

## BENEFIT EXCLUSION OVERRIDES POLICY

**POLICY:** Weight Loss – Glucagon-Like Peptide-1 Agonists Benefit Exclusion Overrides Policy for EncircleRx

- 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 insulintropic polypeptide (GIP) receptor agonist.<sup>1,2,9</sup> 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:<sup>2,9</sup>

- **Saxenda and Zepbound:** Adults with an initial body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup> (obese), or  $\geq 27$  kg/m<sup>2</sup> (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension<sup>2,9</sup>, dyslipidemia<sup>2,9</sup>, type 2 diabetes<sup>2,9</sup>, obstructive sleep apnea<sup>9</sup>, or cardiovascular disease<sup>9</sup>).
- **Saxenda:** Pediatric patients  $\geq 12$  years of age with body weight  $> 60$  kg and an initial BMI corresponding to 30 kg/m<sup>2</sup> for adults (obese) by international cutoffs.<sup>2</sup>

**Wegovy** is 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>1,7</sup>
- 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.<sup>1</sup>
  - Adults and pediatric patients  $\geq 12$  years of age with obesity.<sup>1</sup>

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  $\geq 40$  kg/m<sup>2</sup>

In pediatric patients the CDC classifies obesity as a BMI  $\geq 95^{\text{th}}$  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  $\geq 95^{\text{th}}$  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 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.<sup>2</sup> If a patient does not tolerate an increased dose during dose escalation, consider delaying dose escalation for approximately one additional week. For adults, the recommended maintenance dose of 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 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  $\geq 45$  years of age with BMI  $\geq 27$  kg/m<sup>2</sup> and established CV disease without diabetes (n = 17, 604).<sup>7</sup> 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<sup>2</sup>; 28.5% of patients had a BMI of 27 to  $< 30$  kg/m<sup>2</sup>, 42.5% of patients had a BMI of 30 to  $< 35$  kg/m<sup>2</sup>, 19% of patients had a BMI of 35 to  $< 40$  kg/m<sup>2</sup>, 7% of patients had a BMI of 40 kg/m<sup>2</sup> to  $< 45$  kg/m<sup>2</sup>, and just over 3% of patients had a BMI  $\geq 45$  kg/m<sup>2</sup>. 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).<sup>9</sup> The mean hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) was just over 5.7%; 67% of patients had an HbA<sub>1c</sub>  $\geq 5.7\%$  (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.<sup>7,9</sup> 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.<sup>9</sup> The primary efficacy endpoint was a composite of death from CV causes, non-fatal MI, or non-



fatal stroke.<sup>7</sup> Confirmatory secondary endpoints, assessed in a time-to-first-event analysis and tested in hierarchical order were, death from CV causes, a composite heart failure endpoint (death from CV causes or hospitalization for heart failure [HHF] or an urgent medical visit for heart failure), and death from any cause. A gatekeeping approach was used with statistical significance at each step required in order to test the next hypothesis.

**Results.** Patients were followed for a mean of 39.8 months.<sup>7</sup> 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).<sup>7</sup> Among patients with prediabetes at baseline ( $HbA_{1c} \geq 5.7\%$ ), the odds of achieving a normal  $HbA_{1c}$  level ( $< 5.7\%$ ) by Week 104 were greater with Wegovy vs. placebo (65.7% [ $n = 3,775/5,750$ ] vs. 21.4% [ $n = 1,211/5,663$ ] of patients, respectively, achieved a normal  $HbA_{1c}$ ; odds ratio 8.74; 95% CI: 7.91, 9.65; no  $P$ -value provided). Other secondary endpoints generally favored Wegovy at Week 104 (e.g., waist circumference, blood pressure, lipids).

## 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  $\geq 27 \text{ kg/m}^2$  with at least two weight-related comorbidities or with a body mass index of  $\geq 32 \text{ kg/m}^2$  and for pediatric patients with a patient a BMI  $\geq 95^{\text{th}}$  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. 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.

**Automation:** Patient has been enrolled and engaged in the Wellspark program 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.

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

ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND

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

a) At baseline, patient had a BMI  $\geq 32$  kg/m<sup>2</sup> **[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, 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  $\geq 18$  years of age; AND

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

a) At baseline, patient had a BMI  $\geq 32$  kg/m<sup>2</sup> **[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, 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).



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- iii. Patient has lost  $\geq 4\%$  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 insulintropic 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  $\geq 12$  years of age and  $< 18$  years of age; AND
    - ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
    - iii. At baseline, patient had a BMI  $\geq 95^{\text{th}}$  percentile for age and sex **[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 insulintropic 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  $\geq 12$  years of age and  $< 18$  years of age; AND
    - ii. At baseline, patient had a BMI  $\geq 95^{\text{th}}$  percentile for age and sex **[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 insulintropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
    - iii. Patient has had a reduction in BMI of  $\geq 1\%$  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 insulintropic 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:**

- 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  $\geq 18$  years of age; AND
    - ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
    - iii. Patient meets ONE of the following (a or b):
      - a) At baseline, patient had a BMI  $\geq 32 \text{ kg/m}^2$  **[documentation required]**; OR



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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, 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  $\geq 18$  years of age; AND

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

- a) At baseline, patient had a BMI  $\geq 32$  kg/m<sup>2</sup> **[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, 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  $\geq 5\%$  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; 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



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- (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  $\geq 12$  years of age and  $< 18$  years of age; AND
- ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
- iii. At baseline, patient had a BMI  $\geq 95^{\text{th}}$  percentile for age and sex **[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  $\geq 12$  years of age and  $< 18$  years of age; AND
- ii. At baseline, patient had a BMI  $\geq 95^{\text{th}}$  percentile for age and sex **[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  $\geq 1\%$  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 ALL of the following (i, ii, iii, iv, and v):

- i. Patient is  $\geq 18$  years of age; AND
- ii. Patient has a BMI  $\geq 27 \text{ kg/m}^2$  **[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



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- 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 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  $\geq 18$  years of age; AND
    - ii. At baseline, patient had a BMI  $\geq 27$  kg/m<sup>2</sup> **[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 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. Coverage of Zepbound** is recommended in those who meet ONE of the following criteria:

- 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  $\geq 18$  years of age; AND
    - ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
    - iii. Patient meets ONE of the following (a or b):
      - a) At baseline, patient had a BMI  $\geq 32$  kg/m<sup>2</sup> **[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, metabolic-dysfunction associated steatotic liver disease/non-



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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  $\geq 18$  years of age; AND

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

a) At baseline, patient had a BMI  $\geq 32$  kg/m<sup>2</sup> [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, 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  $\geq 5\%$  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; 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:



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1. **Concomitant Use with Other Weight Loss Medications.** Concomitant use with other medications intended for weight loss is not recommended.<sup>2,3,8</sup> Note: Examples of other medications FDA-approved for weight loss include but are not limited to phentermine (Lomaira, generic), benzphetamine, diethylpropion, phendimetrazine, Contrave (naltrexone/bupropion extended-release tablets), Qsymia (phentermine/topiramate extended-release capsules), and Xenical (orlistat 120 mg capsules). Additionally, Alli (orlistat 60 mg capsules) is available over-the-counter.
2. **Concomitant Use with Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonists.** The GLP-1 agonists and the GLP-1/GIP agonist should not be combined with each other or with any other GLP-1 agonists or GLP-1/GIP agonist.<sup>1,2,9</sup> There are other GLP-1 and GLP-1/GIP products not included in this policy that are FDA-approved for type 2 diabetes, and not chronic weight management. Note: Examples of other GLP-1 agonists include but are not limited to Adlyxin (lixisenatide subcutaneous [SC] injection), Byetta (exenatide SC injection), Bydureon BCise (exenatide extended-release SC injectable suspension), Ozempic (semaglutide SC injection), Rybelsus (semaglutide tablets), Trulicity (dulaglutide SC injection), and Victoza (liraglutide SC injection, authorized generic). An example of a GLP-1/GIP agonist is Mounjaro (tirzepatide SC injection).
3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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