BlueCross BlueShield
Federal Employee Program

SAXENDA (liraglutide)
WEGOVY (semaglutide)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Obesity rates have increased dramatically in the 21st century and obesity contributes to increased morbidity, mortality, and the burden of healthcare costs. There are anti-obesity medications approved by the FDA for the long and short-term treatment of obesity. These medications for weight loss are indicated in combination with lifestyle modification for the management of obesity, and some are indicated for use in children as young as 12 years of age (1-3).

Regulatory Status

FDA-approved indications: (4-5)

- Saxenda is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in 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 comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)
- Wegovy is indicated in combination with a reduced-calorie diet and increased physical activity:
  - To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight
  - To reduce excess body weight and maintain weight reduction long term in:
    - Adults and pediatric patients aged 12 years and older with obesity
    - Adults with overweight in the presence of at least one weight-related comorbid condition

<u>Limitations of Use:</u>

- The safety and effectiveness of Weight Loss Management Medications in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established (5).

Saxenda and Wegovy contain a boxed warning regarding the development of thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in both genders of rats. The relevance of this to the development of human thyroid C-cell tumors is unknown. Saxenda and Wegovy are

contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of Saxenda and Wegovy and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness) (4-5).

Patients should be periodically assessed for response to therapy. Evaluate decrease in BMI after 12-16 weeks of treatment. If a patient has not shown an appropriate decrease in BMI, discontinue the medication as it is unlikely that the patient will achieve and sustain clinically meaningful decrease in BMI with continued treatment (4-5).

The safety and effectiveness of Saxenda and Wegovy in pediatric patients less than 12 years of age have not been established (4-5).

Summary

Weight loss is a pathway to health improvement for patients with obesity-associated risk factors and comorbidities. Medications approved for chronic weight management can be useful adjuncts to lifestyle change for patients who have been unsuccessful with diet and exercise alone (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Saxenda and Wegovy while maintaining optimal therapeutic outcomes.

References

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2. Apovian CM, Aronne LJ, Bessesen DH, McDonnell ME, M. Hassan M, Uberto Pagotto, Ryan DH, Still CD. 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.
3. Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity. Pediatrics. 2023;151(2):e2022060640. Doi:10.1542/peds.2022-060640

4. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; December 2021.
5. Wegovy [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; March 2024.