

# **Drug Coverage Policy**

Effective Date............08/01/2025 Coverage Policy Number.......IP0621 Policy Title.....Glucagon-Like Peptide-1 Agonists BMI ≥ 32

# Weight Loss - Glucagon-Like Peptide-1 Agonists BMI ≥ 32

- Saxenda® (liraglutide subcutaneous injection Novo Nordisk)
- Wegovy® (semaglutide subcutaneous injection Novo Nordisk)
- Zepbound<sup>™</sup> (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 quidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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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.<sup>1-3</sup>

**Saxenda** is indicated as an adjunct to a reduced-calorie diet and increased physical activity for **chronic weight management** in the following settings:<sup>2</sup>

- Adults with an initial body mass index (BMI) ≥ 30 kg/m² (obese), or ≥ 27 kg/m² (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension²,³, dyslipidemia²,³, type 2 diabetes²,³, obstructive sleep apnea³, or cardiovascular disease³).
- Pediatric patients ≥ 12 years of age with body weight > 60 kg and an initial BMI corresponding to 30 kg/m² for adults (obese) by international cutoffs.

**Wegovy and Zepbound** are indicated in combination with a reduced-calorie diet and increased physical activity:<sup>1,3</sup>

- 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.<sup>1,3</sup>
  - Wegovy and Zepbound: Adults with obesity. 1,3
  - Wegovy: Pediatric patients ≥ 12 years of age.¹

**Wegovy** is also indicated in combination with a reduced-calorie diet and increased physical activity:<sup>1</sup>

 To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight.<sup>1</sup>

**Zepbound** is indicated in combination with a reduced-calorie diet and increased physical activity:<sup>3</sup>

• For the treatment of **moderate to severe obstructive sleep apnea** (OSA) in adults with obesity.

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

- Class 1: BMI  $\geq$  30 to < 35 kg/m<sup>2</sup>
- Class 2: BMI  $\geq$  35 to < 40 kg/m<sup>2</sup>
- **Class 3:** BMI ≥ 40 kg/m<sup>2</sup>

In pediatric patients the CDC classifies obesity as a BMI ≥ 95<sup>th</sup> percentile.<sup>5</sup>

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  $\geq$  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.<sup>6</sup>

#### Dosing

In the prescribing information for Wegovy, a recommended dose escalation schedule of 16 weeks is outlined.<sup>1</sup> 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

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2.4 mg; if a pediatric patient  $\geq$  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. 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  $\geq$  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.<sup>3</sup> The 2.5 mg dose is for treatment initiation and is not intended for chronic weight management. After 4 weeks, the dose can be increased to 5 mg 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.

None of the GLP-1 or GLP-1/GIP agonists are recommended for coadministration with other GLP-1 or GLP-1/GIP agonists.<sup>1-3</sup>

#### **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  $\geq$  27 kg/m² with at least two weight-related comorbidities or with a body mass index of  $\geq$  32 kg/m² and for pediatric patients with a patient a BMI  $\geq$  95<sup>th</sup> 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 and but are provided in this product offering to allow a subset of patients to obtain these medications. All approvals are provided for the duration noted below.

<u>Documentation</u>: 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 standard lifestyle vendor and completes four weigh-ins per month and four app engagements per month. Engagements may include, but are not limited to lesson completion, recorded meals, weigh-ins, 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:

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I. <u>Saxenda</u> 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 <u>or</u> B):
  - **A)** <u>Initial Therapy</u>. 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 <u>or</u> b):
      - a) At baseline patient had a BMI ≥ 32 kg/m² [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/m² [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

<u>Note</u>: 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):

<u>Note</u>: 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/m² [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/m² [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

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disease, polycystic ovarian syndrome, or coronary artery disease **[documentation required]**; AND

<u>Note</u>: 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.** 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 <u>or</u> B):
  - **A)** <u>Initial Therapy</u>. 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 ≥ 95<sup>th</sup> percentile for age and sex **[documentation required]**; AND

<u>Note</u>: 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):

<u>Note</u>: 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 ≥ 95<sup>th</sup> percentile for age and sex **[documentation required]**; AND

<u>Note</u>: 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

<u>Note</u>: 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.** 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):

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- **A)** <u>Initial Therapy</u>. 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 <u>or</u> b):
    - a) At baseline, patient had a BMI ≥ 32 kg/m² [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/m² [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

<u>Note</u>: 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):

<u>Note</u>: 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/m² [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/m² [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

<u>Note</u>: 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  $\geq$  5% of baseline body weight [documentation required]; AND

- <u>Note</u>: 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 <u>or</u> B):
  - **A)** <u>Initial Therapy</u>. 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  $\geq 95^{th}$  percentile for age and sex [documentation required]; AND
      - <u>Note</u>: 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):

<u>Note</u>: 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 ≥ 95<sup>th</sup> percentile for age and sex [documentation required]; AND

<u>Note</u>: 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

<u>Note</u>: 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
- **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 <u>or</u> B):
  - **A)** <u>Initial Therapy</u>. 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

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- **iii.** Patient meets one of the following (a or b):
  - a) At baseline, patient had a BMI ≥ 32 kg/m² [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  $\geq$  27 kg/m<sup>2</sup> [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, metabolicdysfunction 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 1 year if the patient meets ALL of the following (i, ii, iii, and iv):

Note: For a patient who has not completed 8 months of initial therapy, refer to Initial Therapy criteria above.

- i. Patient is  $\geq$  18 years of age; AND
- **ii.** Patient meets ONE of the following (a <u>or</u> b):
  - a) At baseline, patient had a BMI ≥ 32 kg/m² [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/m² [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, metabolicdysfunction 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  $\geq$  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

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**

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

- 1. Concomitant Use with Other Medications FDA-Approved for Weight Loss. Concomitant use with other medications FDA-approved for weight loss is not recommended. 12,20-24 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), phentermine/topiramate extended-release capsules (Qsymia, generic), and orlistat 120 mg capsules (Xenical, authorized generic). 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. <sup>1-3,7-13</sup> There are other GLP-1 and GLP-1/GIP products not included in this policy that are FDA-approved for type 2 diabetes and are not indicated for chronic weight management.
  Note: Examples of other GLP-1 agonists include but are not limited to 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, 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; November 2024.
- 2. Saxenda® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; November 2024.
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- Centers for Disease Control and Prevention. Defining adult overweight and obesity. Available at: https://www.cdc.gov/bmi/adult-calculator/bmicategories.html?CDC\_AAref\_Val=https://www.cdc.gov/obesity/basics/adult-defining.html. Accessed on: January 3, 2025.
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- 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.
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- 10. Jasterboff AM, Aronne LJ, Ahmad NN, et al; for the SURMOUNT-1 Investigators. Tirzepatide once weekly for the treatment of obesity. *N Engl J Med.* 2022;3387(3):205-216.
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- 13. Wadden TA, Hollander P, Klein S, et al; on behalf of the NN8022-1923 Investigators. Weight maintenance and additional weight loss with liraglutide after low-calorie-diet-induced weight loss: The SCALE Maintenance randomized study. *Int J Obes.* 2013;37:1443-1451.

# **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/m² [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 Overweight. This new condition of coverage was added to FDA-approved indications for Wegovy.	12/01/2024

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Calcated Davisio	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.	01/01/2025
Selected Revision Selected Revision	No criteria changes. Saxenda	01/01/2025
Scieda Nevision	Weight Loss, Adult. Patient Continuing on Therapy with Saxenda: Dosing criteria were removed.  Saxenda and Wegovy Weight Loss, Pediatric. Patient Continuing on Therapy with Saxenda: Dosing criteria were removed.  Wegovy Weight Loss, Adult. Patient Continuing on Therapy with Wegovy: Dosing criteria were removed. The approval duration was changed to 1 year.  Weight Loss, Pediatric. Patient Continuing on Therapy with Wegovy: Dosing criteria were removed. The approval duration was changed to 1 year.  Cardiovascular Disease who is Either Obese or Overweight. Initial Therapy. The criterion requiring that the patient has a BMI ≥ 27 kg/m² was clarified to state that the patient has a "current" BMI ≥ 27 kg/m².  Patient Continuing on Wegovy: Dosing criteria were removed.  Zepbound Weight Loss, Adult. Patient Continuing on Therapy with Wegovy: Dosing criteria were removed. The approval duration was changed to 1 year.	03/15/2025
Selected Revision	Policy title changed from" Weight Loss – Glucagon- Like Peptide-1 Agonists Benefit Exclusion Overrides Policy" to "Weight Loss – Glucagon-Like Peptide-1 Agonists BMI ≥ 32"	07/01/2025

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	The Conditions Not Covered statement was reworded.	
Selected Revision	Policy Statement: The Policy Statement was updated to remove reference for approval of Wegovy to reduce the risk of major adverse cardiovascular events in a patient with established cardiovascular disease who is either overweight or obese, as this indication has been removed from the policy.	08/01/2025
	Wegovy: Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease who is Either Obese or Overweight. This indication and accompanying requirements were removed from the policy.	
	Conditions Not Recommended for Approval:  Concomitant Use with Other Medications FDA- Approved for Weight Loss. This condition not recommended for approval was clarified to state that concomitant use with other medications FDA- approved for weight loss is not recommended. Previously, the requirement did not specify medications were "FDA-approved" for weight loss. The note with examples of weight loss medications was updated to reflect product availability for medications FDA-approved for weight loss.	
	Concomitant Use with Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonists. The note was updated to reflect availability for other GLP-1 or GLP-1/GIP agonists.	

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

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