Subject: Saxenda PA with Limit 1227-C P08-2024_R

Drug
SAXENDA *(liraglutide)*

Policy:

Indications

FDA-approved Indications

Saxenda is indicated as an 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/m^2 or greater (obese), or
- 27 kg/m^2 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/m^2 or greater for adults (obese) by international cut-offs (Cole Criteria)

Limitations of Use

- Saxenda contains liraglutide and should not be coadministered with other liraglutide-containing products or with any other GLP-1 receptor agonist.
- The safety and effectiveness of Saxenda in pediatric patients with type 2 diabetes have not been established.
- The safety and effectiveness of Saxenda in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

Coverage Criteria

Chronic Weight Management

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity for chronic weight management 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 [ACTION REQUIRED: Documentation is required for approval.] [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.]
- The patient has a baseline BMI greater than or equal to 27 kg/m^2 [ACTION REQUIRED: Documentation is required for approval.] [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.] 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) [ACTION REQUIRED: Documentation is required for approval.] [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.]
- 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 [ACTION REQUIRED: Documentation is required for approval.] [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.]
- The patient has a baseline BMI corresponding to 30 kg/m^2 or greater for adults by international cut-off points based on the Cole Criteria [ACTION REQUIRED: Documentation is required for approval.] [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.]

Continuation of Therapy

Chronic Weight Management

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity for chronic weight management 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

Place of Service:

Outpatient

The above policy is based on the following references:

1. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; April 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed June 28, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 06/28/2024).
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.

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