

Saxenda® (liraglutide)

When requesting Saxenda® (liraglutide), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:

- Adult patients with an initial body mass index (BMI) of 30 kg/m² or greater (obese) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia)
- Pediatric patients aged 12 years and older with body weight above 60 kg and an initial BMI corresponding to 30 kg/m² for adults (obese) by international cut-offs

Coverage Guidelines

Adult Weight Loss

The individual must meet **all** of the following criteria for authorization:

- Is ≥ 18 years of age;
- Meets one of the following:
 - o Had a BMI ≥ 30 kg/m² at baseline; 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).
 - o Meets both of the following:
 - Had a BMI ≥ 27 kg/m² at baseline; AND
 - Had at baseline, or currently has, one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunction associated steatotic liver 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).
 - o Medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

Initial authorization:

- Has engaged in a trial of behavioral modification and dietary restriction for at least 3 months;

Reauthorization:

Note: For a patient who has not completed 4 months of initial therapy, refer to initial therapy criteria.

- Has lost $\geq 4\%$ of baseline body weight;

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).

- Is able to tolerate a Saxenda maintenance dose of 3 mg once daily;

Pediatric Weight Loss

The individual must meet **all** of the following criteria for authorization:

- Is ≥ 12 years of age and < 18 years of age;
- Had a BMI ≥ 95 th percentile for age and sex at baseline;
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).
- Medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

Initial authorization:

- Has engaged in a trial of behavioral modification and dietary restriction for at least 3 months.

Reauthorization:

Note: For a patient who has not completed 4 months of initial therapy, refer to initial therapy criteria.

- Has had a reduction in BMI of $\geq 1\%$ from baseline;
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).
- Is able to tolerate a Saxenda maintenance dose of 2.4 mg once daily or 3 mg once daily;

Approval duration (initial): 4 months

Approval duration (renewal): 12 months

Dosing Recommendations

Administer Saxenda subcutaneously once daily.

- The recommended dose is 3 mg daily. Pediatric patients may have their dose reduced to 2.4 mg daily if the 3 mg dose is not tolerated.
- Initiate Saxenda with a dose of 0.6 mg daily for one week, then follow the dose escalation schedule below:

Week	Daily Dose
1	0.6 mg

Saxenda® (liraglutide)

2	1.2 mg
3	1.8 mg
4	2.4 mg
5 and onward	3 mg

References

1. Saxenda® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; April 2023.
2. Apovian CM, Aronne LJ, Bessesen DH, et al; Endocrine Society. Pharmacological management of obesity: an endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2015;100(2):342-62.
3. Garvey WT, Mechanick JL, 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;22 Suppl 3:1-203.
4. 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;102(3):709-757.
5. Grunwald E, Shah R, Hernaez R, et al; AGA Clinical Guidelines Committee. AGA Clinical Practice Guideline on Pharmacological Interventions for Adults with Obesity. *Gastroenterology*. 2022;163(5):1198-1225.
6. Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents with Obesity. *Pediatrics*. 2023;151(2):e2022060640.
7. American Diabetes Association. Standards of medical care in diabetes – 2024. *Diabetes Care*. 2024;47(Suppl 1):S1-S321.