Drug Coverage Policy

Effective Date.....01/01/2025
Coverage Policy Number.....IP0621
Policy Title.....Glucagon-Like Peptide-1 Agonists (BEO)

Weight Loss – Glucagon-Like Peptide-1 Agonists Benefit Exclusion Overrides Policy

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

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

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** (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight.[1,7]
- 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]
    - Adults and pediatric patients ≥ 12 years of age with obesity.[1]

According to the Centers for Disease Control and Prevention (CDC), in adults, obesity is frequently subdivided into three categories:[4]

- **Class 1:** BMI ≥ 30 to < 35 kg/m^2
- **Class 2:** BMI ≥ 35 to < 40 kg/m^2
- **Class 3:** BMI ≥ 40 kg/m^2

In pediatric patients the CDC classifies obesity as a BMI ≥ 95th percentile.[5]

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.[6]

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.[3] 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 than 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 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.

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).[7] 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).[9] 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.[7,9] 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.[9] The primary efficacy endpoint was a composite of death from CV causes, non-fatal MI, or non-fatal stroke.[7] 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 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.[7] 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% 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).[7] Among patients with prediabetes at baseline (HbA_{1c} ≥ 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).

Policy Statement
This Benefit Exclusion Overrides policy has been developed to authorize coverage of the targeted drugs for the treatment of weight loss in adults with a body mass index (BMI) of ≥ 27 kg/m^2 with at least two weight-related comorbidities or with a body mass index of ≥ 32 kg/m^2 and for pediatric patients with a patient a BMI ≥ 95th percentile for age and sex (see authorization criteria for details). The BMI thresholds for the weight loss indications in adults are not based on clinical data but are provided in this product offering to allow a subset of patients to obtain these medications. Additionally, the policy authorizes coverage of Wegovy to reduce the risk of major adverse cardiovascular event(s) in a patient with established cardiovascular disease who is either obese or overweight (see authorization criteria for details). All approvals are provided for the duration noted below.

Documentation: Documentation is required for use of Saxenda, Wegovy, and Zepbound as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Additional Benefit Coverage Requirement: Patient has been enrolled and engaged in designated standard lifestyle vendor and completes four weigh-ins per month and four digital engagements per month. Engagements may include, but are not limited to recorded meals, glucose readings, blood pressure readings, engaging with community resources, completing a lesson, or setting/achieving a goal.

Benefit Exclusion Override Criteria

Glucagon-like peptide-1 (GLP-1) receptor agonists are covered when ONE of the following is met:

I. Saxenda is covered 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 ≥ 32 kg/m^2 **[documentation required]**;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 **[documentation required]**; AND

(2) At baseline, patient had, or patient currently has, at least TWO 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 **[documentation required]**; 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 ≥ 32 kg/m^2 **[documentation required]**; 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 **[documentation required]**; AND

(2) At baseline, patient had, or patient currently has, at least TWO 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 **[documentation required]**; 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 **[documentation required]**; 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 **[documentation required]**; 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 **[documentation required]**; 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 **[documentation required]**; 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. Wegovy is covered 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 ≥ 32 kg/m^2 **[documentation required]**; 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 **[documentation required]**; AND
(2) At baseline, patient had, or patient currently has, at least TWO 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 **[documentation required]**; 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 ≥ 32 kg/m^2 **[documentation required]**; 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 **[documentation required]**; AND
(2) At baseline, patient had, or patient currently has, at least TWO 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 **[documentation required]**; 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 **[documentation required]**; 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 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 **[documentation required]**; 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 ≥ 12 years of age and < 18 years of age; AND
      ii. At baseline, patient had a BMI ≥ 95th percentile for age and sex **[documentation required]**; 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 **[documentation required]**; 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 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 **[documentation required];** AND
      iii. Patient meets ONE of the following (a, b, or c):
         a) Patient has had a prior myocardial infarction **[documentation required]**; OR
         b) Patient has had a prior stroke **[documentation required]**; OR
         c) Patient has a history of symptomatic peripheral arterial disease as evidenced by ONE of the following [(1), (2), or (3)] **[documentation required]**:
            (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 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 **[documentation required]**; 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 **[documentation required]**; OR
         b) Patient has had a prior stroke **[documentation required]**; OR
         c) Patient has a history of symptomatic peripheral arterial disease as evidenced by ONE of the following [(1), (2), or (3)] **[documentation required]**:
            (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. Zepbound is covered 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 ≥ 32 kg/m^2 **[documentation required]**; 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 **[documentation required]**; AND

(2) At baseline, patient had, or patient currently has, at least TWO 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 **[documentation required]**; 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 ≥ 32 kg/m^2 **[documentation required]**; 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 **[documentation required]**; AND

(2) At baseline, patient had, or patient currently has, at least TWO 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 **[documentation required]**; 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 **[documentation required]**; 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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive) Criteria will be updated as new published data are available:

1. **Concomitant Use with Other Weight Loss Medications.** Concomitant use with other medications intended for weight loss is not recommended.[2,3,8] 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) Receptor Agonists.** The GLP-1 agonists and the GLP-1/GIP agonist should not be combined with each other or with any other GLP-1 agonists or GLP-1/GIP agonist.[1,2,9] There are other GLP-1 and GLP-1/GIP products not included in this policy that 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 BCise (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, authorized generic). An example of a GLP-1/GIP agonist is Mounjaro (tirzepatide SC injection).

References

1. Wegovy® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; March 2024.
2. Saxenda® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; April 2023.
3. Zepbound® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; March 2024.
4. Centers for Disease Control and Prevention. Defining adult overweight and obesity. Available at: https://www.cdc.gov/obesity/basics/adult-defining.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fobesity%2Fadult%2Fdefining.html. Accessed on: January 5, 2024.
5. Centers for Disease Control and Prevention. Defining child BMI categories. Available at: https://www.cdc.gov/obesity/basics/childhood-defining.html. Accessed on January 5, 2024.
6. Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents with Obesity. *Pediatrics*. 2023;151(2):e2022060640.
7. Lincoff AM, Brown-Frandsen K, Colhoun HM, et al; for the SELECT Trial Investigators. Semaglutide and cardiovascular outcomes in obesity without diabetes. *N Engl J Med.* 2023;389(24):2221-2232.
8. Wilding JPH, Batterham RL, Calanna S, et al; STEP 1 Study Group. Once-weekly semaglutide in adults with overweight or obesity. *N Engl J Med*. 2021;384(11):989.
9. Lingvay I, Brown-Frandson K, Colhoun HM et al. Semaglutide for cardiovascular event reduction in people with overweight or obesity: SELECT study baseline characteristics. Obesity. 2023;31(1):111-122.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	07/01/2024
Selected Revision	Saxenda, Wegovy, and Zepbound **Weight Loss, Adult**: Initial Therapy and Patient is Continuing on Therapy: Metabolic-associated steatotic liver disease (new nomenclature for non-alcoholic fatty liver disease) was added to the list of two of the weight-related comorbidities [documentation required] for a patient with a BMI ≥ 27 kg/m^2 [documentation required]. Additionally, for the two or more weight-related comorbidities, the criterion was modified to state that the comorbidities are at baseline or current.	08/15/2024
Selected Revision	**Policy Statement:** The Policy Statement was updated to reflect that Wegovy is also approved in the policy to reduce the risk of major adverse cardiovascular events in a patient with established cardiovascular disease who is either overweight or obese. Wegovy **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease who is Either Obese or**	12/01/2024

	Overweight. This new condition of coverage was added to FDA-approved indications for Wegovy. **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. Conditions Not Recommended for Approval: **Concomitant Use with Other Weight Loss Medications.** This condition was added to the Conditions Not Covered.	
Selected Revision	No criteria changes.	01/01/2025

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