ≥ 25 to 29.9 kg/m^2
Obesity*	BMI ≥ 30 kg/m^2
• Obesity Class 1 • Obesity Class 2 • Obesity Class 3	BMI 30 to 34.9 kg/m^2 BMI 35.0 to 39.9 kg/m^2 BMI ≥ 40 kg/m^2

*In Asian populations, NIH/WHO define overweight as a BMI of ≥ 23 to 24.9 kg/m^2 and obesity as a BMI of > 25 kg/m^2.

Table 2: CDC BMI Classifications for adults 20 years of age and older.

Weight Status	**BMI**
Underweight	BMI < 18.5 kg/m^2
Normal Weight	BMI ≥ 18.5 to 24.9 kg/m^2
Overweight	BMI ≥ 25 to 29.9 kg/m^2
Obesity	BMI ≥ 30 kg/m^2
• Obesity Class 1 • Obesity Class 2 • Obesity Class 3	BMI 30 to 34.9 kg/m^2 BMI 35.0 to 39.9 kg/m^2 BMI ≥ 40 kg/m^2

Table 3: USPTF BMI Categories for Adults 18 years of age and older

Weight Status	**BMI**
Normal Weight	BMI ≥ 18.5 to 24.9 kg/m^2
Overweight	BMI ≥ 25 to 29.9 kg/m^2
Obesity	BMI ≥ 30 kg/m^2
• Obesity Class 1 • Obesity Class 2 • Obesity Class 3	BMI 30 to 34.9 kg/m^2 BMI 35.0 to 39.9 kg/m^2 BMI ≥ 40 kg/m^2

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Wegovy (semaglutide) injection is indicated in combination with a reduced calorie diet and increased physical activity:

- To reduce excess body weight and maintain weight reduction long term in adult and pediatric patients aged 12 years and older with obesity and adults with overweight in the presence of at least one weight-related comorbid condition.
- 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.
- 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.

Wegovy (semaglutide) tablets are indicated in combination with a reduced calorie diet and increased physical activity:

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

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Cardiovascular Outcomes Trial in Adult Patients with Established Cardiovascular Disease with Overweight or Obesity

The safety and efficacy of Wegovy injection for secondary prevention of CVD in overweight/obese patients were evaluated in a multi-national, multi-center, placebo-controlled, double-blind trial (known as SELECT) to determine the effect of Wegovy injection relative to placebo on MACE when added to current standard of care, which included management of cardiovascular (CV) risk factors and individualized healthy lifestyle counseling (including diet and physical activity). A total of 17,604 patients ≥ 45 years of age with BMI ≥ 27 kg/m^2 or greater and established CVD were randomized to receive Wegovy injection 2.4 mg weekly or placebo. Established CVD was defined as prior myocardial MI, prior hemorrhagic or ischemic stroke, and/or symptomatic PAD, as evidenced by intermittent claudication with ankle-brachial index < 0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease. Patients with a history of type 1 or type 2 diabetes or with a HbA1C ≥ 6.5% were excluded from the study. Wegovy was titrated up to a target dose of 2.4 mg weekly over 16 weeks. However, the trial protocol did allow patients to take a lower dose if dose escalation led to adverse effects. 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 CVD. 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%).

The primary endpoint was time from randomization to first occurrence of a major adverse CV event (a three-part composite endpoint consisting of CV death, non-fatal MI, or non-fatal stroke) in a time-to-first-event analysis. The median follow-up time was 39.8 months. At week 104, approximately 77% of patients receiving Wegovy injection were taking the target 2.4 mg weekly dose. However, no results were reported for those patients taking less than the 2.4 mg target dose. Wegovy injection demonstrated a statistically significant and superior reduction in MACE compared to placebo. A primary endpoint event occurred in 6.5% vs. 8.0% of patients in the Wegovy injection vs. placebo groups, respectively (hazard ratio [HR] 0.80; 95% confidence interval [CI]: 0.72, 0.90; $P < 0.001$). The first confirmatory secondary endpoint was death from CV events and was found not significant; therefore, superiority testing was not performed for the remaining confirmatory secondary endpoints of heart failure composite and all-cause death.

Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis with Moderate to Advanced Liver Fibrosis in Adults

The efficacy of Wegovy injection for the treatment of MASH was evaluated based on analysis at Week 72 from a two-part, ongoing, randomized, double-blind, placebo-controlled trial (known as ESSENCE); results from Part 1 have been published. The Week 72 analysis included 800 F2 and F3 (at eligibility) patients randomized 1:2 to receive placebo (n = 266) or Wegovy injection once weekly (n = 534), in addition to standard of care for cardiometabolic comorbidities and healthy lifestyle counseling. Wegovy injection or matching placebo was escalated to 2.4 mg once weekly during the initial 16 weeks of the treatment period. Dose escalation could be prolonged or patients could remain at a lower dose if 2.4 mg once weekly was not tolerable. Enrolled patients were ≥ 18 years of age with a baseline or recent liver biopsy showing clinically significant MASLD, defined as MASH with fibrosis stage 2 or 3 according to NASH Clinical Research Network classification, and a NAFLD Activity Score (NAS) ≥ 4 with a score of 1 or more in steatosis, lobular inflammation, and hepatocyte ballooning, based on 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. Patients taking stable doses of pioglitazone, vitamin E, glucose lowering agent(s), lipid-lowering medication(s), and weight loss medication(s) were allowed to continue these therapies; however, concomitant use of any other GLP-1 or GLP-1/GIP agonist was not allowed. Rezdiffra (resmetirom tablets) was not approved at the time the trial commenced; therefore, no patients were taking Rezdiffra in Part 1 of this trial.

Efficacy determination was based on the effect of Wegovy injection on resolution of steatohepatitis without worsening of liver fibrosis and on at least one stage improvement in liver fibrosis without worsening of steatohepatitis, on post-baseline liver biopsies collected at 72 weeks. Resolution of steatohepatitis is defined as a score of 0 to 1 for lobular inflammation, 0 for ballooning, and any value for steatosis. No worsening of steatohepatitis is defined as no increase from baseline in score for ballooning, lobular inflammation, or steatosis. Wegovy injection demonstrated a significant

improvement in liver fibrosis with no worsening of steatohepatitis, as well as resolution of steatohepatitis with no worsening of liver fibrosis. At Week 72, 63% vs. 34% of patients treated with Wegovy injection vs. placebo, respectively, achieved resolution of steatohepatitis with no worsening of liver fibrosis (estimated difference 28.7%; 95% CI: 21.1%, 36.2%; P < 0.001). In addition, at Week 72, 36.8% vs. 22.4% of patients treated with Wegovy injection vs. placebo, respectively, had a reduction in liver fibrosis with no worsening of steatohepatitis (estimated difference 14.4%; 95% CI: 7.5%, 21.3%; P < 0.001). At the time of the primary endpoint assessment, 83.5% of patients were taking Wegovy 2.4 mg injection once weekly. Confirmatory secondary endpoints also generally favored Wegovy injection (e.g., resolution of steatohepatitis with improvement in liver fibrosis, weight change). At Week 72, the proportion of patients with both resolution of steatohepatitis and improvement in fibrosis was 32.7% vs. 16.1% of patients receiving Wegovy injection vs. placebo, respectively (difference 16.5%; 95% CI: 10.2% to 22.8%, respectively; P < 0.001). Another secondary endpoint was the percent change in body weight from baseline to Week 72. Patients treated with Wegovy injection achieved an average of 10.5% weight loss from baseline at Week 72, and patients treated with placebo achieved an average of 2% weight loss from baseline at Week 72; treatment with Wegovy injection resulted in an average of 8.5% greater weight loss from baseline compared to placebo (95% CI: 7.4% to 9.5%). Starting at Week 12 and through Week 72, there was a trend of greater reductions from baseline in average ALT and AST in the Wegovy injection group as compared to the placebo group. Part 2 of the trial is ongoing with results expected in 2029.

The purpose of this medical policy is to ensure the medication targeted in this policy is being used according to the FDA label and in populations which have been studied in clinical trials. Because coverage of medications for obesity, weight loss, weight management, or weight maintenance is considered an exclusion in most member contracts, the purpose of this policy is to provide coverage criteria for Wegovy (semaglutide) injection and tablets for risk reduction of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (as noted in the patient selection criteria) and for the injectable formulation, either obesity or overweight and for the treatment of MASH with moderate to advanced liver fibrosis in adults.

Wegovy (semaglutide) is not FDA approved for the reduction of the risk of MACE in pediatric patients with established cardiovascular disease and either obesity or overweight, nor has its safety and efficacy been evaluated in clinical trials in pediatric populations with established cardiovascular disease population. Wegovy (semaglutide) is not FDA approved for the treatment of MASH with moderate to advanced liver fibrosis in pediatric patients, nor has its safety and efficacy been evaluated in clinical trials including pediatric patients. Therefore, this policy does not include pediatric considerations (e.g., pediatric BMI classifications, pediatric BMI-for-age percentiles, or pediatric obesity treatment guidelines/recommendations).

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Policy History

Original Effective Date: 08/12/2024
Current Effective Date: 05/01/2026

07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. New policy.
10/02/2025	Medical Policy Committee review
10/08/2025	Medical Policy Implementation Committee approval. Added new indication for MASH with relevant criteria. Updated Background and Rationale sections.
12/04/2025	Medical Policy Committee review
12/10/2025	Medical Policy Implementation Committee approval. Removed criterion regarding liver function test requirements. Updated liver biopsy time frame requirement from within the last 6 months to within the last year. Updated criterion requiring that patient does not have excessive alcohol use to clarify that timeframe is within the past 3 months. Combined criteria requiring steatohepatitis and F2 to F3 fibrosis into one criterion and clarified that non-invasive testing is based on elastography.
04/02/2026	Medical Policy Committee review
04/10/2026	Medical Policy Implementation Committee approval. Added the new formulation, Wegovy tablet to the policy with relevant criteria. Updated background section.

Next Scheduled Review Date: 04/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan.