PRIOR AUTHORIZATION CRITERIA

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

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit

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

- The requested drug will be used with a reduced calorie diet and increased physical activity for chronic weight management
  AND
  - The patient is 18 years of age or older
    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 baseline body mass index (BMI) greater than or equal to 30 kg/m^2. [ACTION REQUIRED: Documentation is required for approval.]

      OR
      - The patient has a baseline body mass index (BMI) greater than or equal to 27 kg/m^2. [ACTION REQUIRED: Documentation is required for approval.]
        AND

- The patient has at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia). [ACTION REQUIRED: Documentation is required for approval.]

OR

- The patient has completed at least 16 weeks of therapy with the requested drug
  AND
  - 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.]

OR

- The patient is 12 to 17 years of age
  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 baseline body weight above 60 kg. [ACTION REQUIRED: Documentation is required for approval.]

    AND
    - The patient has a baseline body mass index (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.]

  OR
  - The patient has completed at least 12 weeks of therapy on the maintenance dose of therapy with the requested drug
    AND
    - 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 reduction in BMI from baseline. [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.; April 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed May 10, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 05/10/2023).
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.