VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Weight Loss – Glucagon-Like Peptide-1 Agonists Prior Authorization Policy
- Saxenda® (liraglutide subcutaneous injection – Novo Nordisk)
- Wegovy® (semaglutide subcutaneous injection – Novo Nordisk)
- Zepbound® (tirzepatide subcutaneous injection – Eli Lilly)

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OVERVIEW

Saxenda, Wegovy, and Zepbound are glucagon-like peptide-1 (GLP-1) receptor agonists; Zepbound is also a glucose-dependent insulinotropic polypeptide (GIP) receptor agonist.[1,2,9]

Saxenda is indicated as an adjunct to a reduced-calorie diet and increased physical activity for **chronic weight management** in the following settings:[2]
- Adults with an initial body mass index (BMI) ≥ 30 kg/m^2 (obese), or ≥ 27 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension[2,9], dyslipidemia[2,9], type 2 diabetes[2,9], obstructive sleep apnea[9], or cardiovascular disease[9]).
- Pediatric patients ≥ 12 years of age with body weight > 60 kg and an initial BMI corresponding to 30 kg/m^2 for adults (obese) by international cutoffs.[2]

Wegovy and Zepbound are indicated in combination with a reduced-calorie diet and increased physical activity:[1,9]
- To **reduce excess body weight and maintain weight reduction long term** in:
  - **Wegovy and Zepbound:** Adults with overweight in the presence of at least one weight-related comorbid condition.[1,9,11]
  - **Wegovy and Zepbound:** Adults with obesity.[1,9]
  - **Wegovy:** Pediatric patients ≥ 12 years of age with obesity.[1,12]

Wegovy is 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, or non-fatal stroke] in adults with established CV disease and either obesity or overweight.[1,10]

Zepbound is indicated in combination with a reduced-calorie diet and increased physical activity:[9]
- 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.[1] If a patient does not tolerate a dose during dose escalation, consider delaying dose escalation for 4 weeks. In adults, the maintenance dose of Wegovy is 2.4 mg (recommended) or 1.7 mg injected subcutaneously once weekly (QW); consider treatment response and tolerability when selecting the maintenance dose. In pediatric patients, the maintenance dose of Wegovy is 2.4 mg; if a pediatric patient ≥ 12 to < 18 years of age does not tolerate the maintenance dose of 2.4 mg QW, the dose can be reduced to 1.7 mg QW. Discontinue Wegovy if the patient cannot tolerate the 1.7 mg dose. The 0.25 mg, 0.5 mg, and 1 mg QW doses are initiation and escalation doses; they are not approved doses for chronic weight management.

In the prescribing information for Saxenda, 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 recommended maintenance dose of Saxenda is 3 mg once daily; discontinue Saxenda 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 Saxenda and discontinue Saxenda 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.

In the prescribing information for Zepbound, the recommended starting dose is 2.5 mg injected subcutaneously QW.[9] 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 subcutaneously 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 subcutaneously QW. The recommended maintenance dose in OSA is 10 mg or 15 mg subcutaneously 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 subcutaneously 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.[1,2,9]

Clinical Efficacy

Secondary Prevention of MACE

SELECT was a randomized, double-blind, placebo-controlled, event-driven study that assessed Wegovy (2.4 mg QW) 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).[10] Established CV disease was defined as one of the following: prior myocardial infarction, 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). Patients who developed diabetes during the study remained in the study and received treatment (excluding use of another GLP-1 agonist). Wegovy was titrated to reach the 2.4 mg maintenance dose over 16 weeks. However, if dose escalation led to unacceptable effects, the dose escalation intervals could be extended, treatment could be paused, or maintenance doses < 2.4 mg QW could be used. Most patients were male (72%) and White (84%). The mean weight was 97 kg. The mean BMI was 33.3 kg/m^2; 28.5% of patients had a BMI of 27 to < 30 kg/m^2, 42.5% of patients had a BMI of 30 to < 35 kg/m^2, 19% of patients had a BMI of 35 to < 40 kg/m^2, 7% of patients had a BMI of 40 kg/m^2 to < 45 kg/m^2, and just over 3% of patients had a BMI ≥ 45 kg/m^2. Very few patients (< 0.1%) were treated with weight-lowering pharmacotherapy at baseline (further detail is not available; however, concomitant GLP-1 agonist use was not allowed).[11] The mean hemoglobin A_{1c} (HbA_{1c}) was just over 5.7%; 67% of patients had an HbA_{1c} ≥ 5.7% (pre-diabetes). The most common prior CV event was myocardial infarction (68% of patients), followed by stroke (18%), and 4.5% of patients had symptomatic peripheral arterial disease; 8% of patients had two or more of these conditions. At baseline, 91.8% of patients were receiving CV risk-lowering pharmacotherapy, 90% of patients were receiving lipid-lowering agents (87.3% of patients were taking statins, 13.0% of patients were taking ezetimibe, 2.7% of patients were taking fibrates, and 2.0% of patients were taking proprotein convertase subtilisin/kexin type 9 inhibitors), 86.2% of patients were receiving platelet aggregation inhibitors, and 12.6% of patients were receiving antithrombotic medications.[10,11] In addition, 70.2% of patients were taking beta-blockers, 45.0% of patients were taking angiotensin converting enzyme inhibitors, and 29.5% of patients were taking angiotensin receptor blockers.[11] The primary efficacy endpoint was a composite of death from CV causes, non-fatal MI, or non-

fatal stroke.[10] Confirmatory secondary endpoints, assessed in a time-to-first-event analysis and tested in hierarchical order were: death from CV causes, a composite heart failure endpoint (death from CV causes or hospitalization for heart failure [HHF] or an urgent medical visit for heart failure), and death from any cause. A gatekeeping approach was used with statistical significance at each step required in order to test the next hypothesis.

Results. Patients were followed for a mean of 39.8 months.[10] At Week 104, approximately 77% of patients receiving Wegovy were taking the target 2.4 mg QW dose (details on the exact proportions of patients on other Wegovy doses are not available; efficacy results are only provided for the 2.4 mg dose). 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 [HR] 0.80; 95% CI: 0.72, 0.90; P < 0.001). Death from CV events, the first confirmatory secondary endpoint, occurred in 2.5% vs. 3.0% of Wegovy- vs. placebo-treated patients, respectively (HR 0.85; 95% CI: 0.71, 1.01; P = not significant for superiority). Because the difference between groups for death from CV events did not meet the required P-value for superiority, testing was not performed for the remaining confirmatory and secondary endpoints. The mean change in body weight at Week 104 was -9.39% vs. -0.88% with Wegovy and placebo, respectively (estimated treatment difference -8.51%; 95% CI: -8.75%, -8.27%; no P-value provided).[7] Among patients with prediabetes at baseline ($HbA_{1c} \geq 5.7\%$), the odds of achieving a normal HbA_{1c} level (< 5.7%) by Week 104 were greater with Wegovy vs. placebo (65.7% [n = 3,775/5,750] vs. 21.4% [n = 1,211/5,663] of patients, respectively, achieved a normal HbA_{1c}; odds ratio 8.74; 95% CI: 7.91, 9.65; no P-value provided). Other secondary endpoints generally favored Wegovy at Week 104 (e.g., waist circumference, blood pressure, lipids).

OSA

The SURMOUNT-OSA (n = 469) [published] 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.[14] ***Inclusion/exclusion.*** 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 method 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. Key exclusion criteria were the presence of type 1 or type 2 diabetes ($HbA_{1c} \geq 6.5\%$ at Visit 1), change in weight of > 5 kg in the past 3 months, planned surgery for sleep apnea or obesity, diagnosis of central or mixed sleep apnea with the percentage of mixed or central apneas/hypopneas ≥ 50%, or diagnosis of Cheyne Stokes respiration, diagnosis of obesity hypoventilation syndrome or daytime hypocapnia, active device treatment of OSA other than PAP therapy (e.g., dental appliance), and major craniofacial abnormalities that may affect breathing. In addition, use of medications (prescribed or over-the-counter) or alternative remedies to promote weight loss in the past 3 months were not allowed, this included other GLP-1 agonists. Of note, although patients with diabetes at baseline were excluded, if a patient developed diabetes while in the study, the patient was referred to their usual care provider. The decision to further evaluate, to initiate antihyperglycemic therapy, and the choice of antihyperglycemic medication was at the discretion of the provider.

Study design. Following a 4-week screening period, patients were assigned to Trial 1 or Trial 2 and randomly assigned to receive Zepbound or placebo SC QW.[14] All patients received regular lifestyle counseling sessions focused on the maintenance of healthy nutrition, adherence to a 500 calorie/day deficit, and ≥ 150 minutes per week of physical activity. The dose of Zepbound was escalated over a period of up

to 20 weeks starting at 2.5 mg SC QW and increased by 2.5 mg every 4 weeks during the dose-escalation period until the patient reached the maximum tolerated dose of 10 mg or 15 mg SC QW at Week 20. Dose modification was permitted for the management of intolerable GI symptoms. Patients who did not tolerate ≥ 10 mg even after one de-escalation and re-escalation attempt, were discontinued from the study intervention but remained in the study for continued follow-up. During the first 24 weeks of the treatment period (20-week dose escalation plus 4 weeks), participants unable to tolerate 2.5 mg or 5 mg were discontinued from the study intervention but remained in the study. For patients unable to tolerate any dose escalation between 7.5 mg and 15 mg (inclusive), a dose de-escalation step with subsequent re-escalation by 2.5 mg every 4 weeks up to the maximum tolerated dose was allowed in a blinded fashion, to reach either the 10 mg or 15 mg dose. Only one cycle of dose de-escalation and re-escalation was permitted during the first 24 weeks of the treatment period. The 10 mg maintenance dose was used in patients who tolerated 10 mg, but not 12.5 mg or 15 mg even following one de-escalation and re-escalation attempt. In addition, patients who tolerated 12.5 mg, but not 15 mg even after one de-escalation and re-escalation attempt, continued 10 mg as their maximum tolerated dose. Patients who tolerated 15 mg continued 15 mg as their maximum tolerated dose. ***Endpoints.*** The primary endpoint was the superiority of Zepbound vs. placebo for the change in the AHI from baseline. Several key secondary endpoints were assessed including the proportion of patients with an AHI reduction of ≥ 50%, the proportion of patients with an AHI of < 5 events/hour or with an AHI of 5 to 14 events/hour and a score of ≤ 10 on the Epworth Sleepiness Scale (ESS; scores range from 0 to 24 with higher scores indicating greater daytime sleepiness), percent change in body weight, change in high-sensitivity C-reactive protein (hsCRP), change in sleep apnea specific hypoxic burden, changes in patient reported outcome measures, and the change in systolic blood pressure. The primary endpoint was assessed using the treatment-regimen estimand (average treatment effect of Zepbound relative to placebo for all patients who had received at least one dose of Zepbound or placebo regardless of ether they discontinued trial treatment for any reason). ***Baseline characteristics.*** In Trial 1, the mean age was 47.9 years, most patients were male (67.1% of patients) and White (65.8% of patients); 41.9% of patients were Hispanic or Latino, 10.1% of patients were Asian, 7.7% of patients were American Indian or Alaska Native, and 5.6% of patients were Black or African American. 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 age was 51.7 years, most patients were male (72.3% of patients) and White (73.1% of patients); 32.3% of patients were Hispanic or Latino, 14.1% of patients were Asian, 8.1% of patients were American Indian or Alaska Native, and 4.7% of patients were Black or African American. The mean BMI was 38.7 kg/m^2 and the mean AHI was 49.5 events/hour. Most patients had severe OSA (68%).

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 [95% CI: -29.3, -21.2] vs. -5.3 events/hour [95% confidence interval [CI]: -9.4, -1.1]), respectively; estimated treatment difference of -20.0 events/hour; 95% CI: -25.8, -14.2; P < 0.001). In Trial 2, the change in AHI at Week 52 with Zepbound was superior to placebo (-29.3 events/hour [95% CI: -33.2, -25.4] vs. -5.5 events/hour [95% CI: -9.9, -1.2]; estimated treatment difference -23.8 events/hour; 95% CI: -26.9, -17.9; 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, systolic blood pressure, and hsCRP concentrations as well.

Guidelines

Weight Management

Adult

Guidelines from the American Gastroenterological Association on pharmacological interventions for adults with obesity (2022) state that in adults with obesity or overweight with weight-related complications, who have had an inadequate response to lifestyle interventions, it is recommended to add pharmacological agents to lifestyle interventions over continuing lifestyle interventions alone (strong recommendation, moderate quality evidence).[6] Wegovy and Saxenda are listed among the therapeutic options. It is also noted that given the magnitude of net benefit, Wegovy may be prioritized over other approved anti-obesity medications for the long-term treatment of obesity for most patients.

Guidelines from the Endocrine Society regarding pharmacological management of obesity (2015) recommend pharmacotherapy as adjunct to behavioral modification to reduce food intake and increase physical activity for patients with BMI $\geq$ 30 kg/m^2 or $\geq$ 27 kg/m^2 in the presence of at least one comorbidity, such as hypertension, dyslipidemia, type 2 diabetes, or obstructive sleep apnea.[3] If a patient's response to a weight loss medication is deemed effective (weight loss $\geq$ 5% of body weight at 3 months) and safe, it is recommended that the medication be continued. In clinical studies of Saxenda and semaglutide, eligible patients were required to have a prior unsuccessful dietary weight loss attempt. The American Diabetes Association also cites weight loss $\geq$ 5% of body weight at 3 months as "effective"; when early response is insufficient (typically < 5% weight loss after 3 months), other therapies should be evaluated.[8]

Per American Association of Clinical Endocrinologists/American College of Endocrinology obesity guidelines (2016), pharmacotherapy for overweight and obesity should be used only as an adjunct to lifestyle therapy and not alone.[4] The addition of pharmacotherapy produces greater weight loss and weight-loss maintenance compared with lifestyle therapy alone. The concurrent initiation of lifestyle therapy and pharmacotherapy should be considered in patients with weight-related complications that can be ameliorated by weight loss. Pharmacotherapy should be offered to patients with obesity, when potential benefits outweigh the risks, for the chronic treatment of the disease. Short-term treatment (3 to 6 months) using weight-loss medications has not been demonstrated to produce longer-term health benefits and cannot be generally recommended based on scientific evidence.

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 $\geq$ 95th percentile) weight loss pharmacotherapy, according to medication indications, risks, and benefits, as an adjunct to health behavior and lifestyle treatment.[7]

A 2017 Endocrine Society clinical practice guideline on pediatric obesity recommends that pharmacotherapy in combination with lifestyle modification be considered in obese children or adolescents only after failure of a formal program of intensive lifestyle (dietary, physical activity and behavioral) modification to limit weight gain or to ameliorate comorbidities.[5] The Endocrine Society recommends pharmacotherapy in overweight children and adolescents < 16 years of age only in the context of a clinical trial. Pharmacotherapy should be provided only by clinicians who are experienced in the use of anti-obesity agents and aware of the potential for adverse events. These guidelines recommend limited use of pharmacotherapy because pediatric obesity should be managed preferably as a serious lifestyle condition with important lifelong consequences. The Endocrine Society defines overweight as BMI in at least the 85th percentile but less than the 95th percentile, and obesity as BMI in at least the 95th percentile for age and sex against routine endocrine studies, unless the height velocity is attenuated or inappropriate for the family background or stage of puberty.[5]

Sleep Apnea

The American Academy of Sleep Medicine (2017) recommends that diagnostic testing for obstructive sleep apnea (OSA) be performed in combination with a comprehensive sleep evaluation.[15] Polysomnography is the standard diagnostic test for the diagnosis of OSA in adults in whom there is concern for OSA based on the sleep evaluation. Polysomnography is accepted as the gold standard test for the diagnosis of OSA. 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 does 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) recommend patients with OSA who are overweight or obese (BMI $\geq$ 25 kg/m^2) participate in comprehensive lifestyle intervention that includes a reduced calorie diet, exercise/increased physical activity, and behavioral counseling.[16] For patients with OSA and a BMI $\geq$ 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 guideline also cites agreement with the American Association of Clinical Endocrinologists and the American College of Endocrinology guidelines (2016)[4], which state the weight-loss goal in patients with overweight or obesity with OSA should be at least $\geq$ 7% to 11% of total body weight.[16] In patients with a BMI $\geq$ 35 kg/m^{2}referral for bariatric surgery evaluation is suggested.

The American College of Physicians clinical practice guideline for the management of OSA (2013) recommend that all overweight and obese patients diagnosed with OSA be encouraged to lose weight.[17] Continuous positive airway pressure (PAP) is recommended as initial therapy for patients with OSA. Mandibular advancement devices are recommended for patients with OSA who prefer such devices or for those with adverse events associated with continuous PAP treatment.

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)[18] 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[19] note that treatment success has 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.[20]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Saxenda, Wegovy, and Zepbound. Of note, this policy targets Saxenda, 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. 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of Saxenda is recommended in those who meet ONE of the following criteria:

FDA-Approved Indications

1. Weight Loss, Adult. 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., Saxenda, 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., Saxenda, 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 Continuing Therapy with Saxenda. 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., Saxenda, 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., Saxenda, 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., Saxenda, 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, Pediatric. 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., Saxenda, 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 Continuing Therapy with Saxenda. 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., Saxenda, 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., Saxenda, 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. Coverage of Wegovy is recommended in those who meet ONE of the following criteria:

FDA-Approved Indications

1. **Weight Loss, Adult.** 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 ≥ 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., Saxenda, 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., Saxenda, 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 Continuing Therapy with Wegovy. 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 ≥ 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., Saxenda, 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., Saxenda, 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., Saxenda, 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, Pediatric. 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 ≥ 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., Saxenda, 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 Continuing Therapy with Wegovy. 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 ≥ 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., Saxenda, 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., Saxenda, 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 who is Either Obese or 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 ≥ 18 years of age; AND

ii. Patient has a current BMI ≥ 27 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

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 Continuing Therapy with Wegovy. 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 ≥ 18 years of age; AND

ii. At baseline, patient had a BMI ≥ 27 kg/m^2; AND
Note: This refers to baseline prior to Wegovy.

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.

Coverage of Zepbound is recommended in those who meet ONE of the following criteria:

FDA-Approved Indications

1. Weight Loss, Adult. 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., Saxenda, 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., Saxenda, 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 Continuing Therapy with 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., Saxenda, 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., Saxenda, 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., Saxenda, 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.** Patient has a current BMI ≥ 30 kg/m^2; AND
- **iii.** Patient has had a sleep study within the past 1 year 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, 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 with percent of central apneas/hypopneas ≥ 50%; OR
  - **b)** Cheyne Stokes respiration; OR
- **v.** The medication will be used in concomitantly with behavioral modification and a reduced-calorie diet. OR

B) Patient is Continuing Therapy with 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 before 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 Zepbound.

b) 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 RECOMMENDED FOR APPROVAL

Coverage of Saxenda, Wegovy, and Zepbound is not recommended in the following situations:

1. **Concomitant Use with Other Weight Loss Medications.** Concomitant use with other medications intended for weight loss is not recommended.[2,9,12,14] Note: Examples of other medications FDA-approved for weight loss include but are not limited to phentermine (Lomaira, generic), benzphetamine, diethylpropion, phendimetrazine, Contrave (naltrexone/bupropion extended-release tablets), Qsymia (phentermine/topiramate extended-release capsules), and Xenical (orlistat 120 mg capsules). Additionally, Alli (orlistat 60 mg capsules) is available over-the-counter.

2. **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.[1,2,9,14] 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 Adlyxin (lixisenatide subcutaneous [SC] injection), Byetta (exenatide SC injection), Bydureon BCise (exenatide extended-release SC injectable suspension), Ozempic (semaglutide SC injection), Rybelsus (semaglutide tablets), Trulicity (dulaglutide SC injection), and liraglutide SC injection (Victoza, authorized generic). An example of a GLP-1/GIP agonist is Mounjaro (tirzepatide SC injection).

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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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 **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 Wegovy), 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 require that at baseline (prior to the initiation of Wegovy), patient had a BMI ≥ 95th percentile for age and sex. 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 Saxenda), 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 require that at baseline (prior to the initiation of Saxenda), patient had a BMI ≥ 95th percentile for age and sex.	09/13/2023

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 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). 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 Recommended for Approval	11/15/2023

	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.	

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
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-related comorbidity, the criterion was modified to state that the comorbidity is at baseline or current.	05/08/2024
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	Updated Zepbound indication added to overview.	10/24/2024

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 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.	01/08/2025