MEDICAL MUTUAL®

Drug Policy

Policy: **SD**	**Weight Loss Glucagon-Like Peptide-1 (GLP1) Agonists** **Saxenda (liraglutide)** **Wegovy (semaglutide)** **Zepbound (tirzepatide)**	**Annual Review Date:** **03/21/2024** **Last Revised Date:** **03/21/2024**

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/m^2 (obese), or ≥ 27 kg/m^2 (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/m^2 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)** Initial Therapy. Approve for 4 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) ≥ 30 kg/m^2; OR
         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
       - **b)** At baseline, the patient had a BMI ≥ 27 kg/m^2 and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND
         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
     - **iv.** Saxenda 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 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 ≥ 30 kg/m^2; OR
         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
       - **b)** At baseline, patient had a BMI ≥ 27 kg/m^2 and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND
         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
     - **iii.** Patient has lost ≥ 4% of baseline body weight; AND
       Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
     - **iv.** Patient is able to tolerate a Saxenda maintenance dose of 3 mg once daily; AND
     - **v.** Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet.

2. **Weight Loss, Pediatric.** Approve Saxenda for the duration noted if the patient meets one of the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 4 months if the patient meets the following criteria (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, 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.

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 ≥ 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.

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 or B):
   - **A.** Initial Therapy: Approve for 7 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) ≥ 30 kg/m^2; OR
         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
       - b. At baseline, the patient had a BMI ≥ 27 kg/m^2 and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND
         Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).
     - iv. Wegovy will be used concomitantly with behavioral modification and a reduced-calorie diet.
   - **B.** Patient is Continuing Therapy with Wegovy: Approve for the duration noted below if the patient meets the following 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 ≥ 18 years of age; AND

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

a. At baseline, patient had a BMI of ≥ 30 kg/m^2; OR
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

b. At baseline, patient had a BMI of ≥ 27 kg/m2 and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iii. Patient has lost ≥ 5% of baseline body weight; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

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

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

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

b. Approve for up to 5 months if the patient meets both of the following [(1) and (2)]:
Note: Approve a sufficient duration for 12 consecutive months of therapy (for example, if the patient has completed 8 months of Wegovy therapy, approve for 4 additional months).
1) Patient has received < 12 consecutive months of Wegovy; AND
2) According to the prescriber, the patient is continuing to titrate the Wegovy dose to a target of 1.7 mg once weekly or 2.4 mg once weekly.

2. Weight Loss, Pediatric. Approve Wegovy for the duration noted if the patient meets one of the following criteria (A or B):

A) Initial Therapy. Approve for 7 months if the patient meets the following criteria (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, 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.

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. 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.

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) ≥ 30 kg/m^2; OR
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

b) At baseline, the patient had a BMI ≥ 27 kg/m^2 and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

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

b) At baseline, patient had a BMI ≥ 30 kg/m^2; OR
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

c) At baseline, patient had a BMI ≥ 27 kg/m^2 and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iii. Patient has lost ≥ 5% of baseline body weight; AND
Note: This refers to baseline prior to any glucagon-like peptide-1 (GLP-1) agonist (e.g., Saxenda, Wegovy) or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (e.g., Zepbound).

iv. Zepbound will be used concomitantly with behavioral modification and a reduced-calorie diet; AND

v. 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 achieve the 5 mg once weekly maintenance dose within the 8 months of initial therapy provided above.

Initial Approval/ Extended Approval.
A) *Initial Approval:* Saxenda- 4 months; Wegovy- 7 months, Zepbound- 8 months
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 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

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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.
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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.
7. 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. Zepbound™ subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; November 2023.