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 and Zepbound are indicated as an adjunct to a reduced-calorie diet and increased physical activity for **chronic weight management** in the following settings:[2,9]

- **Saxenda and Zepbound:** 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]).
- **Saxenda:** 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 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]
- To **reduce excess body weight and maintain weight reduction long term** in:
  - Adults with overweight in the presence of at least one weight-related comorbid condition.[1,11]
  - Adults and pediatric patients ≥ 12 years of age with obesity.[1,12]

Dosing

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 (QD); 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 at least 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 of Saxenda is 3 mg QD. However, pediatric patients who do not tolerate 3 mg QD may have their maintenance dose reduced to 2.4 mg QD. Discontinue Saxenda if the patient cannot tolerate the 2.4 mg dose. Additionally, for pediatric patients, the prescribing information states to evaluate the change in BMI after 12 weeks on the maintenance dose and discontinue Saxenda if the patient has not had a reduction in BMI of at least 1% from baseline, since it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

In the prescribing information for Wegovy, a recommended dose escalation schedule of 16 weeks is outlined.[1] If a patient does not tolerate an increased dose during dose escalation, consider delaying dose

escalation for 4 weeks. The maintenance dose of Wegovy is 2.4 mg (recommended) or 1.7 mg injected subcutaneously (SC) once weekly; consider treatment response and tolerability when selecting the maintenance dose. The 0.25 mg, 0.5 mg, and 1 mg once weekly doses are initiation and escalation doses and are not approved doses for chronic weight management. If a pediatric patient ≥ 12 to < 18 years of age does not tolerate the maintenance dose of 2.4 mg once weekly, the dose can be reduced to 1.7 mg once weekly. Discontinue Wegovy if the patient cannot tolerate the 1.7 mg dose.

In the prescribing information for Zepbound, the recommended starting dose is 2.5 mg injected SC once weekly.[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 SC once weekly. The dose can then be increased in 2.5 mg increments, after at least 4 weeks on the current dose. The recommended maintenance doses are 5 mg, 10 mg, or 15 mg SC once weekly. 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 SC once weekly. The 5 mg, 10 mg, and 15 mg maintenance doses would be reached after Week 4, Week 12, and Week 20, respectively.

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%). 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 being treated with weight-lowering pharmacotherapy at baseline (further detail is not available; however, concomitant GLP-1 agonist use was not allowed).[11] The mean HbA_{1c} was just over 5.7%; 67% of patients had an HbA_{1c} ≥ 5.7% (pre-diabetes). Mean high-sensitivity C-reactive protein level was approximately 1.8 mg/dL. 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% were receiving lipid-lowering agents (87.3% statins, 13.0% ezetimibe, 2.7% fibrates, and 2.0% proprotein convertase subtilisin/kexin type 9 inhibitors), 86.2% were receiving platelet aggregation inhibitors, and 12.6% 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 HF endpoint (death from CV causes or hospitalization for HF [HHF] or an urgent medical visit for HF), and death form 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). 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% confidence interval [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).[10] 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 [OR] 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).

Guidelines

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 ≥ 30 kg/m^2 or ≥ 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.

Guidelines in Pediatric Obesity

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

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]

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, iv, and v):

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. Patient is able to tolerate a Saxenda maintenance dose of 3 mg once daily; AND

v. 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, iv, and v):
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.** Patient is able to tolerate a Saxenda maintenance dose of 2.4 mg once daily or 3 mg once daily; AND
- **v.** 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 the duration noted below if the patient meets ALL of the following (i, ii, iii, iv, and v):
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; AND

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

a) Patient is able to tolerate a Wegovy maintenance dose of 1.7 mg once weekly or 2.4 mg once weekly: Approve for 1 year; OR

b) Approve for up to 5 months if the patient meets both of the following [(1) and (2)]:

Note: Approve a sufficient duration for 12 consecutive months of therapy (for example, if the patient has completed 8 months of Wegovy therapy, approve for 4 additional months).

(1) Patient has received < 12 consecutive months of Wegovy; AND

(2) According to the prescriber, the patient is continuing to titrate the Wegovy dose to a target of 1.7 mg once weekly or 2.4 mg once weekly.

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 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. Wegovy will be used concomitantly with behavioral modification and a reduced-calorie diet.

B) Patient is Continuing Therapy with Wegovy. Approve for the duration noted below if the patient meets the following (i, ii, iii, iv, and v):

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; AND

v. Patient meets one of the following (a or b):

a) Patient is able to tolerate a Wegovy maintenance dose of 1.7 mg once weekly or 2.4 mg once weekly: Approve for 1 year; OR

b) Approve for up to 5 months if the patient meets both of the following [(1) and (2)]:
Note: Approve a sufficient duration for 12 consecutive months of therapy (for example, if the patient has completed 8 months of Wegovy therapy, approve for 4 additional months).

(1) Patient has received < 12 consecutive months of Wegovy; AND

(2) According to the prescriber, the patient is continuing to titrate the Wegovy dose to a target of 1.7 mg once weekly or 2.4 mg once weekly.

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 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, v, and vi):
Note: A patient who has received < 1 year of therapy should be considered under criterion A (Initial Therapy).

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; AND
vi. Patient is able to tolerate a Wegovy maintenance dose of 1.7 mg once weekly or 2.4 mg once weekly.

III. 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 the duration noted below if the patient meets ALL of the following (i, ii, iii, iv, and v):
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; AND

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

a) Patient is able to tolerate a Zepbound maintenance dose of 5 mg, 10 mg, or 15 mg once weekly: Approve for 1 year; OR

b) Approve for up to 4 months if the patient meets BOTH of the following [(1) and (2)]:
Note: Approve a sufficient duration for 12 consecutive months of therapy (for example, if the patient has completed 8 months of Zepbound therapy, approve for 4 additional months).

(1) Patient has received < 12 consecutive months of Zepbound; AND

(2) According to the prescriber, the patient is continuing to titrate the Zepbound dose to a target of 10 mg once weekly or 15 mg once weekly.
Note: Although 5 mg once weekly is an acceptable maintenance dose, the patient should be able to achieve the 5 mg once weekly maintenance dose within the 8 months of initial therapy provided above.

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] 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 other Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Agonists.** Saxenda, Wegovy, and Zepbound should not be combined with each other or with any other GLP-1 agonists.[1,2,9] Other GLP-1 and GLP-1/GIP products are FDA-approved for type 2 diabetes and are not indicated 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 (exenatide extended-release SC injectable suspension), Bydureon BCise (exenatide extended-release SC injectable suspension), Ozempic (semaglutide SC injection), Rybelsus (semaglutide tablets), Trulicity (dulaglutide SC injection), and Victoza (liraglutide SC injection). 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	Wegovy **Weight Loss:** Under continuation criteria, as an alternative to the requirement that the patient is able to tolerate a Wegovy dose of 2.4 mg once weekly, a pathway was added to allow approval for up to 12 months of therapy if the patient has received < 12 months of consecutive Wegovy, and according to the prescriber, the patient is continuing to titrate the Wegovy dose to a target of 2.4 mg once weekly.	07/13/2022
Selected Revision	Wegovy **Weight Loss, Adult:** The approval condition was reworded to as listed; previously this was titled "weight loss". **Weight Loss, Pediatric:** A new condition of approval was added to the policy. Saxenda **Weight Loss, Pediatric:** In the initial therapy criteria, the requirement for a trial of behavioral modification and dietary restriction was shortened from 4 months to 3 months. Additionally, the requirement regarding current body mass index (BMI) was updated such that the patient is required to have a BMI ≥ 95th percentile for age and sex (obesity). Previously, the patient could alternatively have a BMI ≥ 85th percentile and < 95th percentile for age and sex (overweight) if the patient had at least one comorbidity (type 2 diabetes, cardiovascular disease) or a strong family history of type 2 diabetes or premature cardiovascular disease. In the continuation criteria, the requirement that the patient currently has BMI > 85th percentile was removed. Additionally, the requirement regarding baseline BMI was updated such that the patient is required to have had a baseline BMI ≥ 95th percentile for age and sex (obesity). Previously, the patient could alternatively have had a baseline BMI ≥ 85th percentile and < 95th percentile for age and sex (overweight) if the patient had at least one comorbidity (type 2 diabetes, cardiovascular disease) or a strong family history of type 2 diabetes or premature cardiovascular disease.	01/18/2023
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