

Subject: Saxenda PA Policy 1227-A 08-2022

Drug

WEIGHT LOSS MANAGEMENT

SAXENDA (*liraglutide injection*)

Note: • •

Policy:

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/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 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

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient is 18 years of age or older
AND
 - The patient has completed at least 16 weeks of therapy with the requested drug
AND
 - o The patient lost at least 4 percent of baseline body weight OR the patient has continued to maintain their initial 4 percent weight loss.
[Documentation is required for approval.]
- OR**
 - The requested drug will be used with a reduced calorie diet and increased physical activity for chronic weight management in an adult
AND
 - 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
AND
 - o The patient has a body mass index (BMI) greater than or equal to 30 kilogram per square meter
OR
 - o The patient has a body mass index (BMI) greater than or equal to 27 kilogram per square meter AND has at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia)
- OR**
 - The patient is 12 to 17 years of age
AND
 - The patient has completed at least 12 weeks of therapy on the maintenance dose of therapy with the requested drug
AND
 - The patient has at least 1 percent reduction in body mass index (BMI) from baseline OR the patient has continued to maintain their initial 1 percent reduction in BMI from baseline. [Documentation is required for approval.]
- OR**
 - The requested drug will be used with a reduced calorie diet and increased physical activity for chronic weight management

AND

- 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

AND

- The patient has a body weight above 60 kilograms

AND

- The patient has an initial body mass index (BMI) corresponding to 30 kilogram per square meter or greater for adults by international cut-off points based on the Cole Criteria

Place of Service:

Outpatient

The above policy is based on the following references:

1. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc; June 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, Ohio: UpToDate, Inc.; 2022; Accessed May 18, 2022.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/>. Accessed May 18, 2022.
4. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. National Heart, Lung, and Blood Institute. NIH Publication No. 12-7486. October 2012. http://www.nhlbi.nih.gov/guidelines/cvd_ped/peds_guidelines_full.pdf. 141-159. Accessed May 17, 2022.
5. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism, Volume 100, Issue 2, 1 February 2015, Pages 342–362. <https://academic.oup.com/jcem/article/100/2/342/2813109>. Accessed May 17, 2022.
6. Jensen MD, 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. 2013; 129:S102–S138.

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