PRIOR AUTHORIZATION POLICY

POLICY: Weight Loss – Glucagon-Like Peptide-1 Agonists Prior Authorization Policy
- Wegovy™ (semaglutide subcutaneous injection – Novo Nordisk)
- Saxenda® (liraglutide subcutaneous injection – Novo Nordisk)

REVIEW DATE: 07/13/2022; selected revision 01/18/2023

OVERVIEW

Wegovy, a glucagon-like peptide-1 (GLP-1) receptor agonist, is indicated as an adjunct to a reduced-calorie diet and increased physical activity for **chronic weight management** in the following settings:[1]

- 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).
- Pediatric patients ≥ 12 years of age with an initial BMI at the 95th percentile or greater for age and sex (obesity).

Saxenda is indicated as an adjunct to a reduced-calorie diet and increased physical activity for **chronic weight management** in:[2]

- Adults with an initial 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).
- 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.

Dosing

In the prescribing information for Wegovy, a recommended dose escalation schedule of 16 weeks is outlined.[1] If a patient does not tolerate a dose during dose escalation, consider delaying dose escalation for 4 weeks. The maintenance dose of Wegovy is 2.4 mg injected subcutaneously once weekly. If an adult patient does not tolerate the maintenance 2.4 mg once weekly dose, the dose can be temporarily decreased to 1.7 mg once weekly, for a maximum of 4 weeks. After 4 weeks, increase Wegovy to the maintenance 2.4 mg once weekly dose. Discontinue Wegovy if the patient cannot tolerate the 2.4 mg dose. If a pediatric patient ≥ 12 to < 18 years of age does not tolerate the maintenance dose of 2.4 mg once weekly, the dose can be reduced to 1.7 mg once weekly. Discontinue Wegovy if the patient cannot tolerate the 1.7 mg dose.

In the prescribing information for Saxenda, a recommended dose escalation schedule of 4 weeks is outlined.[2] If a patient does not tolerate an increased dose during dose escalation, consider delaying dose escalation for approximately one additional week. For adults, the recommended maintenance dose of Saxenda is 3 mg once daily; discontinue Saxenda if the patient cannot tolerate the 3 mg dose. Additionally, for adults, the prescribing information states to evaluate the change in body weight 16 weeks after initiating Saxenda and discontinue Saxenda if the patient has not lost at least 4% of baseline body weight, since it is unlikely the patient will achieve and sustain clinically meaningful weight loss with continued treatment. For pediatric patients, the recommended maintenance dose of Saxenda is 3 mg once daily. However, pediatric patients who do not tolerate 3 mg once daily may have their maintenance dose reduced to 2.4 mg once daily. Discontinue Saxenda if the patient cannot tolerate the 2.4 mg dose. Additionally, for pediatric patients, the prescribing information states to evaluate the change in BMI after 12 weeks on the maintenance dose and discontinue Saxenda if the patient has not had a reduction in BMI of at least 1% from baseline, since it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

Guidelines

Guidelines from the American Gastroenterological Association on pharmacological interventions for adults with obesity (2022) state that in adults with obesity or overweight with weight-related complications, who have had an inadequate response to lifestyle interventions, it is recommended to add pharmacological agents to lifestyle interventions over continuing lifestyle interventions alone (strong recommendation, moderate quality evidence).[6] Wegovy and Saxenda are listed among the therapeutic options. It is also noted that given the magnitude of net benefit, Wegovy may be prioritized over other approved anti-obesity medications for the long-term treatment of obesity for most patients.

Guidelines from the Endocrine Society regarding pharmacological management of obesity (2015) recommend pharmacotherapy as adjunct to behavioral modification to reduce food intake and increase physical activity for patients with BMI $\geq$ 30 kg/m^2 or $\geq$ 27 kg/m^2 in the presence of at least one comorbidity, such as hypertension, dyslipidemia, type 2 diabetes, or obstructive sleep apnea.[3] If a patient's response to a weight loss medication is deemed effective (weight loss $\geq$ 5% of body weight at 3 months) and safe, it is recommended that the medication be continued. In clinical studies of Saxenda and semaglutide, eligible patients were required to have a prior unsuccessful dietary weight loss attempt.

Per AACE/ACE obesity guidelines (2016), pharmacotherapy for overweight and obesity should be used only as an adjunct to lifestyle therapy and not alone.[4] The addition of pharmacotherapy produces greater weight loss and weight-loss maintenance compared with lifestyle therapy alone. The concurrent initiation of lifestyle therapy and pharmacotherapy should be considered in patients with weight-related complications that can be ameliorated by weight loss. Pharmacotherapy should be offered to patients with obesity, when potential benefits outweigh the risks, for the chronic treatment of the disease. Short-term treatment (3 to 6 months) using weight-loss medications has not been demonstrated to produce longer-term health benefits and cannot be generally recommended based on scientific evidence.

Guidelines in Pediatric Obesity

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.[7]

A 2017 Endocrine Society clinical practice guideline on pediatric obesity recommends pharmacotherapy in combination with lifestyle modification be considered in obese children or adolescents only after failure of a formal program of intensive lifestyle (dietary, physical activity and behavioral) modification to limit weight gain or to ameliorate comorbidities.[5] The Endocrine Society recommends pharmacotherapy in overweight children and adolescents < 16 years only in the context of a clinical trial. Pharmacotherapy should be provided only by clinicians who are experienced in the use of anti-obesity agents and aware of the potential for adverse events. These guidelines recommend limited use of pharmacotherapy because pediatric obesity should be managed preferably as a serious lifestyle condition with important lifelong consequences.

The Endocrine Society defines overweight as BMI in at least the 85th percentile but less than the 95th percentile, and obesity as BMI in at least the 95th percentile for age and sex against routine endocrine studies, unless the height velocity is attenuated or inappropriate for the family background or stage of puberty.[5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Saxenda and Wegovy. Of note, this policy targets Saxenda and Wegovy; other glucagon-like peptide-1 agonists which do not carry an FDA-approved indication for weight loss are not targeted in this policy. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of Wegovy is recommended in those who meet one of 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)** Patient currently has a body mass index (BMI) ≥ 30 kg/m^2; OR
  - **b)** Patient currently has a BMI ≥ 27 kg/m^2 and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, or cardiovascular disease; AND
- **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 (prior to the initiation of Wegovy), patient had a BMI ≥ 30 kg/m^2; OR
  - **b)** At baseline (prior to the initiation of Wegovy), 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, or cardiovascular disease; AND
- **iii.** Patient has lost ≥ 5% of baseline (prior to the initiation of Wegovy) body weight; AND
- **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 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 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.** Patient currently has a BMI ≥ 95th percentile for age and sex; AND
- **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 (prior to the initiation of Wegovy), patient had a BMI ≥ 95th percentile for age and sex; AND
- **iii.** Patient has had a reduction in BMI of ≥ 1% from baseline (prior to the initiation of Wegovy); AND
- **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.

II. 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)** Patient currently has a body mass index (BMI) ≥ 30 kg/m^2; OR
  - **b)** Patient currently has a BMI ≥ 27 kg/m^2 and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, or cardiovascular disease; AND
- **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 (prior to the initiation of Saxenda), patient had a BMI ≥ 30 kg/m^2; OR
  - **b)** At baseline (prior to the initiation of Saxenda), 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, or cardiovascular disease; AND
- **iii.** Patient has lost ≥ 4% of baseline (prior to the initiation of Saxenda) body weight; AND
- **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.** Patient currently has a BMI ≥ 95th percentile for age and sex; AND
- **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 (prior to the initiation of Saxenda), patient had a BMI ≥ 95th percentile for age and sex; AND
- **iii.** Patient has had a reduction in BMI of ≥ 1% from baseline (prior to the initiation of Saxenda); AND
- **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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Wegovy and Saxenda is not recommended in the following situations:

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.** Wegovy and Saxenda should not be combined with each other or with any other GLP-1 agonists.[1,2] Examples of other GLP-1 agonists include Adlyxin (lixisenatide 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). These products are FDA-approved for type 2 diabetes and are not indicated for chronic weight management.

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

REFERENCES

1. Wegovy™ subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; December 2022.
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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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Wegovy: New criteria were developed. Saxenda Criteria were rolled in to this policy. Previously these criteria were part of the *Weight Loss Drugs Prior Authorization Policy*. The following changes were made: **Weight Loss, Adult:** The approval condition was changed from "Weight Loss in Patients ≥ 18 years of age" to "Weight Loss, Adult". Initial Therapy. A requirement that the patient is ≥ 18 years of age was added to criteria. For the trial of behavioral modification and dietary restriction, the phrase "and has failed to achieve the desired weight loss" was removed. For the criterion involving a patient with body mass index (BMI) ≥ 27 kg/m^2, the phrase "for those with comorbidities besides obesity" was changed to "and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, or cardiovascular disease". The Note with examples of comorbidities was removed. The reference to a BMI chart in the Appendix was removed. The requirement that "patient is currently engaged in behavioral modification and on a reduced-calorie diet" was changed to "Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet." Patient is Continuing Therapy with Saxenda. A criterion that the patient is ≥ 18 years of age was added (previously, this was listed in the approval condition). In continuation criteria referencing initial BMI values, the phrase "patient had an initial BMI" was replaced with "at baseline (prior to the initiation of Saxenda), patient had a BMI". For the criterion involving a patient with body mass index (BMI) ≥ 27 kg/m^2, the phrase "for those with comorbidities besides obesity" was changed to "and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, or cardiovascular disease". For the requirement regarding loss of ≥ 4% of baseline body weight, baseline was clarified to mean "prior to the initiation of Saxenda". A requirement that the patient is able to tolerate a Saxenda maintenance dose of 3 mg once daily was added. The criterion "patient is currently engaged in behavioral modification and on a reduced-calorie diet" was changed to "Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet." **Weight Loss, Pediatric:** The approval condition was changed from "Weight Loss in Patients Aged ≥ 12 to < 18 years" to "Weight Loss, Pediatric". Initial Therapy. A requirement that the patient is ≥ 12 years of age and < 18 years of age was added (previously this was captured in the approval condition). For the trial of behavioral modification and dietary restriction, the phrase "and has failed to limit weight gain or modify comorbidities" was removed. The requirement that "patient is currently engaged in behavioral modification and on a reduced-calorie diet" was changed to "Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet." Patient is Continuing Therapy with Saxenda. A requirement that the patient is ≥ 12 years of age and < 18 years of age was added (previously this was captured in the approval condition). In continuation criteria referencing initial BMI values, the phrase "patient had an initial BMI" was replaced with "at baseline (prior to the initiation of Saxenda), patient had a BMI". For the requirement regarding loss of ≥ 1% of baseline BMI, baseline was clarified to mean "prior to the initiation of Saxenda". A requirement that the patient is able to tolerate a Saxenda maintenance dose of 2.4 mg once daily or 3 mg once daily was added. The criterion "patient is currently engaged in behavioral modification and on a reduced-calorie diet" was changed to "Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet."	06/14/2021
Annual Revision	Wegovy **Weight Loss:** Under continuation criteria, as an alternative to the requirement that the patient is able to tolerate a Wegovy dose of 2.4 mg once weekly, a pathway was added to allow approval for up to 12 months of therapy if the patient has received < 12 months of consecutive Wegovy, and according to the prescriber, the patient is continuing to titrate the Wegovy dose to a target of 2.4 mg once weekly.	07/13/2022

HISTORY (CONTINUED)