



## Drug Coverage Policy

Effective Date .....03/01/2026  
Coverage Policy Number.....IP0206  
Policy Title.....Weight Loss –  
Glucagon-Like Peptide-1 Agonists BMI  
≥ 30

# Weight Loss – Glucagon-Like Peptide-1 Agonists BMI ≥ 30

- Saxenda® (liraglutide subcutaneous injection – Novo Nordisk, generic)
- Wegovy® (semaglutide tablet and subcutaneous injection – Novo Nordisk)
- Zepbound™ (tirzepatide subcutaneous injection – Eli Lilly)

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### **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.

Weight loss medications are specifically excluded under many benefit plans [both Employer Groups and Individual and Family Plans]. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.

### Overview

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.<sup>1,2,4</sup>

**Liraglutide, Wegovy injection, Wegovy tablet, and Zepbound** are indicated in combination with a reduced-calorie diet and increased physical activity:<sup>1,2,4</sup>

- To **reduce excess body weight and maintain weight reduction long term** in:
  - **Liraglutide, Wegovy injection, Wegovy tablet, and Zepbound:** Adults with overweight in the presence of at least one weight-related comorbid condition.<sup>1,2,4,6</sup>
  - **Liraglutide, Wegovy injection, Wegovy tablet, and Zepbound:** Adults with obesity.<sup>1,4</sup>
  - **Liraglutide:** Pediatric patients  $\geq 12$  years of age and  $\geq 60$  kg with obesity.<sup>2</sup>
  - **Wegovy injection:** Pediatric patients  $\geq 12$  years of age with obesity.<sup>1,7</sup>

**Wegovy injection, Wegovy tablet,** are indicated in combination with a reduced-calorie diet and increased physical activity:<sup>1</sup>

- 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**.<sup>1,5</sup>
- 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.<sup>1,19,20</sup>

**Zepbound** is indicated in combination with a reduced-calorie diet and increased physical activity:<sup>4</sup>

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

### Dosing

In the prescribing information for Wegovy, a recommended dose escalation schedule of 16 weeks is outlined (the 2.4 mg dose would be reached at the start of Week 17).<sup>1</sup> If a patient does not tolerate a dose during dose escalation, consider delaying dose escalation for 4 weeks. For CV risk reduction and weight reduction, the maintenance dose of Wegovy is 2.4 mg (recommended) or 1.7 mg injected subcutaneously (SC) once weekly (QW); consider treatment response and tolerability when selecting the maintenance dose. For MASH, the recommended maintenance dose is 2.4 mg QW. If the patient does not tolerate 2.4 mg QW, the dose can be decreased to 1.7 mg QW. Consider re-escalation to 2.4 mg QW.

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).<sup>1</sup> 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 once daily (QD). If the patient does not tolerate the 25 mg QD maintenance dosage, consider switching to Wegovy 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 injection QW and follow the recommended dosage escalation for Wegovy injection.

Adults taking Wegovy 2.4 mg injection for CV risk reduction or weight reduction may switch to Wegovy 25 mg tablets.<sup>1</sup> One week after discontinuing Wegovy 2.4 mg injection, initiate 25 mg of Wegovy tablets orally QD. A patient may switch from Wegovy 25 mg tablets to Wegovy 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.<sup>2</sup> If a patient does not tolerate an increased dose during dose escalation, consider delaying dose escalation for approximately one additional week. For adults, the recommended maintenance dose of liraglutide is 3 mg SC once daily (QD); discontinue liraglutide if the patient cannot tolerate the 3 mg dose. Additionally, 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  $\geq 4\%$  of baseline body weight, since it is unlikely the patient will achieve and sustain clinically meaningful weight loss with continued treatment. For pediatric patients, the recommended maintenance dose is 3 mg SC QD; patients who do not tolerate 3 mg QD may have the maintenance dose reduced to 2.4 mg QD. Discontinue liraglutide if the patient cannot tolerate the 2.4 mg dose. If a pediatric patient does not tolerate an increased dose during dose escalation, the dose may be lowered to the prior dose level; dose escalation may take up to 8 weeks. Evaluate the change in body mass index (BMI) after 12 weeks on the maintenance dose in pediatric patients; if the patient has not had a reduction in BMI of  $\geq 1\%$  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.<sup>4</sup> The 2.5 mg dose is for treatment initiation and is not intended for chronic weight management. After 4 weeks, the dose can be increased to 5 mg QW. The dose can then be increased in 2.5 mg increments, after at least 4 weeks on the current dose. The recommended maintenance doses for weight reduction and long-term maintenance are 5 mg, 10 mg, or 15 mg QW. The recommended maintenance dose in OSA is 10 mg or 15 mg QW. The treatment response and tolerability should be considered when selecting the maintenance dose. If a patient does not tolerate a maintenance dose, consider a lower maintenance dose. The maximum dose is 15 mg QW. The 5 mg, 10 mg, and 15 mg maintenance doses are reached after 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.<sup>1,2,4</sup>

## **Clinical Efficacy**

### *Secondary Prevention of MACE*

SELECT was a randomized, double-blind, placebo-controlled, event-driven study that assessed Wegovy vs. placebo, when added to standard of care, for the secondary prevention of CV events in adults  $\geq 45$  years of age with BMI  $\geq 27$  kg/m<sup>2</sup> and established CV disease without diabetes (n = 17,604).<sup>5</sup> 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.<sup>5</sup> The trial achieved its primary endpoint, demonstrating a statistically significant and superior reduction in MACE for Wegovy vs. placebo. A primary endpoint event occurred in 6.5% vs. 8.0% of patients in the Wegovy 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 or placebo, both in addition to standard of care (optimization of treatment for type 2 diabetes, dyslipidemia, and CV risk management).<sup>19,20</sup> 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. Rezdifra™ (resmetirom tablets) was not approved at the time the trial commenced; therefore, no patients were taking Rezdifra 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<sup>2</sup>. 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<sup>2</sup> [≥ 23 kg/m<sup>2</sup> 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 vs. placebo.<sup>20</sup> Wegovy demonstrated a significant improvement in liver fibrosis with no worsening of steatohepatitis, as well as resolution of steatohepatitis with no worsening of liver fibrosis. Confirmatory secondary endpoints also generally favored Wegovy (e.g., resolution of steatohepatitis with improvement in liver fibrosis, weight change). Part 2 of the trial is ongoing and expected to read out in 2029.

#### *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.<sup>9</sup> 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<sup>2</sup> (≥ 27 kg/m<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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.<sup>9</sup> 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;  $P < 0.001$ ).<sup>9</sup> 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  $\geq 50\%$  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  $\leq 10$  at Week 52 also favored Zepbound. Patients receiving Zepbound in both trials had significant reductions in body weight.

## **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.<sup>23</sup> BMI is appropriate to screen for ABCD/obesity and is used to classify individuals into categories of overweight (BMI  $\geq 25.0$  to  $\leq 29.9$  kg/m<sup>2</sup>), Class I obesity (BMI  $\geq 30.0$  to  $\leq 34.9$  kg/m<sup>2</sup>), Class II obesity (BMI  $\geq 35.0$  to  $\leq 39.9$  kg/m<sup>2</sup>), or Class III obesity (BMI  $\geq 40$  kg/m<sup>2</sup>). 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  $\geq 5\%$  weight loss, longer-term efficacy will not likely be sufficient; a change in therapeutic approach is recommended. Individuals with weight reduction  $\geq 5\%$  should continue with their current treatment. Patients who achieve  $\geq 15\%$  weight loss (noted to be the percent weight loss observed on average with Wegovy [only injection was approved at the time] and Zepbound) will have achieved a response to therapy that predictably prevents or improves a wide range of obesity-related comorbidities.

#### Pediatric

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  $\geq 12$  years of age with obesity (BMI  $\geq 95^{\text{th}}$  percentile) weight loss pharmacotherapy, according to medication indications, risks, and benefits, as an adjunct to health behavior and lifestyle treatment.<sup>7</sup>

#### *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.<sup>21,22</sup> Best practices in the management of MASH include comprehensive lifestyle modification (nutrition, exercise, behavioral modification), and optimal control of comorbid metabolic conditions.<sup>21</sup> 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.<sup>22</sup> There are no FDA-approved non-invasive tests to diagnose MASH with stage F2 to F3 fibrosis or to monitor the response to pharmacotherapy.<sup>21</sup> 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).<sup>21</sup> 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.<sup>22</sup> For the blood-based ELF score, a cutoff of 9.2 provides optimal sensitivity and specificity for detecting  $\geq$  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.<sup>10</sup> 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  $\geq$  25 kg/m<sup>2</sup>) participate in comprehensive lifestyle intervention that includes a reduced calorie diet, exercise/increased physical activity, and behavioral counseling.<sup>11</sup> For patients with OSA and a BMI  $\geq$  27 kg/m<sup>2</sup> 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  $\geq$  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 result in additional benefit.<sup>23</sup>

Clinical success in OSA has been described by several publications. The American Academy of Sleep Medicine (2019) cites a clinically significant threshold of  $\geq$  15 events/hour (on AHI)<sup>12</sup> 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<sup>13</sup> 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.<sup>14</sup>

## Coverage Policy

### **Policy Statement**

Prior Authorization is required for 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 which 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 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 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 Saxenda for weight loss and Wegovy for MASH/NASH as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.

**Glucagon-like peptide-1 (GLP-1) receptor agonists are considered medically necessary when ONE of the following is met (I, II, III, or IV):**

**I. Liraglutide (Saxenda, generic) is considered medically necessary when ONE of the following is met (1 or 2):**

**FDA-Approved Indications**

**1. Weight Loss in an Adult with Obesity or is Overweight.** 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, iv, and v):

**i.** Patient is  $\geq 18$  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  $\geq 30$  kg/m<sup>2</sup>; 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  $\geq 27$  kg/m<sup>2</sup>

**(2)** At baseline, patient had, or patient currently has, and 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; AND
- v. Preferred product criteria is met for the product(s) as listed in the below table(s);  
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  $\geq 18$  years of age; AND
- ii. Patient meets ONE of the following (a or b):
  - a) At baseline, patient had a BMI  $\geq 30$  kg/m<sup>2</sup>; 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  $\geq 27$  kg/m<sup>2</sup>
    - (2) At baseline, patient had, or patient currently has, and 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  $\geq 4\%$  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, iv, and v):

- i. Patient is  $\geq 12$  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  $\geq 95^{\text{th}}$  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: AND
- v. Preferred product criteria is met for the product(s) as listed in the below table(s);  
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  $\geq 12$  years of age and  $< 18$  years of age; AND
- ii.** At baseline, patient had a BMI  $\geq 95^{\text{th}}$  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  $\geq 1\%$  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.

**Employer Plans:**

Product	Criteria
<b>Saxenda</b> (liraglutide subcutaneous injection)	The patient has tried the bioequivalent generic product, <b><u>liraglutide subcutaneous injection (generic for Saxenda)</u></b> , AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction. <b>[documentation required]</b>

**II. Wegovy injection is considered medically necessary when ONE of the following is met (1, 2, 3 or 4):**

**FDA-Approved Indications**

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

- A) Initial Therapy.** Approve for 7 months if the patient meets ALL of the following (i, ii, iii, and iv):
  - i.** Patient is  $\geq 18$  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  $\geq 30$  kg/m<sup>2</sup>; 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  $\geq 27$  kg/m<sup>2</sup>
      - (2)**At baseline, patient had, or patient currently has, and 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.

**B) Patient is Currently Receiving Wegovy injection.** Approve for 1 year if the patient ALL of the following (i, ii, iii, and iv):

Note: For a patient who has not completed 7 months of initial therapy, refer to Initial Therapy criteria above.

i. Patient is  $\geq 18$  years of age; AND

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

a) At baseline, patient had a BMI  $\geq 30$  kg/m<sup>2</sup>; 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  $\geq 27$  kg/m<sup>2</sup>

(2) At baseline, patient had, or patient currently has, and 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  $\geq 5\%$  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 7 months if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is  $\geq 12$  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  $\geq 95^{\text{th}}$  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. Wegovy will be used concomitantly with behavioral modification and a reduced-calorie diet.

**B) Patient is Currently Receiving Wegovy 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 7 months of initial therapy, refer to Initial Therapy criteria above.

- i. Patient is  $\geq 12$  years of age and  $< 18$  years of age; AND
- ii. At baseline, patient had a BMI  $\geq 95^{\text{th}}$  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  $\geq 1\%$  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 Obesity or is Overweight.** 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  $\geq 18$  years of age; AND
- ii. Patient has a current BMI  $\geq 27 \text{ kg/m}^2$ ; AND
- iii. Patient meets ONE of the following (a, b, or c):
  - a) Patient has had a prior myocardial infarction; OR
  - b) Patient has had a prior stroke; OR  
Note: This does not include a transient ischemic attack (TIA).
  - c) Patient has a history of symptomatic peripheral arterial disease as evidenced by ONE of the following (1, 2, or 3):
    - (1) Intermittent claudication with ankle-brachial index  $< 0.85$ ; OR
    - (2) Peripheral arterial revascularization procedure; OR
    - (3) Amputation due to atherosclerotic disease; AND
- iv. According to the prescriber, the medication will be used in combination with optimized pharmacotherapy for established cardiovascular disease; AND
- v. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

**B) Patient is Currently Receiving Wegovy injection.** Approve if the patient meets ALL of the following (i, ii, iii, iv, and v):

Note: For a patient who has not completed 1 year of initial therapy, refer to Initial Therapy criteria above.

- i. Patient is  $\geq 18$  years of age; AND
- ii. At baseline, Patient had a BMI  $\geq 27 \text{ kg/m}^2$ ; AND  
Note: This refers to baseline prior to Wegovy injection or tablet.
- iii. Patient meets ONE of the following (a, b, or c):
  - a) Patient has had a prior myocardial infarction; OR
  - b) Patient has had a prior stroke; OR
  - c) Patient has a history of symptomatic peripheral arterial disease as evidenced by ONE of the following (1, 2, or 3):
    - (1) Intermittent claudication with ankle-brachial index  $< 0.85$ ; OR
    - (2) Peripheral arterial revascularization procedure; OR
    - (3) Amputation due to atherosclerotic disease; AND
- iv. According to the prescriber, the medication will be used in combination with optimized pharmacotherapy for established cardiovascular disease; AND
- v. 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, and vii):
- i.** Patient is  $\geq 18$  years of age; AND
  - ii.** Patient does not have cirrhosis (F4); AND
  - iii.** Patient has stage F2 or F3 fibrosis prior to initiating treatment with Rezdifra or Wegovy [**documentation required**] identified by ONE of the following (a, b, c, or d):
    - a)** Liver biopsy performed within the 3 years preceding treatment with Rezdifra or Wegovy [**documentation required**]; OR
    - b)** Vibration-controlled transient elastography (VCTE) performed within the 6 months preceding treatment with Rezdifra or Wegovy [**documentation required**]; OR
    - c)** Magnetic resonance elastography (MRE) performed within the 6 months preceding treatment with Rezdifra or Wegovy [**documentation required**]; OR
    - d)** Enhanced Liver Fibrosis™ (ELF) test performed within the 6 months preceding treatment with Rezdifra or Wegovy [**documentation required**] with a score of  $\geq 9.2$  to  $\leq 10.5$  [**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:** Approve if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
- Note: A patient who has received  $< 1$  year of therapy or who is restarting therapy should be considered under criterion A (Initial Therapy).
- i.** Patient has completed  $\geq 1$  year of therapy with Wegovy AND according to the prescriber, the patient has not had worsening of fibrosis or MASH/NASH; AND

Note: This applies to a patient starting their second (or more) year of therapy with Wegovy (i.e., the patient has already completed 1 year or more of therapy with Wegovy).

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

\*Refer to the Policy Statement

**III. Wegovy tablet is considered medically necessary when ONE of the following is met (1 or 2):**

**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 6 months if the patient meets ALL of the following (i, ii, iii, and iv):

- i. Patient is  $\geq 18$  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  $\geq 30$  kg/m<sup>2</sup>; 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  $\geq 27$  kg/m<sup>2</sup>; 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.** 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 6 months of initial therapy, refer to Initial Therapy criteria above.

i. Patient is  $\geq 18$  years of age; AND

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

**a)** At baseline, patient had a BMI  $\geq 30$  kg/m<sup>2</sup>; 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  $\geq 27$  kg/m<sup>2</sup>; 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  $\geq 5\%$  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 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  $\geq 18$  years of age; AND

ii. Patient has a current BMI  $\geq 27$  kg/m<sup>2</sup>; AND

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

**a)** Patient has had a prior myocardial infarction; OR

**b)** Patient has had a prior stroke; OR

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

**c)** Patient has a history of symptomatic peripheral arterial disease as evidenced by ONE of the following [(1), (2), or (3)]:

**(1)**Intermittent claudication with ankle-brachial index  $< 0.85$ ; OR

**(2)**Peripheral arterial revascularization procedure; OR

**(3)**Amputation due to atherosclerotic disease; AND

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

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

**B) Patient is Currently Receiving Wegovy tablet.** Approve if the patient meets ALL of the following (i, ii, iii, iv, and v):

Note: For a patient who has not completed 1 year of initial therapy, refer to Initial Therapy criteria above.

**i.** Patient is  $\geq 18$  years of age; AND

**ii.** At baseline, patient had a BMI  $\geq 27$  kg/m<sup>2</sup>; AND

Note: This refers to baseline prior to Wegovy injection or Wegovy tablet.

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

**a)** Patient has had a prior myocardial infarction; OR

**b)** Patient has had a prior stroke; OR

**c)** Patient has a history of symptomatic peripheral arterial disease as evidenced by ONE of the following [(1), (2), or (3)]:

**(1)** Intermittent claudication with ankle-brachial index  $< 0.85$ ; OR

**(2)** Peripheral arterial revascularization procedure; OR

**(3)** Amputation due to atherosclerotic disease; AND

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

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

**IV. Zepbound is considered medically necessary when ONE of the following is met (1 or 2):**

#### **FDA-Approved Indications**

**1. Weight Loss in an Adult with Obesity or is Overweight.** 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  $\geq 18$  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  $\geq 30$  kg/m<sup>2</sup>; 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  $\geq 27$  kg/m<sup>2</sup>

**(2)** At baseline, patient had, or patient currently has, and 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.

**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  $\geq 18$  years of age; AND

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

**a)** At baseline, patient had a BMI  $\geq 30$  kg/m<sup>2</sup>; 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  $\geq 27$  kg/m<sup>2</sup>

**(2)** At baseline, patient had, or patient currently has, and 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  $\geq 5\%$  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  $\geq 18$  years of age; AND

**ii.** Patient has a current BMI  $\geq 30$  kg/m<sup>2</sup>; AND

**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  $\geq 15$  events per hour; AND

Note: A diagnosis of moderate obstructive sleep apnea is an apnea-hypopnea index of  $\geq 15$  events per hour, a diagnosis of severe sleep apnea is an apnea-hypopnea index  $\geq 30$  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 in 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: A patient who has received  $< 1$  year of therapy should be considered under criterion A (Initial Therapy).

**i.** Patient is  $\geq 18$  years of age; AND

- ii. At baseline, patient had a BMI  $\geq 30$  kg/m<sup>2</sup>; AND  
Note: This refers to baseline before Zepbound.
- iii. Patient has completed  $\geq 1$  year of therapy with Zepbound AND the patient meets BOTH of the following (a and b):
  - a) Patient has lost  $\geq 10\%$  of baseline body weight; AND
  - b) According to the prescriber, patient has stability in obstructive sleep apnea signs or symptoms, according to the prescriber; 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

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

1. **Concomitant Use with other Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor 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.<sup>1,2,9,12,20-24</sup> There are other GLP-1 and GLP-1/GIP 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 SC injection, Ozempic (semaglutide 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).

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## Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	Saxenda, Wegovy, and Zepbound <b>Weight Loss, Adult:</b> <u>Initial Therapy and Patient is Continuing on Therapy:</u> 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	08/15/2024

	<p>comorbidities for a patient with a BMI <math>\geq 27</math> kg/m<sup>2</sup>. Additionally, for the one or more weight-related comorbidity, the criterion was modified to state that the comorbidity is at baseline or current.</p>	
<p>Selected Revision</p>	<p><b>Wegovy and Zepbound added to the policy.</b></p> <p><u>Saxenda</u>  <b>Initial Therapy (Adult):</b>  Examples of comorbidities updated.  <b>Patient is Continuing on Therapy (Adult):</b>  Examples of comorbidities updated.  Updated the body weight decrease requirement by removing "only required once"  Added a requirement for the patient to tolerate a maintenance dose.  <b>Initial Therapy (Pediatric)</b>  Removed the option for the patient to alternatively have a BMI <math>\geq 85</math>th percentile and <math>&lt; 95</math>th percentile for age and sex (overweight) if the patient had at least one comorbidity.  <b>Patient is Continuing on Therapy (Pediatric):</b>  Removed the option for the patient to alternatively have a BMI <math>\geq 85</math>th percentile and <math>&lt; 95</math>th percentile for age and sex (overweight) if the patient had at least one comorbidity.  Added a requirement for the patient to tolerate a maintenance dose of.</p> <p><u>Wegovy</u>  <b>Initial Therapy (Adult):</b>  Examples of comorbidities updated.  <b>Patient is Continuing on Therapy (Adult):</b>  Examples of comorbidities updated.  Updated the body weight decrease requirement by removing "only required once"  Added a requirement for the patient to tolerate a maintenance dose.  <b>Initial Therapy (Pediatric)</b>  Removed the option for the patient to alternatively have a BMI <math>\geq 85</math>th percentile and <math>&lt; 95</math>th percentile for age and sex (overweight) if the patient had at least one comorbidity.  <b>Patient is Continuing on Therapy (Pediatric):</b>  Removed the option for the patient to alternatively have a BMI <math>\geq 85</math>th percentile and <math>&lt; 95</math>th percentile for age and sex (overweight) if the patient had at least one comorbidity.  Updated the requirement of a reduction in body weight to a reduction in BMI and by removing "only required once"  A requirement for the patient to tolerate a maintenance dose added.</p>	<p>07/15/2024</p>

	<p><b>Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease who is Either Obese or Overweight.</b>  Added a new condition of coverage to FDA-approved indications for Wegovy.</p> <p><u>Zepbound</u>  <b>Initial Therapy (Adult):</b>  Examples of comorbidities updated.  <b>Patient is Continuing on Therapy (Adult):</b>  Documentation required added to the approach for adult patients with a BMI <math>\geq</math> 30 kg/m<sup>2</sup> or a BMI <math>\geq</math> 27 kg/m<sup>2</sup>  Examples of comorbidities updated.  Updated the body weight decrease requirement by removing "only required once"  Added a requirement for the patient to tolerate a maintenance dose.</p>	
Selected Revision	<p>Saxenda  <b>Weight Loss, Adult.</b> <u>Patient Continuing on Saxenda:</u> Dosing criteria were removed.  Saxenda and Wegovy  <b>Weight Loss, Pediatric.</b> <u>Patient Continuing on Saxenda:</u> Dosing criteria were removed.</p> <p><u>Wegovy</u>  <b>Weight Loss, Adult.</b> <u>Patient Continuing on Wegovy:</u> Dosing criteria were removed. The approval duration was changed to 1 year.  <b>Weight Loss, Pediatric.</b> <u>Patient Continuing on Wegovy:</u> Dosing criteria were removed. The approval duration was changed to 1 year.  <b>Cardiovascular Disease who is Either Obese or Overweight.</b> Initial Therapy. The criterion requiring that the patient has a BMI <math>\geq</math> 27 kg/m<sup>2</sup> was clarified to state that the patient has a current BMI <math>\geq</math> 27 kg/m<sup>2</sup>.  <u>Patient Continuing on Wegovy:</u> Dosing criteria were removed.</p> <p><u>Zepbound</u>  <b>Weight Loss, Adult.</b> <u>Patient Continuing on Zepbound:</u> Dosing criteria were removed. The approval duration was changed to 1 year.</p> <p><b>Obstructive Sleep Apnea Moderate to Severe in a Patient with Obesity.</b> A new FDA-approved condition was added to the Policy.</p>	03/15/2025

Selected Revision	Policy title changed from "Weight Loss – Glucagon-Like Peptide-1 Agonists" to "Weight Loss – Glucagon-Like Peptide-1 Agonists BMI ≥ 30" The Conditions Not Covered statement was reworded.	07/01/2025
Selected Revision	<p><u>Wegovy:</u>  <b>Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease who is Either Obese or Overweight.</b> <u>Initial Therapy.</u> For the requirement that a patient has had a prior stroke, a note was added that a to clarify that this does not include a transient ischemic attack (TIA).</p> <p><u>Zepbound:</u>  <b>Obstructive Sleep Apnea, Moderate to Severe, in a Patient with Obesity.</b> <u>Initial Therapy.</u> 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.</p> <p>Conditions Not Recommended for Approval:  <b>Concomitant Use with Other Medications FDA-Approved for Weight Loss.</b> This condition not recommended for approval was clarified to state that concomitant use with other medications <u>FDA-approved</u> 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.</p> <p><b>Concomitant Use with Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonists.</b> The note was updated to reflect availability for other GLP-1 or GLP-1/GIP agonists.</p>	08/01/2025
Selected Revision	<p><u>Saxenda:</u>  <b>Weight Loss in an Adult with Overweight or Obesity.</b> This condition of approval was modified to add "with obesity or is overweight".  <b>Weight Loss in a Pediatric Patient with Obesity.</b> This condition of approval was modified to add "with obesity".</p> <p><u>Wegovy:</u></p>	09/15/2025

	<p><b>Weight Loss in an Adult with Overweight or Obesity.</b> This condition of approval was modified to add "with obesity or is overweight".</p> <p><b>Weight Loss in a Pediatric Patient with Obesity.</b> This condition of approval was modified to add "with obesity".</p> <p><b>Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease in a Patient with Obesity or Overweight.</b> This condition of approval was re-worded from "in an overweight or obese patient" to "in a patient with obesity or is overweight".</p> <p><u>Zepbound:</u></p> <p><b>Weight Loss in an Adult with Overweight or Obesity.</b> This condition of approval was modified to add "with obesity or is overweight".</p>	
Selected Revision	<p>Liraglutide, generic to Saxenda was added to the policy.</p> <p><b>Policy Statement:</b> The following was added: 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 as well as the monitoring required for adverse events and long-term efficacy, approval requires Wegovy to be prescribed by or in consultation with a physician who specializes in the condition being treated. 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.</p> <p><b>Documentation:</b> A requirement for documentation was added for the use of Wegovy for MASH. Documentation may include, but is not limited to,</p>	12/15/2025

	<p>chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.</p> <p><u>Wegovy:</u></p> <p><b>Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH).</b> A new condition of coverage was added to FDA-Approved Indications.</p> <p>Conditions Not Recommended for Approval:</p> <p><b>Concomitant Use with Other Medications FDA-Approved for Weight Loss.</b> This condition not recommended for approval was removed.</p> <p><u>Liraglutide (Saxenda, generic), Wegovy, and Zepbound:</u></p> <p><b><u>Weight Loss in an Adult with Overweight or Obesity:</u></b> Initial Therapy and Patient is Continuing on Therapy: The notes that define baseline were updated to include liraglutide, generic to Saxenda.</p> <p><u>Liraglutide (Saxenda, generic) and Wegovy:</u></p> <p><b><u>Weight Loss in a Pediatric Patient with Obesity:</u></b> Initial Therapy and Patient is Continuing on Therapy: The notes that define baseline were updated to include liraglutide, generic to Saxenda.</p> <p><u>Saxenda</u></p> <p><b>Weight Loss in an Adult with Obesity or is Overweight.</b></p> <p><u>Initial therapy</u></p> <p><b>Added</b> preferred product requirements.</p> <p><b>Weight Loss in a Pediatric Patient with Obesity.</b></p> <p><u>Initial therapy</u></p> <p><b>Added</b> preferred product requirements.</p>	
Selected Revision	<p><b>Updated</b> the policy statement.</p> <p><b>Changed</b> each "Patient is Continuing Therapy" to "Patient is Currently Receiving"</p> <p><u>Wegovy</u></p> <p><b>Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH).</b></p> <p><u>Initial Therapy.</u> The requirement that the patient does not have cirrhosis was clarified that the patient does not have cirrhosis "(F4)". Criteria for</p>	02/15/2026

	<p>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 Rezdifra or Wegovy confirmed by ONE of the following: Liver biopsy performed within 3 years preceding treatment with Rezdifra or Wegovy <b>[documentation required]</b>, vibration-controlled elastography (VCTE) performed within 6 months preceding treatment with Rezdifra or Wegovy <b>[documentation required]</b>, magnetic resonance imaging (MRE) performed within 6 months preceding treatment with Rezdifra or Wegovy <b>[documentation required]</b>, or Enhanced Liver Fibrosis (ELF) test performed within 6 months preceding treatment with Rezdifra or Wegovy <b>[documentation required]</b> with a score of <math>\geq 9.2</math> to <math>\leq 10.5</math> <b>[documentation required]</b>.</p> <p>Previously, the diagnosis of MASH/NASH was confirmed by either a liver biopsy within 3 years preceding treatment with Wegovy <b>[documentation required]</b> that showed a non-alcoholic fatty liver disease activity score of <math>\geq 4</math> with a score of <math>\geq 1</math> in steatosis, ballooning, and lobular inflammation <b>[documentation required]</b> OR an imaging exam (i.e., elastography, computed tomography, or magnetic resonance imaging) performed within 6 months preceding treatment with Wegovy <b>[documentation required]</b>. The separate criterion that the patient have stage F2 or F3 fibrosis <b>[documentation required]</b> 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 Rezdifra (i.e., prior to initiating treatment with Rezdifra or Wegovy); previously only Wegovy.</p> <p><u>Patient is Currently Receiving Wegovy.</u> The criterion requiring that according to the prescriber the patient has not progressed to stage F4 (cirrhosis) was modified to state, according to the prescriber, patient does not have cirrhosis (F4).</p> <p>Zepbound  <b>Obstructive Sleep Apnea, Moderate to Severe, in a Patient with Obesity.</b>  <u>Initial Therapy.</u> The criterion excluding coverage of a patient with central sleep apneas was modified to</p>	
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	remove the additional requirement that the percent of central apneas/hypopneas is $\geq$ 50%.	
Selected Revision	<p>Wegovy tablet was added to the policy; new criteria were created.</p> <p>Wegovy injection  <b>Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease who is Either Obese or Overweight.</b>  <u>Patient is Currently Receiving Wegovy injection.</u> The note that baseline body mass index refers to baseline prior to Wegovy injection was updated to also include Wegovy tablet.</p>	03/01/2026

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

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