Effective Date **2/15/2024**
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Coverage Policy Number **IP0206**

Weight Loss – Liraglutide (Saxenda®)

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for liraglutide subcutaneous injection (**Saxenda®**).

For Employer Group Standard, Performance, Value, Advantage, Cigna Total Savings, and Legacy Drug List Plans: Coverage for Weight Loss Medications may require the use of preferred or generic products according to the customer's benefit plan. Refer to the customer's benefit plan document for coverage details.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Liraglutide (Saxenda) is considered medically necessary when ONE of the following is met:

1. **Weight Loss, Adult.** Individual meets **ALL** of the following criteria:
   A. Age 18 years or older
   B. Has engaged in a trial of behavioral modification and dietary restriction for at least 3 months

C. **ONE** of the following:
    i. Baseline (prior to therapy with Saxenda, Wegovy or Zepbound) body mass index (BMI) of at least 30 kg/m^2
    ii. Baseline (prior to therapy with Saxenda, Wegovy or Zepbound) body mass index (BMI) of at least 27 kg/m^2 and at least **ONE** of the following weight-related comorbidities:
        a. cardiovascular disease (CVD)
        b. dyslipidemia
        c. impaired glucose tolerance
        d. hypertension
        e. obstructive sleep apnea
        f. type 2 diabetes
D. Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet

2. **Weight Loss, Pediatric.** Individual meets **ALL** of the following criteria:
    A. At least 12 years of age and less than 18 years of age
    B. Has engaged in a trial of behavioral modification and dietary restriction for at least 3 months
    C. **ONE** of the following:
        i. Baseline (prior to therapy with Saxenda, Wegovy or Zepbound) body mass index (BMI) in at least the 95th percentile for age and sex
        ii. Baseline (prior to therapy with Saxenda, Wegovy or Zepbound) BMI in at least the 85th percentile but less than 95th percentile for age and sex AND has at least **ONE** comorbidity (cardiovascular disease [CVD], type 2 diabetes mellitus) or has a strong family history of type 2 diabetes or premature cardiovascular disease (for example, cardiovascular disease occurring in a male less than 55 years of age or in a female less than 65 years of age)
    D. Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet

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When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of liraglutide subcutaneous injection (Saxenda) is considered medically necessary for weight loss in adults when **ALL** of the following are met:

1. Age 18 years of age or older
2. **ONE** of the following:
    A. At baseline (prior to therapy with Saxenda, Wegovy or Zepbound), had a BMI of at least 30 kg/m^2
    B. At baseline (prior to therapy with Saxenda, Wegovy or Zepbound), had a BMI of at least 27 kg/m^2 and at least **ONE** of the following weight-related comorbidities: cardiovascular disease (CVD), dyslipidemia, impaired glucose tolerance, hypertension, obstructive sleep apnea, or type 2 diabetes
3. Has lost at least 4% of baseline (prior to therapy with Saxenda, Wegovy or Zepbound) body weight (only required once)
4. Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet

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Continuation of liraglutide subcutaneous injection (Saxenda) is considered medically necessary for weight loss in pediatrics when **ALL** of the following are met:

1. At least 12 years of age and less than 18 years of age
2. **ONE** of the following:

A. At baseline (prior to therapy with Saxenda, Wegovy or Zepbound), had a BMI in at least the 95th percentile for age and sex
B. At baseline (prior to therapy with Saxenda, Wegovy or Zepbound), had a BMI in at least the 85th percentile but less than 95th percentile for age and sex and has at least **ONE** comorbidity (type 2 diabetes or cardiovascular disease) or has a strong family history of type 2 diabetes or premature cardiovascular disease (for example, cardiovascular disease occurring in a male less than 55 years of age or in a female less than 65 years of age)

3. Has had a reduction in BMI of at least 1% from baseline (prior to therapy with Saxenda, Wegovy or Zepbound)
4. Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet

Authorization Duration

Initial approval duration is up to 4 months
Reauthorization approval duration is up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Concomitant Use with Other Weight loss Medications.** Concomitant use with other medications intended for weight loss is not recommended.[1,2,9]
   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 other Glucagon-Like Peptide-1 (GLP-1) Agonists or GLP-1/ Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Agonists.** Saxenda, Wegovy, and Zepbound should not be combined with each other or with any other GLP-1 agonists.[1,2,9] 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).

Background

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.[1,2,9] These agents are indicated as an adjunct to a reduced-calorie diet and increased physical activity for **chronic weight management** in the following settings:[1,2,9]

- **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[1,2,9], dyslipidemia[1,2,9], type 2 diabetes[1,2,9], obstructive sleep apnea[9], or cardiovascular disease[9]).
- **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.[2]

- **Wegovy:** Pediatric patients ≥ 12 years of age with an initial BMI at the 95th percentile or greater for age and sex (obesity).[1]

Dosing
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 (QD); 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 QD. However, pediatric patients who do not tolerate 3 mg QD may have their maintenance dose reduced to 2.4 mg QD. 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.

In the prescribing information for Wegovy, a recommended dose escalation schedule of 16 weeks is outlined.[1] If a patient does not tolerate an increased dose during dose escalation, consider delaying dose escalation for 4 weeks. The maintenance dose of Wegovy is 2.4 mg (recommended) or 1.7 mg injected subcutaneously (SC) once weekly; consider treatment response and tolerability when selecting the maintenance dose. The 0.25 mg, 0.5 mg, and 1 mg once weekly doses are initiation and escalation doses and are not approved doses for chronic weight management. 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 Zepbound, the recommended starting dose is 2.5 mg injected SC once weekly.[9] 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 SC once weekly. 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 SC once weekly. 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 SC once weekly. The 5 mg, 10 mg, and 15 mg maintenance doses would be reached after Week 4, Week 12, and Week 20, respectively.

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 ≥ 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. The American Diabetes Association also cites weight loss ≥ 5% of body weight at 3 months as "effective"; when early response is insufficient (typically < 5% weight loss after 3 months), other therapies should be evaluated.[8]

Per American Association of Clinical Endocrinologists/American College of Endocrinology 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 ≥ 12 years of age with obesity (BMI ≥ 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 that 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 of age 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]

References

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8. American Diabetes Association. Standards of medical care in diabetes – 2023. *Diabetes Care*. 2023;46(Suppl 1):S1-S291.
9. Zepbound™ subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; November 2023.