# Saxenda Wegovy Zepbound Coverage Exception and Formulary Exception with Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This program applies to FlexRx Closed, FlexRx Open, GenRx Closed, and GenRx Open for weight loss agents on coverage delay.

**FDA APPROVED INDICATIONS AND DOSAGE**[1-3]

| Agent(s) | Indication(s) |
|---|---|
| **Saxenda®** (liraglutide)<br><br>Injection solution | Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:<br><br>• Adults with an initial body mass index (BMI) of:<br>  ○ 30 kg/m^2 or greater (obese), or<br>  ○ 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)<br>• Pediatric patients aged 12 years or older with:<br>  ○ Body weight above 60 kg, and<br>  ○ An initial BMI corresponding to greater than 30 kg/m^2 for adults (obese) by international cut-offs (Cole Criteria)<br><br>Limitations of Use:<br><br>• Contains liraglutide and should not be co-administered with other liraglutide-containing products or with any other GLP-1 receptor agonist<br><br>The safety and effectiveness in pediatric patients with type 2 diabetes have not been established |

| Agent(s) | Indication(s) |
|---|---|
| **Wegovy™** (semaglutide)<br><br>Subcutaneous injection solution | In combination with a reduced calorie diet and increased physical activity:<br><br>• To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight<br>• To reduce excess body weight and maintain weight reduction long term in:<br>  ○ Adults and pediatric patients aged 12 years and older with obesity<br>  ○ Adults overweight in the presence of at least one weight-related comorbid condition<br><br>Limitations of Use: Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended |
| **Zepbound™**<br><br>(tirzepatide)<br><br>Subcutaneous injection solution | As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:<br><br>• 30 kg/m2 or greater (obesity) or<br>• 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea or cardiovascular disease).<br><br>Limitations of Use:<br><br>• Coadministration with other tirzepatide-containing products or any GLP-1 receptor agonist is not recommended.<br>• The safety and efficacy of coadministration with other products for weight management have not been established.<br>• Zepbound has not been studied in patients with a history of pancreatitis. |

## CLINICAL RATIONALE

### Obesity

Obesity rates have increased sharply over the last 30 years, creating a global public health crisis. The National Health and Nutrition Examination Surveys show that nearly 2 of 3 US adults are overweight or obese, and 1 of 3 adults are obese. Adults with body mass index (BMI) 25-29.9 kg/m^2 are considered overweight; those with BMI greater than or equal to 30 kg/m^2 are considered obese.(5) Weight loss is difficult for most people and weight loss medications help reinforce behavioral strategies to lose weight. Medications for weight loss do not work on their own. Numerous guidelines recommend the addition of weight loss medications only in conjunction with lifestyle and behavioral modifications.(4,5,6,11)


 

GLP-1 is an endogenous incretin hormone produced by L cells within the intestinal mucosa in response to the intake of nutrients. GLP-1 receptors are expressed in multiple organs, including pancreas, gastrointestinal (GI) tract, heart, brain, kidney, lung, and thyroid. This ubiquitous expression of GLP-1 receptors could be the reason for its pleiotropic benefits for T2DM, weight loss, and cardio protection. GLP-1 has numerous metabolic effects, including but not limited to, glucose-dependent stimulation of insulin secretion, delayed gastric emptying, inhibition of food intake, and modulation of β-cell proliferation. Semaglutide was approved for the management of obesity in 2021. Having a dose–response effect on weight loss, semaglutide was approved at doses higher than indicated for T2DM. GLP-1 RAs do not have the same neuropsychiatric adverse effects as other FDA-approved drugs on the market. Other benefits include inherent glucoregulatory properties and cardio protection in select populations.(11)

The American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity recommends the following:(5)

- The principal outcome and therapeutic target in the treatment of obesity should be to improve the health of the patient by preventing or treating weight related complications using weight loss, not the loss of body weight per se
- For overweight (BMI 25-29.9 kg/m^2) or obese (BMI greater than or equal to 30 kg/m^2) patients, evaluate for adiposity related complications (e.g., type 2 diabetes, dyslipidemia, hypertension, cardiovascular disease, obstructive sleep apnea).
- Pharmaceutical therapy should only be used as adjunct to lifestyle modifications and depends on the staging of obesity:
    - Overweight Stage 0 (BMI 25-29.9 kg/m^2 or 23-24.9 kg/m^2 in certain ethnicities* with no complications)
        - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions
    - Obesity Stage 0 (BMI greater than or equal to 30 kg/m^2 or greater than or equal to 25 kg/m^2 in certain ethnicities* with no complications)
        - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral intervention
        - Weight loss medications – consider if lifestyle therapy fails to prevent progressive weight gain (BMI greater than or equal to 27 kg/m^2)
    - Obesity Stage 1 (BMI greater than or equal to 25 kg/m^2 or greater than or equal to 23 kg/m^2 in certain ethnicities* with greater than or equal to 1 mild/moderate complications)
        - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions
        - Weight loss medications – consider if lifestyle therapy fails to achieve therapeutic target or initiate concurrently with lifestyle therapy (BMI greater than or equal to 27 kg/m^2)
    - Obesity Stage 2 (BMI greater than or equal to 25 kg/m^2 or greater than or equal to 23 kg/m^2 in certain ethnicities* with greater than or equal to 1 severe complications):
        - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions
        - Weight loss medication – initiate concurrently with lifestyle therapy (BMI greater than or equal to 27 kg/m^2)
        - Consider bariatric surgery (BMI greater than or equal to 35 kg/m^2)


 

*Certain ethnicities (A BMI cutoff point value of greater than or equal to 23 kg/m^2 should be used in the screening and confirmation of excess adiposity in South Asian, Southeast Asian, and East Asian adults)

The Endocrine Society clinical practice guidelines suggests medications approved for chronic weight management can be useful adjuncts to lifestyle change for patients who have been unsuccessful with diet and exercise alone. They recommend adherence to American Heart Association Guidelines (2013) [see below] which include advice for assessment and treatment with diet and exercise, as well as bariatric surgery for appropriate candidates.(4)

- Diet, exercise, and behavioral modification should be included in all overweight and obesity management approaches for BMI greater than or equal to 25 kg/m^2 and other tools [e.g., pharmacotherapy (if BMI greater than or equal to 27 kg/m^2 with comorbidity or BMI greater than 30 kg/m^2) and bariatric surgery (BMI greater than or equal to 35 kg/m^2 with comorbidity or BMI greater than 40 kg/m^2)] should be used as adjuncts to behavioral modification to reduce food intake and increase physical activity when possible. Patients who have a history of being unable to successfully lose and maintain weight and who meet label indications are candidates for weight loss medications.
- Assessment of efficacy and safety of prescribed weight loss medications should be performed at least monthly for the first 3 months, then at least every 3 months thereafter.
- Clinicians are recommended to perform annual and symptom-based screening for major obesity related chronic conditions in all adult patients with a BMI greater than or equal to 30 kg/m^2, including diabetes, cardiovascular disease, hypertension, hyperlipidemia, obstructive sleep apnea, non-alcoholic fatty liver disease, osteoarthritis, and major depression.
- Prescribers should identify chronic medications, for concomitant medical conditions, that contribute to weight gain, and prescribe drugs that are weight neutral or that will promote weight loss when possible.
- If a patient's response to a weight loss medication is deemed effective (weight loss greater than or equal to 5% of body weight at 3 months) and safe, it is recommended that the medication be continued. If deemed ineffective (weight loss less than 5% at 3 months) or if there are safety or tolerability issues at any time, the medication should be discontinued and alternative medications or referral for alternative treatment approaches instead considered.

The American Heart Association/American College of Cardiology/Obesity Society Guideline (2013) suggests if weight and lifestyle history indicates the patient has never participated in a comprehensive lifestyle intervention program as defined in the guidelines (i.e., trained interventionist or nutritional professional supervision of diet, exercise, and behavior therapy), it is recommended that the patient undertake such a program before addition of adjunctive therapies (e.g., pharmacotherapy), since a substantial proportion of patients will lose sufficient weight to improve health with comprehensive lifestyle management alone. If a patient has been unable to lose weight or sustain weight loss with comprehensive lifestyle intervention and has BMI greater than or equal to 30 kg/m^2 or greater than or equal to 27 kg/m^2 with greater than or equal to 1 obesity-associated comorbid condition(s), adjunctive therapy may be considered. The expert panel did not review comprehensive evidence on pharmacotherapy for weight loss. Medications should be FDA approved and clinicians should be knowledgeable about the product label. The provider should weigh potential risks of the medication vs. potential benefits of successful weight loss for the individual patient. If the patient is currently taking an obesity medication but has not lost at


 

least 5% of initial body weight after 12 weeks on a maximal dose of the medication, the provider should reassess the risk-to-benefit ratio of that medication for the patient and consider discontinuation of that drug.(6)

The American Gastroenterological Association (AGA) clinical practice guidelines (2022) strongly recommended the use of pharmacotherapy in addition to lifestyle intervention in adults with overweight and obesity (body mass index 30 kg/m^2 or greater, or 27 kg/m^2 or greater with weight-related complications) who have an inadequate response to lifestyle interventions. The panel suggested the use of semaglutide 2.4 mg, liraglutide 3.0 mg, phentermine-topiramate ER, and naltrexone-bupropion ER (based on moderate certainty evidence), and phentermine and diethylpropion (based on low certainty evidence), for long-term management of overweight and obesity. The guideline panel suggested against the use of orlistat. The panel identified the use of Gelesis100 oral superabsorbent hydrogel as a knowledge gap.(11)

**Pediatric Obesity**

Pediatric obesity has become an epidemic and international problem. In the United States, the prevalence of obesity in children has risen from 5% in 1970 to 17% in 2004. Genetics and environment are the underlying causes of the increase in pediatric obesity. Obese children and adolescents are at risk of developing the same comorbid conditions as obese and overweight adults. Obesity and overweight in children are defined on percentages specific for age and gender defined BMI values. The American Academy of Pediatrics (AAP) define obesity as a BMI greater than or equal to 95$^{th}$ percentile or a BMI greater than or equal to 30 kg/m^2, whichever is lower, and overweight as a BMI within 85$^{th}$ to 94$^{th}$ percentile for children and adolescents 2 years of age and older.(9,10)

The AAP recommends that clinicians should assess medical and behavioral risks in any child with a BMI above the 85$^{th}$ percentile before initiating any intervention.(9,10) The Endocrine Society Pediatric Obesity Treatment Guidelines also recommend that clinicians should evaluate for potential comorbidities in children and adolescents with a BMI greater than or equal to 85$^{th}$ percentile.(8)

The 2023 AAP guidelines recommend the use of weight loss agents in conjunction with lifestyle and behavioral changes. Pediatricians and other primary healthcare providers should treat children and adolescents for overweight with comorbidities (BMI greater than or equal to 85th percentile; comorbidities such as dyslipidemia, prediabetes, Type 2 diabetes, fatty liver disease, hypertension) and obesity (BMI greater than or equal to 95th percentile).(10)

The 2017 Endocrine Society guidelines only recommend the use of FDA approved pharmacotherapy in pediatric patients as adjunctive therapy to lifestyle modifications of the highest intensity available and only by clinicians that are experienced in the use of anti-obesity agents.(8)

- Suggest pharmacotherapy in children or adolescents with obesity (greater than or equal to 95$^{th}$ percentile for age and gender) only after a formal program of intense lifestyle modifications has failed to limit weight gain or to ameliorate comorbidities.
- Recommend against using obesity agents in children and adolescents less than 16 years of age who are overweight, but not obese, except in the context of clinical trials.


 

- Anti-obesity agents should be discontinued, and patients reevaluated if the patient does not have a greater than 4% BMI reduction after 12 weeks at the medication's full dosage.

Discourages prescribing weight loss medications off-label to pediatric patients less than 16 years of age.

**Cardiovascular**

Wegovy (semaglutide) was studied to determine its effect relative to placebo on major adverse cardiovascular events (MACE) when added to current standard of care, which included management of cardiovascular risk factors and individualized healthy lifestyle counseling (including diet and physical activity), in patients who are overweight or with obesity, and without diabetes. The primary endpoint, MACE, was the time to first occurrence of a three-part composite outcome which included cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke. Inclusion requirements of the trial included: (12)

- Patients who have established cardiovascular disease (CVD) as determined by having at least one of the following:
    - Prior myocardial infarction
    - Prior stroke (ischemic or hemorrhagic stroke)
    - Symptomatic peripheral arterial disease (intermittent claudication with ankle-brachial index <0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)
- Patients with a BMI greater than or equal to 27 kg/m^2
- Patients 45 years of age or over

Guidelines recommend that patients work towards goal of tobacco cessation and avoiding tobacco exposure, managing hypertension to goal, and managing lipid levels to goal as risk reduction measures for CVD secondary prevention. (13,14,15)

**Efficacy**

SELECT Trial (Wegovy)

Study 1 (NCT03574597) was a multi-national, multi-center, placebo-controlled, double-blind trial to determine the effect of Wegovy relative to placebo on major adverse cardiovascular events (MACE) when added to current standard of care, which included management of CV risk factors and individualized healthy lifestyle counseling (including diet and physical activity). The primary endpoint, MACE, was the time to first occurrence of a three-part composite outcome which included cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke. All patients were 45 years or older, with an initial BMI of 27 kg/m2 or greater and established cardiovascular disease (prior myocardial infarction, prior stroke, or peripheral arterial disease). Patients with a history of type 1 or type 2 diabetes were excluded.(2)

In this trial, 17,604 patients were randomized to Wegovy or placebo. At baseline, the mean age was 62 years and 12,732 patients (72.3%) were male. The mean BMI was 33 kg/m^2, and 12,580 patients (71.5%) met the BMI criterion for obesity (≥30). The mean glycated


 

hemoglobin level was 5.8%, and 11,696 patients (66.4%) met the glycated hemoglobin criterion for prediabetes (defined as a mean level of 5.7 to 6.4%). At baseline, prior myocardial infarction was reported in 76% of randomized individuals, prior stroke in 23%, and peripheral arterial disease in 9%. Heart failure was reported in 24% of patients. At baseline, cardiovascular disease and risk factors were managed with lipid lowering therapy (90%), platelet aggregation inhibitors (86%), angiotensin converting enzyme inhibitors or angiotensin II receptor blockers (74%), and beta blockers (70%). A total of 10% had moderate renal impairment (eGFR 30 to <60 mL/min/1.73m2) and 0.4% had severe renal impairment eGFR <30 mL/min/1.73m2.(2,16)

Patients were randomly assigned, with the use of a centralized system in a double-blind manner and in a 1:1 ratio without stratification, to receive once-weekly subcutaneous semaglutide at a dose of 2.4 mg or placebo. The starting dose of semaglutide was 0.24 mg once weekly, and the dose was increased every 4 weeks (to once weekly doses of 0.5, 1.0, 1.7, and 2.4 mg) until the target dose of 2.4 mg was reached after 16 weeks. If dose escalation led to unacceptable adverse effects, the dose-escalation intervals could be extended, treatment could be paused, or maintenance doses below the 2.4 mg per week target dose could be used.(16)

Among the 17,604 patients with a BMI of 27 or greater and preexisting cardiovascular disease but without diabetes, treatment with once-weekly subcutaneous semaglutide at a dose of 2.4 mg for a mean duration of 33 months reduced the risk of a composite of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke by 20% (hazard ratio, 0.80; 95% CI, 0.72 to 0.90).

**Safety**

Liraglutide has the following:(1)

- Contraindications:
    - Patients with a personal or family history of medullary thyroid carcinoma (MTC) or patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
    - Patients with a prior serious hypersensitivity reaction to liraglutide or to any of the product components.
    - Pregnancy
- Boxed warnings:
    - Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Saxenda causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined.
    - Saxenda is 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 inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Saxenda.

Semaglutide has the following:(2)


 

- Contraindications:
    - Personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
    - Known hypersensitivity to semaglutide or any of the excipients in Wegovy.
- Boxed warnings:
    - In rodents, semaglutide causes thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Wegovy causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.
    - Wegovy is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Wegovy.

Tirzepatide has the following:(3)

- Contraindications:
    - Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2.
    - Known serious hypersensitivity to tirzepatide or any of the excipients in Zepbound.
- Boxed warnings:
    - In rats, tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Zepbound causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined.
    - Zepbound is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Zepbound.

**Co-Administration**

None of the FDA approved weight loss agents have approval for co-administration with another weight loss agent. New guidelines do not support the use of co-administration of weight loss pharmacological agents.(4,5,10) Use of non-approved drug combinations for obesity treatment should be limited to clinical trials, and patients should be informed when drugs are being used off label alone or in combination.(6)

**References**


| Number | Reference |
|---|---|
| 1 | Saxenda prescribing information. Novo Nordisk Inc. April 2023. |
| 2 | Wegovy prescribing information. Novo Nordisk Inc. March 2024. |
| 3 | Zepbound prescribing information. Lilly USA, LLC. March 2024. |




 

| Number | Reference |
|---|---|
| 4 | Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015 Feb;100(2):342–362. |
| 5 | American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. Endocr Pract. 2016 Jul:22(Suppl 3):1-203. |
| 6 | Jensen MD, Ryan DH, Apovian CM, 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(25 Suppl 2):S102–S138. |
| 7 | Yanovski SZ, Yanovski JA. Long-Term Drug Treatment for Obesity: A Systematic and Clinical Review. JAMA. 2014 Jan;311(1):74-86. |
| 8 | Styne DM, Arslanian SA, Connor EL, et al. Pediatric Obesity - Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017 Jan;102(3):709–757. |
| 9 | Barlow SE, et al. Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report. Pediatrics. 2007 Dec;120(Suppl 4):S164-S192. |
| 10 | American Academy of Pediatrics (AAP) Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents with Obesity. Pediatrics. 2023 Jan;151(2):1-100. |
| 11 | American Gastroenterological Association (AGA) Clinical Practice Guideline on Pharmacological Interventions for Adults with Obesity. Gastroenterology. 2022 Nov;163(5):1198-1225. |
| 12 | Ryan DH, Lingvay I, Colhoun HM, et al. Semaglutide Effects on Cardiovascular Outcomes in People With Overweight or Obesity (SELECT) rationale and design. American Heart Journal. 2020;229:61-69. doi:10.1016/j.ahj.2020.07.008 |
| 13 | Smith SC, Benjamin EJ, Bonow RO, et al. AHA/ACCF Secondary Prevention and Risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update. *Circulation*. 2011;124(22):2458-2473. doi:10.1161/cir.0b013e318235eb4d |
| 14 | Kleindorfer D, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients with stroke and Transient Ischemic Attack: A Guideline from the American Heart Association/American Stroke Association. *Stroke*. 2021;52(7). doi:10.1161/str.0000000000000375 |
| 15 | Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients with Chronic Coronary Disease: A report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation*. 2023;148(9). doi:10.1161/cir.0000000000001168 |
| 16 | Lincoff AM, Brown-Frandsen K, Colhoun HM, et al. Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. N Engl J Med. 2023;389(24):2221-2232. doi:10.1056/NEJMoa2307563. |


**Document History**
Original 04/2024 for BCBSMN
Client Specific Review of New Client Specific (CSReg) criteria, approved by BCBS MN PCT 04/2024
Client Specific Review of Client Specific (CSReg) criteria, approved by BCBS MN PCT 05/2024
Client Specific Mid-Year Review of Client Specific (CSReg) criteria, approved by BCBS MN PCT 07/2024


 

## Saxenda Wegovy Zepbound Coverage Exception and Formulary Exception with Quantity Limit

**TARGET AGENT(S)**
**Saxenda®** (liraglutide)
**Wegovy™** (semaglutide)
**Zepbound™** (tirzepatide)

| Brand (generic) | GPI | Multisource Code | Quantity Limit (per day or as listed) |
|---|---|---|---|
| **Saxenda (liraglutide)** | | | |
| 6 mg/mL, 3 mL/pen | 6125205000D220 | M, N, O, or Y | 0.5 mL |
| **Wegovy (semaglutide)** | | | |
| 0.25 mg/0.5 mL pen* | 6125207000D520 | M, N, O, or Y | 8 pens (4 mL)/180 days |
| 0.5 mg/0.5 mL pen* | 6125207000D525 | M, N, O, or Y | 8 pens (4 mL)/180 days |
| 1 mg/0.5 mL pen* | 6125207000D530 | M, N, O, or Y | 8 pens (4 mL)/180 days |
| 1.7 mg/0.75 mL pen | 6125207000D535 | M, N, O, or Y | 4 pens (3 mL)/28 days |
| 2.4 mg/0.75 mL pen | 6125207000D540 | M, N, O, or Y | 4 pens (3 mL)/28 days |
| **Zepbound (tirzepatide)** | | | |
| 2.5 mg/0.5 mL pen* | 6125258000D520 | M, N, O, or Y | 4 pens (2 mL)/180 days |
| 5 mg/0.5 mL pen | 6125258000D525 | M, N, O, or Y | 4 pens (2 mL)/28 days |
| 7.5 mg/0.5 mL pen | 6125258000D530 | M, N, O, or Y | 4 pens (2 mL)/28 days |
| 10 mg/0.5 mL pen | 6125258000D535 | M, N, O, or Y | 4 pens (2 mL)/28 days |
| 12.5 mg/0.5 mL pen | 6125258000D540 | M, N, O, or Y | 4 pens (2 mL)/28 days |
| 15 mg/0.5 mL pen | 6125258000D545 | M, N, O, or Y | 4 pens (2 mL)/28 days |

* - These strengths are not approvable for maintenance dosing

**COVERAGE EXCEPTION AND FORMULARY EXCEPTION CRITERIA FOR APPROVAL**

**Initial Evaluation**

**Target Agent(s)** will be approved when ALL the following are met**:**

1. ALL of the following:
    A. ONE of the following:
        i. The requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following:
            a. The requested agent is FDA labeled for the requested indication and route of administration **AND**
            b. The patient has a history of ONE of the following: (medical records required)
                1. Myocardial infarction **OR**
                2. Stroke **OR**
                3. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND**
            c. The patient has a BMI greater than or equal to 27 kg/m^2 **AND**
            d. The patient does NOT have type 2 diabetes **AND**
            e. The patient's age is 45 years or over **AND**
            f. ONE of the following:
                1. The patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) **OR**
                2. The patient is being managed for tobacco cessation **AND**
            g. ALL of the following:
                1. The patient is currently being treated in the past 90 days with antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) **AND**
                2. The patient is currently being treated in the past 90 days with lipid lowering therapy (e.g., any statin, ezetimibe) **AND**
                3. The patient will continue antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) AND lipid lowering therapy (e.g., any statin, ezetimibe) in combination with the requested agent **AND**
            h. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis **OR**
        ii. The patient is overweight or obese and is using the requested agent for weight management AND ALL of the following:
            a. Weight loss is NOT excluded from coverage under the patient's pharmacy benefit **AND**
            b. The patient is new to therapy, new to Prime, or attempting a repeat weight loss course of therapy **AND**
            c. ONE of the following:


 

1. The patient is 17 years of age or over and has ONE of the following:
    A. A BMI greater than or equal to 30 kg/m^2 **OR**
    B. A BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent **OR**
    C. A BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., hypertension, type 2 diabetes mellitus, obstructive sleep apnea, cardiovascular disease, dyslipidemia) **OR**
2. The patient is 12 to 16 years of age and has ONE of the following:
    A. A BMI greater than or equal to 95th percentile for age and sex **OR**
    B. A BMI greater than or equal to 30 kg/m^2 **OR**
    C. A BMI greater than or equal to 85th percentile for age and sex AND at least one severe weight-related comorbidity/risk factor/complication **AND**

d. BOTH of the following:
    1. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months **AND**
    2. The patient has experienced weight loss of less than 1 pound per week while on a weight loss regimen from baseline (e.g., low-calorie diet, increased physical activity, and behavioral modifications) prior to any pharmacotherapy **AND**

e. ONE of the following:
    1. The patient has not tried a targeted weight loss agent in the past 12 months **OR**
    2. BOTH of the following:
        A. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months **AND**
        B. The prescriber anticipates success with repeating therapy with any targeted weight loss agent **AND**

f. If the requested agent is Saxenda, then ONE of the following:
    1. The patient is 18 years of age or over AND ONE of the following:
        A. The patient is newly starting therapy **OR**
        B. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR**
        C. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) **OR**
    2. The patient is pediatric (12 to less than 18 years of age) AND BOTH of the following:
        A. The requested agent is NOT being used to treat type 2 diabetes **AND**
        B. ONE of the following:


 

i. The patient is newly starting therapy **OR**
ii. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy **OR**
iii. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) **AND**

g. If the requested agent is Wegovy, then ONE of the following:
    1. The patient is newly starting therapy **OR**
    2. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR**
    3. ONE of the following:
        A. The patient is an adult AND has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
        B. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) **AND**

h. If the requested agent is Zepbound, then ONE of the following:
    1. The patient is newly starting therapy **OR**
    2. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR**
    3. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**

iii. The patient has another FDA labeled indication for the requested agent and route of administration **AND**

B. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication **AND**
C. BOTH of the following:
    i. The patient is currently on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**
    ii. The patient will continue the weight loss regimen in combination with the requested agent **AND**
D. If the patient has an FDA labeled indication, then ONE of the following:
    i. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    ii. There is support for using the requested agent for the patient's age for the requested indication **AND**
E. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**
F. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

2. ONE of the following:
    A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives **OR**
    B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or other harm **AND**


 

3. ONE of the following:
    A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
    B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:
        i. BOTH of the following:
            a. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND**
            b. There is support for therapy with a higher dose for the requested indication **OR**
        ii. BOTH of the following:
            a. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**
            b. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR**
        iii. BOTH of the following:
            a. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**
            b. There is support for therapy with a higher dose for the requested indication

**Length of Approval:**

- For Wegovy, Zepbound: 12 months
- For Saxenda: Pediatric patients (age 12 to less than 18): 5 months; Adults: 4 months

**Renewal Evaluation**

**Target Agent(s)** will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ALL of the following:
    A. ONE of the following:
        i. The requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following:
            a. The requested agent is FDA labeled for the requested diagnosis and route of administration **AND**
            b. The patient has a history of ONE of the following: (medical records required)
                1. Myocardial infarction **OR**
                2. Stroke **OR**
                3. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND**


 

c. The patient does NOT have type 2 diabetes **AND**
d. ONE of the following:
    1. The patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) **OR**
    2. The patient is being managed for tobacco cessation **AND**
e. BOTH of the following:
    1. The patient is currently being treated in the past 90 days with antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) and/or lipid lowering therapy (e.g., any statin, ezetimibe) **AND**
    2. The patient will continue antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) and/or lipid lowering therapy (e.g., any statin, ezetimibe) **AND**
f. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
g. The patient has had clinical benefit with the requested agent **OR**

ii. The patient is overweight or obese and is using the requested agent for weight management AND ALL of the following:
a. Weight loss is NOT excluded from coverage under the patient's pharmacy benefit **AND**
b. The patient is continuing a current weight loss course of therapy **AND**
c. If the patient is 12 to less than 18 years of age, then the current BMI is greater than 85th percentile for age and sex **AND**
d. If the requested agent is Saxenda, then BOTH of the following:
    1. The requested agent is NOT being used to treat type 2 diabetes **AND**
    2. ONE of the following:
        A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
        B. The patient is 18 years of age or over AND the patient has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) **OR**
        C. The patient is pediatric (12 to less than 18 years of age) AND the patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) **AND**
e. If the requested agent is Wegovy, then BOTH of the following:
    1. The requested dose is 1.7 mg or 2.4 mg **AND**
    2. ONE of the following:
        A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**


 

B. The patient is 12 years of age and over AND has received less than 52 weeks of therapy on the maximum-tolerated dose **OR**
C. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) **AND**

f. If the requested agent is Zepbound, then ONE of the following:
1. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
2. The patient has received less than 52 weeks of therapy on the maximum-tolerated dose **OR**

iii. The patient has another FDA labeled indication for the requested agent and route of administration AND has had clinical benefit with the requested agent **AND**

B. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication **AND**
C. BOTH of the following:
i. The patient is currently on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**
ii. The patient will continue the weight loss regimen in combination with the requested agent **AND**
D. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**
E. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

3. ONE of the following:
A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives **OR**
B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or other harm **AND**

4. ONE of the following:
A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:
i. BOTH of the following:
a. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND**
b. There is support for therapy with a higher dose for the requested indication **OR**
ii. BOTH of the following:
a. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**
b. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR**
iii. BOTH of the following:
a. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**


 

b. There is support for therapy with a higher dose for the requested indication

**Length of Approval:** 12 months


 