Reference number(s)
1227-C

Initial Prior Authorization with Quantity Limit Saxenda Weight Loss Management

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Saxenda	liraglutide

Indications

FDA-approved Indications

Saxenda is indicated in combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in:

- Adult and pediatric patients aged 12 years and older with body weight greater than 60 kg and obesity
- Adults with overweight in the presence of at least one weight-related comorbid condition.

Limitations of Use

- Saxenda contains liraglutide. Coadministration with other liraglutide-containing products or with any other glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.
- The safety and effectiveness of Saxenda in pediatric patients with type 2 diabetes have not been established.

Coverage Criteria

Reduction in Excess Body Weight, Maintenance of Weight Reduction Long Term

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity to reduce excess body weight or maintain weight reduction long term when ALL of the following criteria are met:

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced-calorie diet, AND increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy.
- If the patient is 18 years of age or older, then the patient meets ONE of the following:
    - The patient has a baseline body mass index (BMI) greater than or equal to 30 kg/m^2. [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.] [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a baseline BMI greater than or equal to 27 kg/m^2. [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.] [ACTION REQUIRED: Documentation is required for approval.] In addition, the following criteria is met:
        - The patient has at least ONE weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia). [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their weight-related comorbid condition(s) at the start of any drug therapy.] [ACTION REQUIRED: Documentation is required for approval.]
- If the patient is 12 to 17 years of age, then ALL of the following criteria are met:
    - The patient has a baseline body weight above 60 kg. [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline body weight at the start of any drug therapy.] [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a baseline BMI corresponding to 30 kg/m^2 or greater for adults by international cut-offs based on the Cole Criteria. [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.] [ACTION REQUIRED: Documentation is required for approval.]

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Continuation of Therapy

Reduction in Excess Body Weight, Maintenance of Weight Reduction Long Term

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity to reduce excess body weight or maintain weight reduction long term when ONE of the following criteria is met:

- The patient is 18 years of age or older and ALL of the following criteria are met:
  - The patient has completed at least 16 weeks of therapy with the requested drug.
  - The patient has lost at least 4 percent of baseline body weight OR the patient has continued to maintain their initial 4 percent weight loss. [ACTION REQUIRED: Documentation is required for approval.]
- The patient is 12 to 17 years of age and ALL of the following criteria are met:
  - The patient has completed at least 12 weeks of therapy on the maintenance dose of the requested drug.
  - The patient has had at least 1 percent reduction in body mass index (BMI) from baseline OR the patient has continued to maintain their initial 1 percent BMI reduction. [ACTION REQUIRED: Documentation is required for approval.]

Quantity Limits Apply

15 mL (1 package of five 3 mL pens) per 25 days or 45 mL (3 packages of five 3 mL pens each) per 75 days.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 1227-C:
  - Adults: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months
  - Pediatrics: Initial therapy DOA: 5 months; Continuation of therapy DOA: 12 months

References

1. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; May 2025.

2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed July 07, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 07/07/2025).
4. Jensen MD, Ryan DH, Apovian DM, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society. Circulation. 2014;129(suppl 2):S102-S138.
5. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(2):342–362.
6. US Preventive Services Task Force. Interventions for High Body Mass Index in Children and Adolescents US Preventive Services Task Force Recommendation Statement. JAMA. 2024;Online ahead of print. doi: 10.1001/jama.2024.11146.