PRIOR AUTHORIZATION POLICY

POLICY: Weight Loss – Glucagon-Like Peptide-1 Agonists Prior Authorization Policy

- Foundayo™ (orforglipron tablets – Eli Lilly)
- Saxenda® (liraglutide subcutaneous injection – Novo Nordisk, generic)
- Wegovy® (semaglutide tablets and subcutaneous injection – Novo Nordisk)
- Wegovy® HD (semaglutide subcutaneous injection – NovoNordisk)
- Zepbound® (tirzepatide subcutaneous injection [KwikPens, pens, and vials] – Eli Lilly)

REVIEW DATE: 07/09/2025; selected revision 08/27/2025, 09/10/2025, 12/03/2025, 12/30/2025, 02/25/2026, 04/02/2026, and 04/15/2026

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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Foundayo, Liraglutide (Saxenda, generic), Wegovy, and Zepbound are glucagon-like peptide-1 (GLP-1) receptor agonists; Zepbound is also a glucose-dependent insulinotropic polypeptide (GIP) receptor agonist.[1,2,4,25]

Foundayo, Liraglutide, Wegovy injection, Wegovy tablet, and Zepbound are indicated in combination with a reduced-calorie diet and increased physical activity:[1,2,4,25]

- To **reduce excess body weight and maintain weight reduction long term** in:
  - **Foundayo, Liraglutide, Wegovy injection, Wegovy tablet, and Zepbound:** Adults with overweight in the presence of at least one weight-related comorbid condition.[1,2,4,6,25]
  - **Foundayo, Liraglutide, Wegovy injection, Wegovy tablet, and Zepbound:** Adults with obesity.[1,4,25]
  - **Liraglutide:** Pediatric patients ≥ 12 years of age and ≥ 60 kg with obesity.[2]
  - **Wegovy injection:** Pediatric patients ≥ 12 years of age with obesity.[1,7]

Wegovy HD injection is intended for weight reduction in adults who tolerate Wegovy 2.4 mg injection for ≥ 4 weeks and require additional weight reduction.[1]

Wegovy injection and Wegovy tablet are indicated in combination with a reduced-calorie diet and increased physical activity:[1]

- To **reduce the risk of major adverse cardiovascular (CV) events (MACE)** [CV death, non-fatal myocardial infarction {MI}, or non-fatal stroke] in adults with established CV disease and either **obesity or overweight**.[1,5]

Wegovy injection is indicated in combination with a reduced-calorie diet and increased physical activity:[1]

- 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.[1,19,20]

Zepbound is indicated in combination with a reduced-calorie diet and increased physical activity:[4]

- To treat **moderate to severe obstructive sleep apnea** (OSA) in adults with **obesity**.

Dosing

In the prescribing information for Foundayo, the recommended starting dose is 0.8 mg orally once daily (QD).[25] After ≥ 30 days on the 0.8 mg dose, increase the dose to 2.5 mg QD. After ≥ 30 days on the 2.5 mg dose, increase the dose to 5.5 mg QD. The dose may be increased to the next dose level (9 mg, 14.5 mg, or 17.2 mg QD) after ≥ 30 days on the current dose based on treatment response and tolerability. The maximum dose is 17.2 mg QD (reached on Day 151).

In the prescribing information for Wegovy injection, a recommended dose escalation schedule of 16 weeks is outlined (the 2.4 mg dose would be reached at the start of Week 17).[1] Consider the treatment response and tolerability when selecting the maintenance dose. For weight loss in an adult who tolerates 2.4 mg

SC QW for ≥ 4 weeks and additional weight reduction is clinically indicated, the dose may be increased to a maximum of 7.2 mg SC QW (Wegovy HD).

In the prescribing information for Wegovy tablet, a recommended dose escalation schedule of 90 days is outlined (the 25 mg dose would be reached at the start of Day 91).[1] If a patient does not tolerate a dose during dose escalation, consider delaying dose escalation. For CV risk reduction and weight reduction, the maintenance dose of Wegovy tablet is 25 mg orally QD. If the patient does not tolerate the 25 mg QD maintenance dosage, consider switching to Wegovy SC injection 1.7 mg QW. If additional weight reduction is needed in patients with type 2 diabetes mellitus treated with Wegovy 25 mg tablet, consider switching to Wegovy 1.7 mg SC injection QW and follow the recommended dosage escalation for Wegovy SC injection.

Adults taking Wegovy 2.4 mg SC injection for CV risk reduction or weight reduction may switch to Wegovy 25 mg tablets.[1] One week after discontinuing Wegovy 2.4 mg SC injection, initiate 25 mg of Wegovy tablets orally QD. A patient may switch from Wegovy 25 mg tablets to Wegovy SC injection. The day after discontinuing Wegovy 25 mg tablets QD, initiate Wegovy 2.4 mg SC injection QW.

In the prescribing information for liraglutide, a recommended dose escalation schedule of 4 weeks is outlined.[2] If a patient does not tolerate an increased dose during dose escalation, consider delaying dose escalation for approximately one additional week. For adults, the prescribing information states to evaluate the change in body weight 16 weeks after initiating liraglutide and discontinue liraglutide if the patient has not lost ≥ 4% of baseline body weight, since it is unlikely the patient will achieve and sustain clinically meaningful weight loss with continued treatment. For pediatric patients, evaluate the change in body mass index (BMI) after 12 weeks on the maintenance dose; if the patient has not had a reduction in BMI of ≥ 1% from baseline, discontinue liraglutide as it is unlikely the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

In the prescribing information for Zepbound, the recommended starting dose is 2.5 mg SC QW.[4] The 2.5 mg dose is for treatment initiation and is not intended for chronic weight management. The maximum dose is 15 mg QW. The 5 mg, 10 mg, and 15 mg maintenance doses are reached at Week 4, Week 12, and Week 20, respectively.

None of the GLP-1 or GLP-1/GIP agonists are recommended for coadministration with other GLP-1 or GLP-1/GIP agonists.[1,2,4,25]

Clinical Efficacy

Secondary Prevention of MACE

SELECT was a randomized, double-blind, placebo-controlled, event-driven study that assessed Wegovy injection vs. placebo, when added to standard of care, for the secondary prevention of CV events in adults ≥ 45 years of age with BMI ≥ 27 kg/m^2 and established CV disease without diabetes (n = 17,604).[5] Established CV

disease was defined as one of the following: prior MI, prior stroke (ischemic or hemorrhagic), and/or symptomatic peripheral arterial disease (as evidenced by intermittent claudication with ankle-brachial index < 0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease). The primary efficacy endpoint was a composite of death from CV causes, non-fatal MI, or non-fatal stroke.

Results. Patients were followed for a mean of 39.8 months.[5] The trial achieved its primary endpoint, demonstrating a statistically significant and superior reduction in MACE for Wegovy injection vs. placebo. A primary endpoint event occurred in 6.5% vs. 8.0% of patients in the Wegovy injection vs. placebo groups, respectively (hazard ratio 0.80; 95% confidence interval: 0.72, 0.90; P < 0.001).

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 injection or placebo, both in addition to standard of care (optimization of treatment for type 2 diabetes, dyslipidemia, and CV risk management).[19,20] 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/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 BMI was 34.6 kg/m^2. 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/m^2 [≥ 23 kg/m^2 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 ≥ 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 injection vs. placebo.[20] 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. Confirmatory secondary endpoints also generally favored Wegovy injection (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.

OSA

The SURMOUNT-OSA (n = 469) trials were two 52-week, Phase III, multicenter, double-blind, randomized trials that evaluated the efficacy and safety of maximally tolerated Zepbound (10 mg or 15 mg QW) in adults with obesity (without diabetes) and moderate to severe OSA.[9] Two patient populations were included. In Trial 1, patients were unable or unwilling to use positive airway pressure (PAP) therapy, and in Trial 2, patients had been using PAP therapy for ≥ 3 months at the time of screening and planned to continue PAP therapy during the trial. All patients had a diagnosis of moderate to severe OSA with an apnea-hypopnea index (AHI) ≥ 15 events/hour as diagnosed with polysomnography, home sleep apnea test, or other methods that met local guidelines prior to Visit 1. Patients had a BMI of ≥ 30 kg/m^2 (≥ 27 kg/m^2 in Japan) despite the history of at least one self-reported unsuccessful dietary effort to lose weight. Patients with a diagnosis of central or mixed sleep apnea with the percentage of mixed or central apneas/hypopneas ≥ 50%, and Cheyne Stokes respiration were excluded. In Trial 1, the mean BMI was 39.1 kg/m^2 and the mean AHI was 51.5 events/hour. Most patients had severe OSA (63%). In Trial 2, the mean BMI was 38.7 kg/m^2 and the mean AHI was 49.5 events/hour. Most patients had severe OSA (68%). The primary endpoint was the superiority of Zepbound vs. placebo for the change in the AHI from baseline.[9] Several key secondary endpoints were assessed.

Results. In both trials, Zepbound was superior to placebo for the primary endpoint. In Trial 1, the change in AHI at Week 52 with Zepbound was superior to placebo (-25.3 events/hour vs. -5.3 events/hour, respectively; estimated treatment difference of -20.0 events/hour; P < 0.001).[9] In Trial 2, the change in AHI at Week 52 with Zepbound was superior to placebo (-29.3 events/hour vs. -5.5 events/hour, respectively; estimated treatment difference -23.8 events/hour; P < 0.001). Additionally, patients in both trials who received Zepbound had significant reductions in sleep apnea-specific hypoxic burden. The proportion of patients with a reduction in the AHI of ≥ 50% at Week 52 and the proportion of patients with an AHI of < 5 events/hour or an AHI of 5 to 14 events/hour and an ESS of ≤ 10 at Week 52 also favored Zepbound. Patients receiving Zepbound in both trials had significant reductions in body weight.

Guidelines

Foundayo, Wegovy HD injection, and Wegovy tablet have not been addressed in guidelines.

Weight Management

Adult

The American Academy of Clinical Endocrinology (AACE) Consensus Statement: Algorithm for the Evaluation and Treatment of Adults with Obesity/Adiposity-Based Chronic Disease (ABCD) [2025 update] places an emphasis on a complication-centric, person-centered care model.[23] BMI is appropriate to screen for ABCD/obesity and is used to classify individuals into categories of overweight (BMI ≥ 25.0 to ≤ 29.9 kg/m^2), Class I obesity (BMI ≥ 30.0 to ≤ 34.9 kg/m^2), Class II obesity (BMI ≥ 35.0 to ≤ 39.9 kg/m^2), or Class III obesity (BMI ≥ 40 kg/m^2).

Pharmacotherapy, in adjunct to lifestyle modification, is indicated to prevent, improve, or reverse obesity-related complications and diseases; not solely to reduce BMI. The choice of pharmacotherapy is based on obesity-related comorbidities. The degree of weight reduction with a given medication can serve as a guide toward improvement of various comorbidities. Response to pharmacologic therapy to therapy should be assessed after 3 months on a therapeutic dose. If treatment has not resulted in ≥ 5% weight loss, longer-term efficacy will not likely be sufficient; a change in therapeutic approach is recommended. Individuals with weight reduction ≥ 5% should continue with their current treatment. Patients who achieve ≥ 15% weight loss (noted to be the percent weight loss observed on average with Wegovy injection and Zepbound) will have achieved a response to therapy that predictably prevents or improves a wide range of obesity-related comorbidities.

The American Diabetes Association Professional Practice Committee for Obesity (2026) Standards of Care in Overweight and Obesity prioritize obesity pharmacotherapy that is most likely to achieve and maintain intended treatment goals.[24] The treatment goal should be individualized based on the severity of obesity, obesity-related complications and diseases, and individual needs. A sustained weight reduction of ≥ 5% from baseline may achieve some clinically meaningful health benefits, while a sustained weight reduction of ≥ 10% is recommended to manage many obesity-related diseases or complications. In some cases, ≥ 15% weight reduction may be indicated to achieve greater therapeutic benefit. Zepbound and Wegovy injection (listed in order of relative benefit) are recognized as agents with high efficacy (> 10% weight loss). Medications should be continued after reaching treatment goals to maintain health benefits. When there is an inadequate response to therapy, dose escalation to the maximum dose is recommended. If the maximum dose has been reached and the response is inadequate, switching to an alternative medication, adding intensive lifestyle therapy, combining medications, or referring for metabolic surgery is recommended. Patients who achieve early weight reduction (usually ≥ 5% after 3 months) should continue medication long term.

<u>Pediatric</u>

Guidelines from the American Academy of Pediatrics on evaluation and treatment of children and adolescents with obesity (2023) note that pediatricians and other primary healthcare providers should offer adolescents ≥ 12 years of age with obesity (BMI ≥ 95th percentile) weight loss pharmacotherapy, according to medication indications, risks, and benefits, as an adjunct to health behavior and lifestyle treatment.[7]

MASH

The American Association for the Study of Liver Diseases (AASLD) 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 approval of Wegovy for MASH.[21,22] Best practices in the management of MASH include comprehensive lifestyle modification (nutrition, exercise, behavioral modification), and optimal control of comorbid metabolic

conditions.[21] 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.[22] There are no FDA-approved non-invasive tests to diagnose MASH with stage F2 to F3 fibrosis or to monitor the response to pharmacotherapy.[21] 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).[21] 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.[22] 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.

Sleep Apnea

The American Academy of Sleep Medicine (2017) recommends that diagnostic testing for OSA be performed in combination with a comprehensive sleep evaluation.[10] Polysomnography is the gold standard test for the diagnosis of OSA in adults in whom there is concern for OSA based on the sleep evaluation. In some cases, and within the appropriate context, the use of home sleep apnea test as the initial sleep study may be acceptable, however, polysomnography should be used when home sleep apnea test results do not provide satisfactory posttest probability of confirming or ruling out OSA.

Available treatment guidelines for OSA do not specifically mention the GLP-1 agonists. The American Thoracic Society clinical practice guideline on the role of weight management in the treatment with adults with OSA (2018) recommends that patients with OSA who are overweight or obese (BMI ≥ 25 kg/m^2) participate in comprehensive lifestyle intervention that includes a reduced calorie diet, exercise/increased physical activity, and behavioral counseling.[11] For patients with OSA and a BMI ≥ 27 kg/m^2 who have not had an improvement in weight despite a comprehensive weight-loss lifestyle program, and have no contraindications (no active CV disease), evaluation for anti-obesity medication is suggested. The weight-loss goal in patients with overweight or obesity with OSA should be ≥ 7% to 10% of total body weight. The AACE Consensus Statement: Algorithm for the Evaluation and Treatment of Adults with Obesity/ABCD (2025 update) recommends

a weight loss target of 7% to 10% in patients with OSA and ABCD/obesity; > 10% weight loss is noted to results in additional benefit.[23]

Clinical success in OSA has been described by several publications. The American Academy of Sleep Medicine (2019) cites a clinically significant threshold of ≥ 15 events/hour (on AHI)[12] and a clinical practice guideline for the treatment of OSA and snoring with oral appliance therapy (2015) from the American Academy of Sleep Medicine and American Academy of Dental Sleep Medicine[13] notes that treatment success is usually defined as a reduction in the AHI to a specific level (e.g., post-treatment AHI < 5 events/hour, or a > 50% reduction in AHI). Of note, a meta-analysis on the impact of weight reduction on AHI reported that weight reduction in patients with obesity and OSA was associated with improvements in the severity of OSA. A BMI reduction of 20% was associated with an AHI reduction of 57%; further weight reduction beyond 20% in BMI was associated with a smaller effect on AHI.[14]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Foundayo, liraglutide (Saxenda, generic), Wegovy injection, Wegovy HD injection, Wegovy tablet, and Zepbound. Other glucagon-like peptide-1 agonists that do not carry an FDA-approved indication for weight loss are not targeted in this policy. 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 injection/Wegovy HD injection for metabolic dysfunction-associated steatohepatitis (MASH)/non-alcoholic steatohepatitis (NASH) as well as the monitoring required for adverse events and long-term efficacy, approval requires Wegovy injection/Wegovy HD injection 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. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Documentation: Documentation is required for use of Wegovy injection/Wegovy HD injection 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.

I. Liraglutide (Saxenda, generic) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Weight Loss in an Adult with Overweight or Obesity.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** At baseline, patient had a BMI ≥ 30 kg/m^2; OR
         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
       - **b)** Patient meets BOTH of the following [(1) and (2)]:
         - **(1)** At baseline, patient had a BMI ≥ 27 kg/m^2; AND
         - **(2)** At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic dysfunction-associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND

         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
     - **iv.** The medication will be used concomitantly with behavioral modification and a reduced-calorie diet; OR
   - **B)** Patient is Currently Receiving liraglutide (Saxenda, generic). Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
     Note: For a patient who has not completed 4 months of initial therapy, refer to Initial Therapy criteria above.
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** At baseline, patient had a BMI ≥ 30 kg/m^2; OR
         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
       - **b)** Patient meets BOTH of the following [(1) and (2)]:
         - **(1)** At baseline, patient had a BMI ≥ 27 kg/m^2; AND

(2) At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic dysfunction-associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iii. Patient has lost ≥ 4% of baseline body weight; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

2. **Weight Loss in a Pediatric Patient with Obesity.** Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 12 years of age and < 18 years of age; AND

ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND

iii. At baseline, patient had a BMI ≥ 95th percentile for age and sex; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet; OR

B) Patient is Currently Receiving liraglutide (Saxenda, generic). Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
Note: For a patient who has not completed 4 months of initial therapy, refer to Initial Therapy criteria above.

i. Patient is ≥ 12 years of age and < 18 years of age; AND

ii. At baseline, patient had a BMI ≥ 95th percentile for age and sex; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iii. Patient has had a reduction in BMI of ≥ 1% from baseline; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

II. Foundayo is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Weight Loss in an Adult with Overweight or Obesity.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 8 months if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** At baseline, patient had a BMI ≥ 30 kg/m^2; OR
         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
       - **b)** Patient meets BOTH of the following [(1) and (2)]:
         - **(1)** At baseline, patient had a BMI ≥ 27 kg/m^2; AND
         - **(2)** At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic dysfunction-associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND

         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
     - **iv.** The medication will be used concomitantly with behavioral modification and a reduced-calorie diet; OR
   - **B)** Patient is Currently Receiving Foundayo. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
     Note: For a patient who has not completed 8 months of initial therapy, refer to Initial Therapy criteria above.
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** At baseline, patient had a BMI ≥ 30 kg/m^2; OR
         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-

1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

b) Patient meets BOTH of the following [(1) and (2)]:

(1) At baseline, patient had a BMI ≥ 27 kg/m^2; AND

(2) At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic dysfunction-associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iii. Patient has lost ≥ 5% of baseline body weight; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

III. Wegovy injection and Wegovy HD injection is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Weight Loss in an Adult with Overweight or Obesity.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 8 months if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** At baseline, patient had a BMI ≥ 30 kg/m^2; OR
         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
       - **b)** Patient meets BOTH of the following [(1) and (2)]:
         - **(1)** At baseline, patient had a BMI ≥ 27 kg/m^2; AND
         - **(2)** At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic dysfunction-associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND

         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
     - **iv.** The medication will be used concomitantly with behavioral modification and a reduced-calorie diet; OR
   - **B)** Patient is Currently Receiving Wegovy injection, Wegovy HD injection, or Wegovy tablet. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
     Note: For a patient who has not completed 8 months of initial therapy with Wegovy injection, Wegovy HD injection, and/or Wegovy tablet, refer to Initial Therapy criteria above.
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** At baseline, patient had a BMI ≥ 30 kg/m^2; OR
         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

b) Patient meets BOTH of the following [(1) and (2)]:
(1) At baseline, patient had a BMI ≥ 27 kg/m^2; AND
(2) At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic dysfunction-associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iii. Patient has lost ≥ 5% of baseline body weight; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

2. Weight Loss in a Pediatric Patient with Obesity. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 8 months if the patient meets ALL of the following (i, ii, iii, and iv):
i. Patient is ≥ 12 years of age and < 18 years of age; AND
ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
iii. At baseline, patient had a BMI ≥ 95th percentile for age and sex; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet; OR

B) Patient is Currently Receiving Wegovy injection, Wegovy HD injection, or Wegovy tablet. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
Note: For a patient who has not completed 7 months of initial therapy with Wegovy injection, Wegovy HD injection, and/or Wegovy tablet, refer to Initial Therapy criteria above.
i. Patient is ≥ 12 years of age and < 18 years of age; AND
ii. At baseline, patient had a BMI ≥ 95th percentile for age and sex; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
iii. Patient has had a reduction in BMI of ≥ 1% from baseline; AND

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

3. **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease with Overweight or Obesity.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** At baseline, patient had a BMI ≥ 27 kg/m^2; AND
     Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
   - **C)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Patient has had a prior myocardial infarction; OR
     - **ii.** Patient has had a prior stroke; OR
       Note: This does not include a transient ischemic attack (TIA).
     - **iii.** Patient has a history of symptomatic peripheral arterial disease as evidenced by ONE of the following [a, b, or c]:
       - **a)** Intermittent claudication with ankle-brachial index < 0.85; OR
       - **b)** Peripheral arterial revascularization procedure; OR
       - **c)** Amputation due to atherosclerotic disease; AND
   - **D)** According to the prescriber, the medication will be used in combination with optimized pharmacotherapy for established cardiovascular disease; AND
   - **E)** The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

4. **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, 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 Rezdiffra, Wegovy injection, Wegovy HD injection, or Wegovy tablet **[documentation required]** identified by ONE of the following (a, b, c, or d):
       - **a)** Liver biopsy performed within the 3 years preceding treatment with Rezdiffra, Wegovy injection, Wegovy HD injection, or Wegovy tablet **[documentation required]**; OR
       - **b)** Vibration-controlled transient elastography (VCTE) performed within the 6 months preceding treatment with Rezdiffra, Wegovy injection, Wegovy HD injection, or Wegovy tablet **[documentation required]**; OR

c) Magnetic resonance elastography (MRE) performed within the 6 months preceding treatment with Rezdiffra, Wegovy injection, Wegovy HD injection, or Wegovy tablet **[documentation required]**; OR

d) Enhanced Liver Fibrosis™ (ELF) test performed within the 6 months preceding treatment with Rezdiffra, Wegovy injection, Wegovy HD injection, or Wegovy tablet **[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 injection, Wegovy HD injection, or Wegovy tablet: Approve if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
Note: For a patient who has received < 1 year of therapy with Wegovy injection, Wegovy HD injection, and/or Wegovy tablet or who is restarting therapy, refer to Initial Therapy criteria above.

i. Patient has completed ≥ 1 year of therapy with Wegovy injection, Wegovy HD injection, and/or Wegovy tablet 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 injection, Wegovy HD injection, and/or Wegovy tablet (i.e., the patient has already completed 1 year or more of therapy with Wegovy injection and/or tablet).

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

IV. Wegovy tablet is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. Weight Loss in an Adult with Overweight or Obesity. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 8 months if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND

iii. Patient meets ONE of the following (a or b):

a) At baseline, patient had a BMI ≥ 30 kg/m^2; OR
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

c) Patient meets BOTH of the following [(1) and (2)]:

(1) At baseline, patient had a BMI ≥ 27 kg/m^2; AND

(2) At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic dysfunction-associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet; OR

B) Patient is Currently Receiving Wegovy tablet, Wegovy injection, or Wegovy HD injection. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
Note: For a patient who has not completed 8 months of initial therapy with Wegovy tablet and/or Wegovy injection, refer to Initial Therapy criteria above.

i. Patient is ≥ 18 years of age; AND

ii. Patient meets ONE of the following (a or b):

a) At baseline, patient had a BMI ≥ 30 kg/m^2; OR
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

b) Patient meets BOTH of the following [(1) and (2)]:

(1) At baseline, patient had a BMI ≥ 27 kg/m^2; AND

(2) At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic dysfunction-associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iii. Patient has lost ≥ 5% of baseline body weight; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

2. Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease with Overweight or Obesity. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):

A) Patient is ≥ 18 years of age; AND

B) At baseline, patient had a BMI ≥ 27 kg/m^2; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

C) Patient meets ONE of the following (i, ii, or iii):

i. Patient has had a prior myocardial infarction; OR

ii. Patient has had a prior stroke; OR

Note: This does not include a transient ischemic attack (TIA).

iii. Patient has a history of symptomatic peripheral arterial disease as evidenced by ONE of the following [a, b, or c]:
- **a)** Intermittent claudication with ankle-brachial index < 0.85; OR
- **b)** Peripheral arterial revascularization procedure; OR
- **c)** Amputation due to atherosclerotic disease; AND

D) According to the prescriber, the medication will be used in combination with optimized pharmacotherapy for established cardiovascular disease; AND

E) The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

V. Zepbound is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Weight Loss in an Adult with Overweight or Obesity.** Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 8 months if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND

iii. Patient meets ONE of the following (a or b):

a) At baseline, patient had a BMI ≥ 30 kg/m^2; OR

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

b) Patient meets BOTH of the following [(1) and (2)]:

(1) At baseline, patient had a BMI ≥ 27 kg/m^2; AND

(2) At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic dysfunction-associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND

Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet; OR

B) Patient is Currently Receiving Zepbound. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
Note: For a patient who has not completed 8 months of initial therapy, refer to Initial Therapy criteria above.
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient meets ONE of the following (a or b):
  - **a)** At baseline, patient had a BMI ≥ 30 kg/m^2; OR
    Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
  - **b)** Patient meets BOTH of the following [(1) and (2)]:
    - **(1)** At baseline, patient had a BMI ≥ 27 kg/m^2; AND
    - **(2)** At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic dysfunction-associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND

    Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
- **iii.** Patient has lost ≥ 5% of baseline body weight; AND
  Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
- **iv.** The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

2. Obstructive Sleep Apnea, Moderate to Severe, in a Patient with Obesity.
Approve for 1 year if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, iv, and v):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** At baseline, patient had a BMI ≥ 30 kg/m^2; AND
  Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
- **iii.** Patient has had a sleep study that shows BOTH of the following (a and b):
  - **a)** Patient has been diagnosed with moderate to severe obstructive sleep apnea; AND
  - **b)** Patient has an apnea-hypopnea index ≥ 15 events per hour; AND
    Note: A diagnosis of moderate obstructive sleep apnea is an apnea-hypopnea index of ≥ 15 events per hour and a diagnosis of severe

sleep apnea is an apnea-hypopnea index ≥ 30 events per hour. The apnea-hypopnea index is the number of apneas and hypopneas during 1 hour of sleep.

iv. The patient does NOT meet either of the following (a or b):
Note: A patient who has one or more of the following conditions/diagnoses below is not approved.
a) Central sleep apnea; OR
b) Cheyne Stokes respiration; AND

v. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet; OR

B) Patient is Currently Receiving Zepbound. Approve if the patient meets ALL of the following (i, ii, iii, and iv):
Note: For a patient who has not completed 1 year of initial therapy, refer to Initial Therapy criteria above.

i. Patient is ≥ 18 years of age; AND

ii. At baseline, patient had a BMI ≥ 30 kg/m^2; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iii. Patient has completed ≥ 1 year of therapy with Zepbound AND the patient meets BOTH of the following (a and b):
a) Patient has lost ≥ 10% of baseline body weight; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
b) According to the prescriber, patient has stability in obstructive sleep apnea signs or symptoms; AND
Note: Examples of signs or symptoms of obstructive sleep apnea include but are not limited to snoring, excessive daytime sleepiness, fatigue.

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

CONDITIONS NOT COVERED

- **Foundayo (orforglipron tablets – Eli Lilly)**
- **Saxenda (liraglutide subcutaneous injection – Novo Nordisk, generic)**
- **Wegovy (semaglutide tablets and subcutaneous injection – Novo Nordisk)**
- **Wegovy HD (semaglutide subcutaneous injection – NovoNordisk)**
- **Zepbound (tirzepatide subcutaneous injection [KwikPens, pens, and vials] - Eli Lilly)**

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

1. **Concomitant Use with Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonists.** The GLP-1 agonists and the GLP-1/GIP agonist should not be combined with each other or with any other GLP-1 agonists or GLP-1/GIP agonist.[1,2,4,25] There are other GLP-1 agonist and GLP-1/GIP agonist products not included in this policy that are FDA-approved for type 2 diabetes, and not for chronic weight management. Note: Examples of other GLP-1 agonists include but are not limited to, exenatide subcutaneous (SC) injection, Ozempic (semaglutide tablets and SC injection), Rybelsus (semaglutide tablets), 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® tablet and subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; March 2026.
2. Saxenda® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; May 2025.
3. Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents with Obesity. *Pediatrics*. 2023;151(2):e2022060640.
4. Zepbound® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; April 2025.
5. Lincoff AM, Brown-Frandsen K, Colhoun HM, et al; for the SELECT Trial Investigators. Semaglutide and cardiovascular outcomes in obesity without diabetes. *N Engl J Med.* 2023;389(24):2221-2232
6. Lingvay I, Brown-Frandson K, Colhoun HM et al. Semaglutide for cardiovascular event reduction in people with overweight or obesity: SELECT study baseline characteristics. *Obesity.* 2023;31(1):111-122.
7. Wilding JPH, Batterham RL, Calanna S, et al; STEP 1 Study Group. Once-weekly semaglutide in adults with overweight or obesity. *N Engl J Med*. 2021;384(11):989.
8. Weghuber D, Barrett T, Barrientos-Pérez M, et al; STEP TEENS Investigators. Once-weekly semaglutide in adolescents with obesity. *N Engl J Med.* 2022;387(24):2245-2257.
9. Malhorta A, Grunstein RR, Fietze I, et al; for the SURMOUNT-OSA Investigators. Tirzepatide for the treatment of obstructive sleep apnea and obesity. *N Engl J Med.* 2024;391(13):1193-1205.
10. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479-504.
11. Hudgel DW, Patel SR, Ahasic AM, et al; on behalf of the American Thoracic Society Assembly on Sleep and Respiratory Neurology. The role of weight management in the treatment of adult obstructive sleep apnea. *Am J Respir Crit Care Med.* 2018;198(6):e70-e87.
12. Ramar K, Dort LC, Katz SG et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. An American Academy of Sleep Medicine and American Academy of Dental Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med.* 2015;11(7):773-827.
13. Patil SP, Ayappa IA, Caples SM, et al. Treatment of adult obstructive sleep apnea with positive airway pressure: An American Academy of Sleem Medicine Systematic Review, Meta-analysis, and GRADE Assessment. *J Clin Sleep Med.* 2019;15(2):301-334.
14. Malhorta A, Heilman CR, Banerjee, et al. Weight reduction and the impact on apnea-hypopnea index: a systematic meta-analysis. *Sleep Medicine.* 2023;121:26-31.
15. Jasterboff AM, Aronne LJ, Ahmad NN, et al; for the SURMOUNT-1 Investigators. Tirzepatide once weekly for the treatment of obesity. *N Engl J Med.* 2022;3387(3):205-216.

16. Garvey TW, Frias JP, Jasterboff, et al; for the SURMOUNT-2 Investigators. Tirzepatide once weekly for the treatment of obesity in people with type 2 diabetes (SURMOUNT-2): a double-blind, randomized, multicenter, placebo-controlled, phase 3 trial. *Lancet*. 2023;402(10402):613-6262.
17. Wadden TA, Chao AM, Machineni, et al. Tirzepatide after intensive lifestyle intervention in adults with overweight or obesity: The SURMOUNT-3 phase 3 trial. *Nature Med.* 2023;29(11):2909-2918.
18. Wadden TA, Hollander P, Klein S, et al; on behalf of the NN8022-1923 Investigators. Weight maintenance and additional weight loss with liraglutide after low-calorie-diet-induced weight loss: The SCALE Maintenance randomized study. *Int J Obes.* 2013;37:1443-1451.
19. 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.
20. 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.
21. 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.
22. 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].
23. Nadolsky K, Garvey WT, Agarwal M, et al. American Association of Clinical Endocrinology consensus statement: algorithm for the evaluation and treatment of adults with obesity/adiposity-based chronic disease — 2025 Update. *Endocrine Practice*. 2025;31:1351–1394.
24. American Diabetes Association Professional Practice Committee for Obesity. Pharmacologic treatment of obesity in adults: Standards of care in overweight and obesity. *DOCM Care.* 13 Jan 2026 [Online ahead of print].
25. Foundayo™ tablets [prescribing information]. Indianapolis, IN: Eli Lilly; April 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/12/2023
Selected revision	Wegovy **Weight Loss, Adult:** Continuation criteria were updated to reflect the new approved maintenance dose of Wegovy (1.7 mg once weekly) in adults. The continuation criterion that approves continuation of Wegovy for 1 year, was modified to approve if the patient is able to tolerate a Wegovy maintenance dose of 1.7 mg once weekly or 2.4 mg once weekly. The continuation criterion that approves continuation of Wegovy for up to 5 months, was modified to approve if according to the prescriber, the patient is continuing to titrate the Wegovy dose to a target of 1.7 mg weekly or 2.4 mg once weekly. Other conditions of coverage still apply for continued approval of Wegovy.	07/26/2023
Selected revision	Wegovy and Saxenda **Weight Loss, Adult:** In the initial therapy criteria, the requirement for a current BMI ≥ 30 kg/m^2 or ≥ 27 kg/m^2 and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, or cardiovascular disease was modified to require that at baseline (prior to the initiation of the requested agent), the patient had a BMI ≥ 30 kg/m^2 or ≥ 27 kg/m^2 and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, or cardiovascular disease. **Weight Loss, Pediatric:** In the initial therapy criteria, the requirement for a current BMI ≥ 95th percentile for age and sex was modified to	09/13/2023

	require that at baseline (prior to the initiation of the requested agent), patient had a BMI ≥ 95th percentile for age and sex.	

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected revision	Zepbound was added to the policy. New criteria were created for this product. Initial approval is for 8 months, continuation approval is for 1 year (up to 4 months if still titrating). Saxenda **Weight Loss, Adult:** Initial Therapy: Baseline body mass index (BMI) criteria were modified to remove the requirement that the BMI is prior to initiation of Saxenda. A note was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound). Patient is Continuing Therapy with Saxenda: Baseline BMI criteria were modified to remove the requirement that the BMI is prior to initiation of Saxenda. A note was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound). The criterion that a patient has lost ≥ 4% of baseline weight was modified to remove the requirement that baseline body weight was prior to initiation of Saxenda. A note was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound). **Weight Loss, Pediatric:** Initial Therapy: The baseline BMI criterion was modified to remove the requirement that the BMI is prior to initiation of Saxenda. A note was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound). Patient is Continuing Therapy with Saxenda: The baseline BMI criterion was modified to remove the requirement that the BMI is prior to initiation of Saxenda. A note was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound). The criterion that a patient has lost ≥ 1% of baseline weight was modified to remove the requirement that baseline body weight was prior to initiation of Saxenda. A note was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound). Wegovy **Weight Loss, Adult:** Initial Therapy: Baseline BMI criteria were modified to remove the requirement that the BMI is prior to initiation of Wegovy. A note was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound). Patient is Continuing Therapy with Wegovy: Baseline BMI criteria were modified to remove the requirement that the BMI is prior to initiation of Wegovy. A note was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor	11/15/2023

	agonist (e.g., Zepbound). The criterion that a patient has lost ≥ 5% of baseline weight was modified to remove the requirement that baseline body weight was prior to initiation of Wegovy. A note was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound). **Weight Loss, Pediatric:** Initial Therapy: The baseline BMI criterion was modified to remove the requirement that the BMI is prior to initiation of Wegovy. A note was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).	

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	**Weight Loss, Adult:** Patient is Continuing Therapy with Wegovy: The baseline BMI criterion was modified to remove the requirement that the BMI is prior to initiation of Wegovy. A note was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound). The criterion that a patient has lost ≥ 1% of baseline weight was modified to remove the requirement that baseline body weight was prior to initiation of Wegovy. Conditions Not Covered **Concomitant Use with other Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Agonists.** GLP-1/GIP receptor agonists were added to this condition not recommended for approval.	11/15/2023
Selected Revision	Saxenda, Wegovy, and Zepbound **Weight Loss, Adult**: Initial Therapy and Patient is Continuing on Therapy: The criterion for a patient with a BMI ≥ 27 kg/m^2 and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, or cardiovascular disease was modified to expand the list of comorbid conditions to include knee osteoarthritis, asthma, chronic obstructive pulmonary disease, non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease.	01/31/2024
DEU Revision	The revised and new indication for Wegovy was added to the overview of the document.	03/25/2024
Selected Revision	Wegovy **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease who is Either Obese or Overweight.** A new condition of coverage was added to FDA-approved indications for Wegovy.	04/03/2024
Selected Revision	Saxenda, Wegovy, and Zepbound **Weight Loss, Adult**: Initial Therapy and Patient is Continuing on Therapy: Metabolic-dysfunction associated steatotic liver disease (new nomenclature for non-alcoholic fatty liver disease) was added to the list of one of the weight-related comorbidities for a patient with a BMI ≥ 27 kg/m^2. Additionally, for the one or more weight-	05/08/2024

	related comorbidity, the criterion was modified to state that the comorbidity is at baseline or current.	
Annual Revision	No criteria changes. **Concomitant Use with Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonists.** This condition not recommended for approval was reworded. Previously, the condition read "Concomitant Use with Other Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/Glucose Dependent Insulinotropic Polypeptide (GIP) Receptor Agonists.	07/17/2024
DEU Revision	10/24/2024: Updated Zepbound indication added to overview.	--

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	Saxenda **Weight Loss, Adult.** Patient is Continuing on Therapy with Saxenda: Criterion that required the patient was able to tolerate the Saxenda maintenance dose of 3 mg once daily was removed. **Weight Loss, Pediatric.** Patient is Continuing on Therapy with Saxenda: Criterion that required the patient was able to tolerate the Saxenda maintenance dose of 2.4 mg once daily or 3 mg once daily was removed. Wegovy **Weight Loss, Adult.** Patient is Continuing on Therapy with Wegovy: Criteria related to dosing were removed. Specifically, the criteria that required the patient was able to tolerate the Wegovy maintenance dose of 1.7 mg once weekly or 2.4 mg once weekly OR if the patient had received < 12 consecutive months of Wegovy and was continuing to titrate the Wegovy dose to a target of 1.7 mg once weekly or 2.4 mg once weekly, according to the prescriber, was removed. The approval duration was changed to 1 year for a patient continuing on therapy with Wegovy; previously the approval duration was 1 year if the patient was able to tolerate the Wegovy maintenance dose of 1.7 mg once weekly or 2.4 mg once weekly and up to 5 months if the patient was continuing to titrate to the Wegovy target dose of 1.7 mg or 2.4 mg once weekly. **Weight Loss, Pediatric.** Patient is Continuing on Therapy with Wegovy: Criteria related to dosing were removed. Specifically, the criteria that required the patient was able to tolerate the Wegovy maintenance dose of 1.7 mg once weekly or 2.4 mg once weekly OR if the patient had received < 12 consecutive months of Wegovy and was continuing to titrate the Wegovy dose to a target of 1.7 mg once weekly or 2.4 mg once weekly, according to the prescriber, was removed. The approval duration was changed to 1 year for a patient continuing on therapy with Wegovy; previously the approval duration was 1 year if the patient was able to tolerate the Wegovy maintenance dose of 1.7 mg once weekly or 2.4 mg once weekly and up to 5 months if the patient was continuing to titrate to the Wegovy target dose of 1.7 mg or 2.4 mg once weekly. **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease who is Either Obese or Overweight.** Initial Therapy. The criterion requiring that the patient has a BMI ≥ 27 kg/m^2 was clarified to state that the patient has a "current" BMI ≥ 27 kg/m^2. Patient is Continuing Therapy with	01/08/2025

	Wegovy: The criterion that required the patient was able to tolerate the Wegovy maintenance dose of 1.7 mg once weekly or 2.4 mg once weekly was removed. Zepbound **Weight Loss, Adult.** Patient is Continuing Therapy with Zepbound: Criteria related to dosing were removed. Specifically, the criteria that required the patient was able to tolerate the Zepbound maintenance dose of 5 mg, 10 mg, or 15 mg once weekly OR if the patient had received < 12 consecutive months of Zepbound and was continuing to titrate the Zepbound dose to a target of 10 mg once weekly or 15 mg once weekly, according to the prescriber, was removed. The approval duration was changed to 1 year for a patient continuing on therapy with Zepbound; previously the approval duration was 1 year if the patient was able to tolerate the Zepbound maintenance dose of 5 mg, 10 mg, or 15 mg once weekly and up to 4 months if the patient was continuing to titrate to the Zepbound target dose of 10 mg or 15 mg once weekly. **Obstructive Sleep Apnea, Moderate to Severe, in a Patient with Obesity.** A new FDA-approved indication was added to the Policy.	

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	Wegovy: **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease who is Either Obese or Overweight.** Initial Therapy. For the requirement that a patient has had a prior stroke, a note was added to clarify that this does not include a transient ischemic attack (TIA). Zepbound: **Obstructive Sleep Apnea, Moderate to Severe, in a Patient with Obesity.** Initial Therapy. The requirement that a patient had a sleep study was modified to remove the timeframe that the sleep study was within the past 1 year. A patient is still required to have a sleep study. Conditions Not Covered : **Concomitant Use with Other Medications FDA-Approved for Weight Loss.** This condition not recommended for approval was clarified to state that concomitant use with other medications FDA-approved for weight loss is not recommended. Previously, the requirement did not specify medications were "FDA-approved" for weight loss. The note with examples of weight loss medications was updated to reflect product availability for medications FDA-approved for weight loss. **Concomitant Use with Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonists.** The note was updated to reflect availability for other GLP-1 or GLP-1/GIP agonists.	05/28/2025

Annual Revision	Saxenda: **Weight Loss in an Adult with Overweight or Obesity.** This condition of approval was modified to add "with overweight or obesity". **Weight Loss in a Pediatric Patient with Obesity.** This condition of approval was modified to add "with obesity". Wegovy: **Weight Loss in an Adult with Overweight or Obesity.** This condition of approval was modified to add "with overweight or obesity". **Weight Loss in a Pediatric Patient with Obesity.** This condition of approval was modified to add "with obesity". **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease in a Patient with Overweight or Obesity.** This condition of approval was re-worded from "in an overweight or obese patient" to "in a patient with overweight or obesity". Zepbound: **Weight Loss in an Adult with Overweight or Obesity.** This condition of approval was modified to add "with overweight or obesity".	07/09/2025

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	**Policy Statement**: The following was added to the Policy Statement: In 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)/non-alcoholic steatohepatitis (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. **Documentation:** A requirement for documentation was added for the use of Wegovy for metabolic dysfunction-associated steatohepatitis MASH/NASH. 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: **Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH).** A new condition of approval was added to FDA-Approved Indications. **Conditions Not Covered:** **Concomitant Use with Other Medications FDA-Approved for Weight Loss.** This condition not recommended for approval was removed.	08/27/2025

Selected Revision	Liraglutide, generic to Saxenda, was added to the policy. **Policy Statement:** The Policy Statement was updated as follows to address the availability of liraglutide, generic to Saxenda: Prior Authorization is recommended for prescription benefit coverage of liraglutide (Saxenda, generic), Wegovy, and Zepbound. Of note, this policy targets liraglutide (Saxenda, generic), Wegovy, and Zepbound; other glucagon-like peptide-1 agonists that do not carry an FDA-approved indication for weight loss are not targeted in this policy. Liraglutide (Saxenda, generic), Wegovy, and Zepbound: **Weight Loss in an Adult with Overweight or Obesity:** Initial Therapy and Patient is Continuing on Therapy: The notes that define baseline were updated to include liraglutide, generic to Saxenda. Liraglutide (Saxenda, generic) and Wegovy: **Weight Loss in a Pediatric Patient with Obesity:** Initial Therapy and Patient is Continuing on Therapy: The notes that define baseline were updated to include liraglutide, generic to Saxenda.	09/10/2025

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	Wegovy: **Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH).** Initial Therapy**.** The requirement that the patient does not have cirrhosis was clarified that the patient does not have cirrhosis "(F4)". Criteria for the diagnosis of MASH/NASH were updated such that the patient must have documentation of stage F2 or F3 fibrosis prior to initiating treatment with Rezdiffra or Wegovy confirmed by ONE of the following: Liver biopsy performed within 3 years preceding treatment with Rezdiffra or Wegovy **[documentation required]**, vibration-controlled elastography (VCTE) performed within 6 months preceding treatment with Rezdiffra or Wegovy **[documentation required]**, magnetic resonance imaging (MRE) performed within 6 months preceding treatment with Rezdiffra or Wegovy **[documentation required]**, or Enhanced Liver Fibrosis (ELF) test performed within 6 months preceding treatment with Rezdiffra or Wegovy **[documentation required]** with a score of ≥ 9.2 to ≤ 10.5 **[documentation required].** Previously, the diagnosis of MASH/NASH was confirmed by a either a liver biopsy within 3 years preceding treatment with Wegovy **[documentation required]** that showed a non-alcoholic fatty liver disease activity score of ≥ 4 with a score of ≥ 1 in steatosis, ballooning, and lobular inflammation **[documentation required]** OR an imaging exam (i.e., elastography, computed tomography, or magnetic resonance imaging) performed within 6 months preceding treatment with Wegovy **[documentation required].** The separate criterion that the patient have stage F2 or F3 fibrosis **[documentation required]** was removed (this is part of the updated criterion outlined above; patients must still have documentation of F2 or F3 fibrosis). Reference to prior to initiating therapy throughout criteria were updated to include Rezdiffra(i.e., prior to initiating treatment with Rezdiffra or Wegovy); previously only Wegovy. Patient is Currently Receiving Wegovy. The criterion requiring that according to the prescriber the patient has not progressed to stage F4 (cirrhosis) was	12/03/2025

	modified to state, according to the prescriber, patient does not have cirrhosis (F4). Zepbound: **Obstructive Sleep Apnea, Moderate to Severe, in a Patient with Obesity.** Initial Therapy. The criterion excluding coverage of a patient with central sleep apneas was modified to remove the additional requirement that the percent of central apneas/hypopneas is ≥ 50%.	
Selected Revision	Wegovy tablet was added to the policy; new criteria were created. Wegovy injection: **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease who is Either Obese or Overweight.** Patient is Currently Receiving Wegovy injection. The note that baseline body mass index refers to baseline prior to Wegovy injection was updated to also include Wegovy tablet.	12/30/2025

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	Wegovy injection: **Weight Loss in an Adult with Overweight or Obesity** and **Weight Loss in a Pediatric Patient with Obesity.** Wegovy tablet was added to the following: Patient is Currently Receiving Wegovy injection or Wegovy tablet. The following note was updated to include Wegovy injection and Wegovy tablet: For a patient who has not completed 7 months of initial therapy with Wegovy injection and/or Wegovy tablet, refer to Initial Therapy criteria above. **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease with Overweight or Obesity.** Initial Therapy and Patient is Currently Receiving Wegovy injection criteria were combined (previously each a 1-year approval); the approval duration is 1 year The requirement that the patient has a current body mass index (BMI) of ≥ 27 kg/m^2 (previously for Initial Therapy, only) was revised that at baseline, the patient had a BMI ≥ 27 kg/m^2. The note defining baseline BMI was revised to state that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound) [previously, baseline was defined as prior to Wegovy injection or Wegovy tablet for Patient is Currently Receiving Wegovy injection or Wegovy tablet]. **Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH).** Initial Therapy. Reference to Wegovy was updated to specify Wegovy injection throughout. Wegovy tablet was added to the requirements related to identification of stage F2 or F3 fibrosis prior to initiating treatment with Rezdiffra, Wegovy injection, or Wegovy tablet **[documentation required]**. Wegovy tablet was added to the following: Patient is Currently Receiving Wegovy injection or Wegovy tablet. The following note was updated to include Wegovy injection and Wegovy tablet: For a patient who has received < 1 year of therapy with Wegovy injection and/or Wegovy tablet, or who is restating therapy, refer to Initial Therapy. For the following requirement (and the associated note), reference to Wegovy was updated to specify Wegovy injection and to add Wegovy tablet: Patient has completed ≥ 1 year of therapy with Wegovy injection and/or Wegovy tablet AND according to the prescriber, the patient has not had worsening of fibrosis or MASH/NASH. Wegovy tablet: **Weight Loss in an Adult with Overweight or Obesity.** Initial Therapy. The approval duration was changed to 7 months (previously 6 months). Wegovy injection was added to Patient is Currently Receiving Wegovy tablet or Wegovy injection. The following note was updated to include Wegovy injection and Wegovy tablet, and to reflect the 7-month initial approval duration: For a patient who has not completed 7 months of initial therapy with Wegovy injection and/or Wegovy tablet, refer to Initial Therapy criteria above. **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease with Overweight or Obesity.** The same changes were made as described for Wegovy injection; refer to Wegovy injection *Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient*	02/25/2026

	with Established Cardiovascular Disease with Overweight or Obesity, above. Zepbound: **Obstructive Sleep Apnea, Moderate to Severe, in a Patient with Obesity.** Initial Therapy. The requirement that the patient has a current BMI ≥ 30 kg/m^2 was revised that at baseline, patient had a BMI ≥ 30 kg/m^2. A note defining baseline BMI was added that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound). Patient is Currently Receiving Zepbound. The notes that define baseline were updated that baseline refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., liraglutide [Saxenda, generic], Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound); previously, baseline was defined as prior to Zepbound.	

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	Foundayo was added to the Policy; new criteria were created. **Policy Statement:** Foundayo was added to the list of products to which the Policy applies.	04/02/2026
Selected Revision	Wegovy HD injection was added to the policy; approval criteria are the same as for Wegovy injection. **Policy Statement:** Wegovy HD injection was added to the Policy Statement. The statement was also updated to reflect the availability of Wegovy tablet and Wegovy injection. **Documentation:** Wegovy HD injection was added to the documentation statement. Foundayo **Weight Loss in an Adult with Overweight or Obesity:** The initial approval was changed to 8 months. The corresponding Note	04/15/2026

	for a patient currently receiving Foundayo was updated to reflect the change to initial approval. <u>Wegovy injection</u> Wegovy HD injection was added to the criteria as previously applied to Wegovy injection. In addition, the following changes were made to the Wegovy injection criteria previously in place. **Weight Loss in an Adult with Overweight or Obesity:** The initial approval was changed to 8 months. The corresponding Note for a patient currently receiving Wegovy tablet or Wegovy injection was updated to reflect the change to initial approval. Wegovy HD injection was added to the requirements and corresponding Note that apply to a patient who is currently receiving Wegovy injection or Wegovy tablet. **Weight Loss in a Pediatric Patient with Obesity:** The initial approval was changed to 8 months. The corresponding Note for a patient currently receiving Wegovy tablet or Wegovy injection was updated to reflect the change to initial approval. Wegovy HD injection was added to the requirements and corresponding Note that apply to a patient who is currently receiving Wegovy injection or Wegovy tablet. **Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH):** For initial therapy, Wegovy HD injection was added to the requirements related to identification of stage F2 or F3 fibrosis prior to initiating treatment with Rezdiffra, Wegovy injection, or Wegovy tablet **[documentation required]**. Wegovy HD injection was added to the requirements and corresponding Note that apply to a patient who is currently receiving Wegovy injection or Wegovy tablet. <u>Wegovy tablet</u> **Weight Loss in an Adult with Overweight or Obesity:** The initial approval was changed to 8 months. The corresponding Note for a patient currently receiving Wegovy tablet or Wegovy injection was updated to reflect the change to initial approval. Wegovy HD injection was added to the requirements and corresponding Note that apply to a patient who is currently receiving Wegovy injection or Wegovy tablet.	