
5.99.030

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| Section: | Prescription Drugs | Effective Date: | January 1, 2025 |
| Subsection: | Miscellaneous Products | Original Policy Date: | September 9, 2022 |
| Subject: | Saxenda Wegovy | Page: | 1 of 7 |

Last Review Date: December 13, 2024

Saxenda Wegovy

Description

Saxenda (liraglutide)
Wegovy (semaglutide)

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/m² or greater (obese) or
 - 27 kg/m² 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

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- Adults with overweight in the presence of at least one weight-related comorbid condition

Limitations of Use:

- The effect of Weight Loss Management Medications on cardiovascular morbidity and mortality has not been established (5).
- 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).

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).

Related policies

Imcivree, Weight Loss Medications, Zepbound

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Saxenda and Wegovy may be considered **medically necessary** if the conditions indicated below are met.

Saxenda and Wegovy may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must be using for the following:

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Chronic weight management

AND ALL of the following:

1. Patient has **ONE** of the following:
 - a. Age 18+, must have **ONE** of the following:
 - i. Body mass index (BMI) ≥ 30 kg/m²
 - ii. Body mass index (BMI) ≥ 27 kg/m² **AND ONE** of the following:
 1. Patient has established cardiovascular disease (e.g., congenital heart disease, cerebrovascular disease, peripheral artery disease, coronary heart disease, acute coronary syndrome (ACS), myocardial infarction (MI), unstable angina, coronary or other arterial revascularization, or prior percutaneous coronary intervention/coronary bypass surgery)
 2. Patient has at least one weight related comorbid condition (e.g., type 2 diabetes mellitus, dyslipidemia, or hypertension)
 - b. Age 12-17 **ONLY**: Body mass index (BMI) $\geq 95^{\text{th}}$ percentile for their age
2. Patient has participated in a comprehensive weight management program (e.g., Teledoc or another weight loss program)
3. **NO** dual therapy with other glucagon-like peptide-1 (GLP-1) receptor agonists (see Appendix 1)
4. **NO** dual therapy with another Prior Authorization (PA) medication for weight loss (see Appendix 2)

Prior – Approval *Renewal* Requirements

Age 12 years of age or older

Diagnosis

Patient must be using for the following:

Chronic weight management

AND ALL of the following:

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1. Age 18+ **ONLY**: The patient has lost at least 5 percent of baseline body weight **OR** the patient has continued to maintain their initial 5 percent weight loss
2. Age 12-17 **ONLY**: Patient has maintained clinically significant weight loss
3. Patient has participated in a comprehensive weight management program (e.g., Teledoc or another weight loss program)
4. **NO** dual therapy with other glucagon-like peptide-1 (GLP-1) receptor agonists (See Appendix 1)
5. **NO** dual therapy with another Prior Authorization (PA) medication for weight loss (see Appendix 2)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

| Medication | Quantity Limit |
|------------|------------------------------------------|
| Saxenda | 15 pre-filled pens per 90 days OR |
| Wegovy | 12 single-dose pens per 84 days |

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity

| Medication | Quantity Limit |
|------------|------------------------------------------|
| Saxenda | 15 pre-filled pens per 90 days OR |
| Wegovy | 12 single-dose pens per 84 days |

Duration 12 months

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Rationale

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

1. Tchang BG, Aras M, Kumar RB, Aronne LJ. Pharmacologic Treatment of Overweight and Obesity in Adults. 2021 Aug 2. South Dartmouth (MA): MDText.com, Inc.; 2000. PMID: 25905267.
2. Apovian CM, Aronne LJ, Bessesen DH, McDonnell ME, 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.

Policy History

| Date | Action |
|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| January 2023 | Addition to PA |
| February 2023 | Per PI update: Wegovy age expanded to 12 years of age and older |
| March 2023 | Annual review |
| December 2023 | Annual review. Pediatric reference added. Added initiation requirement to participate in comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity |
| January 2024 | Addition of Zepbound to policy as non-preferred option on MedEx |
| March 2024 | Annual review |

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| April 2024 | Revised indication to include established CVD for overweight patients. Per FEP, made the list of co-morbid and established cardiovascular conditions specific |
| September 2024 | Annual review |
| December 2024 | Annual review. Per FEP, placed Wegovy and Saxenda on their own policy 5.99.030, from 5.99.027. Added behavior modification requirement for initiation and continuation, changed requirement for adults to have a 5% BMI reduction and pediatrics to have clinically significant weight loss for continuation |

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.

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Appendix 1 - List of GLP-1 Agonist Medications

| Generic Name | Brand Name |
|-----------------------------------|--------------------------|
| dulaglutide | Trulicity |
| exenatide | Byetta |
| exenatide | Bydureon, Bydureon BCise |
| liraglutide | Saxenda |
| liraglutide | Victoza |
| liraglutide and insulin degludec | Xultophy |
| lixisenatide | Adlyxin |
| lixisenatide and insulin glargine | Soliqua |
| semaglutide | Ozempic |
| semaglutide | Rybelsus |
| semaglutide | Wegovy |
| tirzepatide | Mounjaro |
| tirzepatide | Zepbound |

Appendix 2 - List of PA Weight Loss Medications

| Generic Name | Brand Name |
|----------------------------------------------|-------------------|
| benzphetamine | N/A |
| carboxymethylcellulose-cellulose-citric acid | Plenity |
| diethylpropion | N/A |
| liraglutide | Saxenda |
| naltrexone/bupropion | Contrave |
| orlistat | Xenical |
| phendimetrazine | N/A |
| phentermine | Adipxex-P/Lomaira |
| phentermine/topiramate ER | Qsymia |
| semaglutide | Wegovy |
| setmelanotide | Imcivree |
| tirzepatide | Zepbound |