



Policy:	Weight Loss Glucagon-Like Peptide-1 (GLP1) Agonists Saxenda (liraglutide) Wegovy (semaglutide) Zephound (tirzepatide)	Annual Review Date: 07/18/2024 Last Revised Date: 01/16/2025
	Zepbound (tirzepatide)	01/16/2025

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. These agents are indicated as an adjunct to a reduced-calorie diet and increased physical activity for **chronic weight management** in the following settings:

- Saxenda, Wegovy, and Zepbound: 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., hypertension, dyslipidemia, type 2 diabetes, obstructive sleep apnea, or cardiovascular disease).
- Saxenda: 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:** Pediatric patients ≥ 12 years of age with an initial BMI at the 95th percentile or greater for age and sex (obesity)

POLICY STATEMENT

This policy involves the use of Saxenda and Wegovy. Of note, other glucagon-like peptide-1 agonists which do not carry an FDA-approved indication for weight loss are not targeted in this policy. Prior authorization is recommended for pharmacy benefit coverage of Saxenda. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications



- 1. Weight Loss, Adult. Approve Saxenda for the duration noted if the patient meets one of the following criteria (A or B):
 - A) <u>Initial Therapy</u>. Approve for 4 months if the patient meets the following criteria (i, ii, iii, <u>and</u> 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, the patient had a body mass index (BMI) ≥ 32 kg/m² *; 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) At baseline, the patient had a BMI ≥ 27 kg/m² * and at least TWO of the following weight-related comorbidities *: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea (OSA), cardiovascular disease (CVD), knee osteoarthritis, asthma, chronic obstructive pulmonary disease (COPD), non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD), polycystic ovarian syndrome (PCOS), or coronary artery disease (CAD); 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. Saxenda will be used concomitantly with a behavioral modification program and a reduced-calorie diet; AND.
 - **v.** The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.
 - **B**) Patient is Continuing Therapy with Saxenda. Approve for 1 year if the patient meets the following criteria (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/m² [documentation required]; OR <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).
 - b) At baseline, patient had a BMI ≥ 27 kg/m² * and at least TWO of the following weight-related comorbidities *: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea (OSA), cardiovascular disease (CVD), knee osteoarthritis, asthma, chronic obstructive pulmonary disease (COPD), non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD), polycystic ovarian syndrome (PCOS), or coronary artery disease (CAD); AND Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
- iii. Patient has lost ≥ 4% of baseline body weight *; AND Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
- iv. Patient is able to tolerate a Saxenda maintenance dose of 3 mg once daily; AND
- v. Saxenda will be used concomitantly with a behavioral modification program and a reduced-calorie diet; AND.
- vi. The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.



- 2. Weight Loss, Pediatric. Approve Saxenda for the duration noted if the patient meets one of the following criteria (A or B):
 - A) <u>Initial Therapy</u>. Approve for 4 months if the patient meets the following criteria (I, ii, iii, <u>and</u> 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, the patient had a BMI ≥ 95th percentile for age and sex *; AND Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
 - iv. Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet; AND
 - **v.** The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.
 - **B)** Patient is Continuing Therapy with Saxenda. Approve for 1 year if the patient meets the following criteria (i, ii, iii, iv, and v):

<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 ≥ 95th percentile for age and sex *; AND
 Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
- iii. Patient has had a reduction in BMI of ≥ 1% from baseline *; AND

 Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
- iv. Patient is able to tolerate a Saxenda maintenance dose of 2.4 mg once daily or 3 mg once daily; AND
- v. Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet; AND
- vi. The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.
- **I.** Coverage of **Wegovy** is recommended in those who meet the following criteria:

FDA-Approved Indications

- **1. Weight Loss, Adult.** Approve Wegovy for the duration noted if the patient meets one of the following criteria (A <u>or</u> B):
 - **A.** <u>Initial Therapy</u>: Approve for 7 months if the patient meets the following criteria (i, ii, iii, <u>and</u> 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, the patient had a body mass index (BMI) ≥ 32 kg/m²*; 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).

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- b. At baseline, the patient had a BMI \geq 27 kg/m² * and at least TWO of the following weight-related comorbidities *: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea (OSA), cardiovascular disease (CVD), knee osteoarthritis, asthma, chronic obstructive pulmonary disease (COPD), non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD), polycystic ovarian syndrome (PCOS), or coronary artery disease (CAD); 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. We govy will be used concomitantly with a behavioral modification program and a reduced-calorie diet; AND.
- v. The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.
- **B.** Patient is Continuing Therapy with Wegovy: Approve for the duration noted below if the patient meets the following criteria (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. The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology; AND
- iii. Patient meets one of the following (a or b):
 - a. At baseline, patient had a BMI of ≥ 32 kg/m²*; 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. At baseline, patient had a BMI of ≥ 27 kg/m² * and at least TWO of the following weight-related comorbidities *: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea (OSA), cardiovascular disease (CVD), knee osteoarthritis, asthma, chronic obstructive pulmonary disease (COPD), non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD), polycystic ovarian syndrome (PCOS), or coronary artery disease (CAD); 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 has lost ≥ 5% of baseline body weight *; AND
 Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
- v. We govy will be used concomitantly with a behavioral modification program and a reduced-calorie diet; AND
- vi. 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)]:



<u>Note</u>: 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 Wegovy for the duration noted if the patient meets one of the following criteria (A or B):
 - A) <u>Initial Therapy</u>. Approve for 7 months if the patient meets the following criteria (I, ii, iii, <u>and</u> 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, the patient had a BMI ≥ 95th percentile for age and sex *; AND Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
 - iv. Wegovy will be used concomitantly with behavioral modification and a reduced-calorie diet; AND
 - **v.** The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.
 - **B)** Patient is Continuing Therapy with Wegovy. Approve for the duration noted below if the patient meets the following criteria (i, ii, iii, iv, and v):

Note: For a patient who has not completed 7 months of initial therapy, refer to Initial Therapy criteria above.

- i. Patient is ≥ 12 years of age and < 18 years of age; AND
- ii. At baseline, patient had a BMI ≥ 95th percentile for age and sex *; AND Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
- iii. Patient has had a reduction in BMI of ≥ 1% from baseline *; AND

 Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
- iv. Wegovy will be used concomitantly with behavioral modification and a reduced-calorie diet; AND
- **v.** The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.
- vi. 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)]:
 - (2) <u>Note</u>: 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). Patient has received < 12 consecutive months of Wegovy; AND
 - (3) 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 Wegovy for 6 months if the patient meets the following criteria:
 - A) Approve if the patient meets ALL of the following (i, ii, iii, iv, <u>and</u> v):
 - i. Patient is ≥ 18 years of age; AND
 - ii. Patient has a BMI $\geq 27 \text{ kg/m}^2 *$; AND
 - iii. Patient meets ONE of the following (a, b, or c) *:
 - a) Patient has had a prior myocardial infarction; OR
 - **b**) Patient has had a prior stroke; OR
 - c) Patient has a history of symptomatic peripheral arterial disease as evidenced by ONE of the following [(1), (2), or (3)]:
 - (1) Intermittent claudication with ankle-brachial index < 0.85; OR
 - (2) Peripheral arterial revascularization procedure; OR
 - (3) Amputation due to atherosclerotic disease; AND
 - **iv.** According to the prescriber, the medication will be used in combination with optimized pharmacotherapy for established cardiovascular disease; AND
 - v. The medication will be used concomitantly with a behavioral modification program and a reduced-calorie diet.
- **III.** Coverage of **Zepbound** is recommended in those who meet the following criteria:

FDA-Approved Indications

- 1. Weight Loss, Adult. Approve Zepbound for the duration noted if the patient meets one of the following criteria (A or B):
 - A) Initial Therapy: Approve for 8 months if the patient meets the following criteria (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, the patient had a body mass index (BMI) ≥ 32 kg/m²*; 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) At baseline, the patient had a BMI ≥ 27 kg/m² * and at least TWO of the following weight-related comorbidities *: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea (OSA), cardiovascular disease (CVD), knee osteoarthritis, asthma, chronic obstructive pulmonary disease (COPD), non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD), polycystic ovarian syndrome (PCOS), or coronary artery disease (CAD); 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. Zepbound will be used concomitantly with a behavioral modification program and a reduced-calorie diet; AND.
 - **v.** The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology.



B) Patient is Continuing Therapy with Zepbound. Approve for the duration noted below if the patient meets the following criteria (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.** The prescriber does not specialize or practice primarily in any of the following areas: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, radiology; AND
- iii. Patient meets one of the following (a or b):
 - b) At baseline, patient had a BMI ≥ 32 kg/m²*; OR <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).
 - c) At baseline, patient had a BMI ≥ 27 kg/m² * and at least TWO of the following weight-related comorbidities *: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea (OSA), cardiovascular disease (CVD), knee osteoarthritis, asthma, chronic obstructive pulmonary disease (COPD), non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD), polycystic ovarian syndrome (PCOS), or coronary artery disease (CAD); 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 has lost ≥ 5% of baseline body weight *; AND Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
- v. Zepbound will be used concomitantly with a behavioral modification program and a reduced-calorie diet; AND
- vi. The patient meets one of the following (a or b):
 - a) The 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
 - <u>Note:</u> 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.
- **2. Obstructive Sleep Apnea, Moderate to Severe, in a Patient with Obesity.** Approve for 1 year if the patient meets ONE of the following (A or B):
 - A) <u>Initial Therapy</u>. Approve if the patient meets ALL of the following (i, ii, iii, iv, <u>and</u> v):
 - i. Patient is ≥ 18 years of age; AND
 - ii. Patient has a current BMI \geq 30 kg/m² *; AND
 - iii. Patient has had a sleep study within the past 1 year that shows BOTH of the following (a and b) *:
 - a) Patient has been diagnosed with moderate to severe obstructive sleep apnea; AND
 - **b**) Patient has an apnea-hypoapnea index ≥ 15 events per hour; AND



Note: A diagnosis of moderate obstructive sleep apnea is an apnea-hypoapnea index of ≥ 15 events per hour, a diagnosis of severe sleep apnea is an apnea-hypoapnea index ≥ 30 events per hour. The apnea-hypoapnea index is the number of apnea and hypoapneas during 1 hour of sleep.

iv. The patient does <u>NOT</u> meet either of the following (a <u>or</u> b):

Note: A patient who has one or more of the following conditions/diagnoses below is not approved.

- a) Central sleep apnea with percent of central apneas/hypoapneas $\geq 50\%$; OR
- **b**) Cheyne Stokes respiration; AND
- v. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.
- **B)** Patient is Continuing Therapy with Zepbound. Approve if the patient meets ALL of the following: Note: For a patient who has not completed 1 year of initial therapy, refer to Initial Therapy criteria above.
 - i. Patient is ≥ 18 years of age or older; AND
 - ii. At baseline, patient had a BMI ≥ 30 kg/m² *; AND Note: This refers to baseline before use of Zepbound.
 - iii. Patient has completed ≥ 1 year of therapy with Zepbound AND the patient meets BOTH of the following (a <u>and</u> b):
 - a) Patient has lost $\geq 10\%$ of baseline body weight *; AND
 - b) Patient has stability in obstructive sleep apnea signs or symptoms, according to the prescriber; AND Note: Examples of signs or symptoms of obstructive sleep apnea include but are not limited to snoring, excessive daytime sleepiness, fatigue.
 - iv. The medication will be used concomitantly with behavioral modifications and a reduced-calorie diet.

Initial Approval/ Extended Approval.

A) Initial Approval: Saxenda- 4 months; Wegovy- up to 7 months, Zepbound- up to 1 year

B) Extended Approval: up to 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Saxenda, Wegovy, and Zepbound have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

- 1. Concomitant use with other weight loss medications. Concomitant use with other medications intended for weight loss is not recommended.^{1,2} Of note, examples of other medications FDA-approved for weight loss include phentermine (Lomaira, generic), benzphetamine, diethylpropion, phendimetrazine, Contrave (naltrexone/bupropion extended-release tablets), Qsymia (phentermine/topiramate extended-release capsules), and Xenical (orlistat 120 mg capsules). Additionally, Alli (orlistat 60 mg capsules) is available over-the-counter.
- 2. Concomitant use with other glucagon-like peptide-1 (GLP-1) agonists or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonists. Wegovy, Saxenda, and Zepbound should not be combined with each other or with any other GLP-1 agonists. ^{1,2} Other GLP-1 and GLP-1/GIP products are FDA-approved for type 2 diabetes and are not indicated for chronic weight management. Note: Examples of other GLP-1 agonists include but are not limited to Adlyxin (lixisenatide subcutaneous [SC] injection), Byetta (exenatide SC injection), Bydureon (exenatide extended-release SC injectable suspension), Bydureon BCise (exenatide extended-release SC injectable)

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suspension), Ozempic (semaglutide SC injection), Rybelsus (semaglutide tablets), Trulicity (dulaglutide SC injection), and Victoza (liraglutide SC injection). An example of a GLP-1/GIP agonist is Mounjaro (tirzepatide SC injection).

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

* Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

- 1. Saxenda [prescribing information]. Plainsboro, NJ: Novo Nordisk A/S; June 2022.
- 2. Wegovy [prescribing information]. Plainsboro, NJ: Novo Nordisk A/S; December 2022.
- 3. Apovian CM, Aronne LJ, Bessesen DH, McDonnell ME, Murad MH, Pagotto U, Ryan DH, Still CD; Endocrine Society. Pharmacological management of obesity: an endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2015 Feb;100(2):342-62.
- 4. Garvey WT, Mechanick JI, Brett EM, Garber AJ, Hurley DL, Jastreboff AM, Nadolsky K, Pessah-Pollack R, Plodkowski R; Reviewers of the AACE/ACE Obesity Clinical Practice Guidelines. American Association of Clinical Endocrinologists and American College of Cardiology comprehensive clinical practice guidelines for medical care of patients with obesity. *Endocr Pract*. 2016 Jul;22 Suppl 3:1-203.
- 5. Styne DM, Arslanian SA, Connor EL, Farooqi IS, Murad MH, Silverstein JH, Yanovski JA. Pediatric Obesity-Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2017 Mar 1;102(3):709-757.
- 6. Grunvald E, Shah R, Hernaez R, et al; AGA Clinical Guidelines Committee. AGA Clinical Practice Guideline on Pharmacological Interventions for Adults with Obesity. *Gastroenterology*. 2022 Nov;163(5):1198-1225.
- Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents with Obesity. *Pediatrics*. 2023 Jan 9:e2022060640.
- 8. ZepboundTM subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; November 2023.