VENTURA COUNTY
HEALTH CARE PLAN

CARE VALUE POLICY

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

REVIEW DATE: 06/16/2021; effective 07/01/2021

OVERVIEW

Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for **chronic weight management** in 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).[1]

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

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 a 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.

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 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 ≥ 30 kg/m^2 or ≥ 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 ≥ 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

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 the following criteria:

FDA-Approved Indications

1. **Weight Loss.** 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 1 year 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.** Patient is able to tolerate a Wegovy maintenance dose of 2.4 mg once weekly; AND
     - **v.** Wegovy will be used concomitantly with behavioral modification and a reduced-calorie diet.

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 4 months; AND

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

a) Patient currently has a BMI ≥ 95th percentile for age and sex; OR

b) Patient currently has a BMI ≥ 85th percentile but < 95th percentile for age and sex and has at least one comorbidity (type 2 diabetes mellitus, cardiovascular disease) or has a strong family history of type 2 diabetes or premature cardiovascular disease; AND

Note: Premature cardiovascular disease is defined as cardiovascular disease occurring in a male < 55 years of age or in a female < 65 years of age.

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, v, and vi):

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

a) At baseline (prior to the initiation of Saxenda), patient had a BMI ≥ 95th percentile for age and sex; OR

b) At baseline (prior to the initiation of Saxenda), patient had a BMI ≥ 85th percentile but < 95th percentile for age and sex and has at least one comorbidity (type 2 diabetes or cardiovascular disease) or strong family history of type 2 diabetes or premature cardiovascular disease; AND

Note: Premature cardiovascular disease is defined as cardiovascular disease occurring in a male < 55 years of age or in a female < 65 years of age.

iii. Patient has had a reduction in BMI of ≥ 1% from baseline (prior to the initiation of Saxenda); AND

iv. Patient currently has a BMI > 85th percentile; AND

v. Patient is able to tolerate a Saxenda maintenance dose of 2.4 mg once daily or 3 mg once daily; AND

vi. 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; June 2021.
2. Saxenda® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; December 2020.
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.