PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**WEIGHT LOSS MANAGEMENT**
BRAND NAME (generic)	**SAXENDA (liraglutide injection)**

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

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
  - 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

- The patient has a body mass index (BMI) greater than or equal to 30 kilogram per square meter
  OR
- 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

REFERENCES

1. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc; December 2020.
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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 June 29, 2021.
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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. *Circulation.* 2013; 129:S102–S138.