Pharmacy Policy Bulletin: J-1370 Wegovy (semaglutide) – Medicare Incentive and Compass	
Number: J-1370	**Category:** Prior Authorization
Line(s) of Business: ☐ Commercial ☐ Healthcare Reform ☒ Medicare	**Benefit(s):** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** Applies to Medicare Incentive and Compass formularies only
Version: J-1370-001	**Original Date:** 04/03/2024
Effective Date: 06/01/2024	**Review Date:** 04/03/2024

Drugs Product(s):	• Wegovy (semaglutide)

FDA-Approved Indication(s):	• Wegovy (semaglutide)
	  ○ In combination with reduced calorie diet and increased physical activity:
	  ▪ 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.
	  ▪ 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.

Background:	• Wegovy (semaglutide) is a glucagon-like peptide-1 receptor agonists (GLP-1 RA). GLP-1 receptors are present in many areas of the body, including the gastrointestinal tract, central and peripheral nervous systems, and cardiovascular (CV) systems. • The CV benefits of Wegovy are likely due to both direct and indirect effects. While some evidence suggests that CV benefit may be partially due to the reduction of visceral fat, CV benefit is most likely also resulting from direct cardiac effects. Animal models have demonstrated anti-inflammatory and anti-atherosclerotic effects of GLP-1 RAs. GLP1-RAs also reduce blood pressure and increase cardiac contractility. • There are a few studies that, when taken as together, suggest that there may be CV benefits associated with Wegovy beyond weight loss. Look AHEAD demonstrated that weight loss of 8.6% as the result of lifestyle modifications in type 2 diabetes mellitus (T2DM) did not correlate with decreased risk of CV clinical outcomes, but a weight loss of ≥ 10% did. SUSTAIN-6 showed CV benefits in patients with T2DM and CV disease (CVD) taking Ozempic (semaglutide 0.5 mg and 1 mg), even with modest weight loss (3.9% for semaglutide 0.5 mg and 5.3% for semaglutide 1 mg at 104 weeks). SELECT demonstrated potential CV benefit prior to peak weight loss in patients taking

Wegovy (semaglutide 2 mg). This suggests that semaglutide demonstrates CV benefit at a lower weight loss than lifestyle modification alone.

- Wegovy has been shown to reduce the risk of major adverse cardiovascular events (MACE) in patients with CVD. In the clinical study, CVD was defined as stroke, myocardial infarction (MI), or peripheral arterial disease (characterized by intermittent claudication with ankle-brachial index [ABI] less than 0.85 at rest, peripheral arterial revascularization procedure, and/or amputation due to atherosclerotic disease. These patients had a BMI ≥ 27 kg/m^2 and concurrently received heart-healthy lifestyle interventions, including diet and exercise.
- Atherosclerotic cardiovascular disease (ASCVD) includes conditions such as coronary heart disease (e.g. MI, angina, and coronary artery stenosis), cerebrovascular disease (e.g. transient ischemic attack, ischemic stroke, and carotid artery stenosis), peripheral arterial disease, and aortic atherosclerotic disease (e.g. abdominal aortic aneurysm and descending thoracic aneurysm).
- In established CVD, statin therapy is used for secondary prevention of CV events. In patients with clinical ASCVD who are 75 years of age and younger, high-intensity statin therapy is recommended with a goal of ≥ 50% reduction in LDL-C levels (ACC/AHA Class I, Level A). If over 75 years of age, consider initiating moderate- or high-intensity statin therapy after evaluation of potential for ASCVD risk reduction, adverse effects, drug-drug interactions, patient frailty, and patient preferences (ACC/AHA Class IIa, Level B-R).
- Prescribing Considerations:
    - According to section 1927(d)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act, Centers for Medicare and Medicaid Services may not cover medications when used for anorexia, weight loss, or weight gain (even if used for a noncosmetic purpose (i.e., morbid obesity)) for Medicare Part D. As such, Wegovy will not be covered for obesity or weight loss alone.
    - Wegovy lowers blood glucose and can cause hypoglycemia.
    - Wegovy should not be used in combination with any other GLP-1 RA.
    - Patients may take at least 17 weeks to reach the maintenance dose. If patients do not tolerate a dose during dosage escalation, consider delaying dosage escalation for 4 weeks.
    - The maintenance dosage of Wegovy is either 2.4 mg (recommended) or 1.7 mg once weekly. The 0.25 mg, 0.5 mg, and 1 mg once weekly dosages are initiation and escalation dosages and are not approved as maintenance dosages.

Low-Intensity Statins	Moderate-Intensity Statins	High-Intensity Statins
Daily dose lowers LDL-C by < 30% on average	Daily dose lowers LDL-C by 30% to < 50%, on average	Daily dose lowers LDL-C by ≥ 50%, on average
• simvastatin 10 mg • pravastatin 10-20 mg • lovastatin 20 mg • fluvastatin 20-40 mg • pitavastatin 1 mg	• atorvastatin 10-20 mg • rosuvastatin 5-10 mg • simvastatin 20-40 mg • pravastatin 40-80 mg • lovastatin 40 mg • fluvastatin XL 80 mg • fluvastatin 40 mg twice daily • pitavastatin 2-4 mg	• atorvastatin 40-80 mg • rosuvastatin 20-40 mg

Approval Criteria

I. Initial Authorization

When a benefit coverage of Wegovy may be approved when all of the following criteria are met **(A. through F.)**:

A. The drug is being used for major adverse cardiovascular event risk reduction.
B. The member has a pre-existing diagnosis of established cardiovascular disease (e.g. prior myocardial infarction, stroke, or peripheral arterial disease).
C. The prescriber attests that the member has a baseline BMI greater than or equal to 27 kg/m^2.
D. The member meets one (1) of the following criteria **(1. or 2.)**:
  1. The member is over 75 years of age and has experienced therapeutic failure, contraindication, or intolerance to moderate or high intensity statin therapy.
  2. The member is 75 years of age or younger and meets one (1) of the following criteria **(a. or b.)**:
    a. The member will be using Wegovy as an adjunct to moderate or high intensity statin therapy.
    b. The member is statin intolerant defined as one (1) of the following **(i. or ii.)**:
      i. While receiving at least two (2) separate trials of different statins, the member experienced one (1) of the following **(A) or B)**):
        A) Statin related rhabdomyolysis, which resolved upon discontinuation of the statins.
        B) Skeletal-related muscle symptoms, which resolved upon discontinuation of the statins.
      ii. The member experienced one (1) of the following during any course of statin therapy **(A), B), or C))**:
        A) Creatinine kinase (CK) increase to 10 times upper limit of normal (ULN).
        B) Liver function tests (LFTs) increase to 3 times ULN.
        C) Hospitalization due to severe statin-related adverse event (e.g., rhabdomyolysis).
E. The prescriber attests that the member will use the requested therapy in combination with a lifestyle modification program that encourages reduced calorie diet and increased physical activity (e.g., increased physical activity, nutritional counseling, participation in a comprehensive weight management program).
F. The member will not be using Wegovy in combination with any of the following products **(1. and 2.)**:
  1. GLP-1 RA
  2. GLP-1 RA combinations (e.g., with insulin, GIP RA)

II. Reauthorization

When a benefit, reauthorization of Wegovy may be approved when all of the following criteria are met **(A. through E.)**:
A. The prescriber attests that the member requires continued therapy with Wegovy.
B. The drug is being used for major adverse cardiovascular event risk reduction.
C. The member meets one (1) of the following criteria **(1. or 2.)**:
  1. The member is currently taking a moderate or high intensity statin.
  2. The member has experienced therapeutic failure, contraindication, or intolerance to statin therapy.
D. The requested dose is 1.7 mg or 2.4 mg once weekly.
E. The prescriber attests that the member is using the product in combination with a lifestyle modification program that encourages reduced calorie diet and increased physical activity (e.g., increased physical activity, nutritional counseling, participation in a comprehensive weight management program).

III. For Medicare Part D beneficiaries, drug(s) addressed in this policy may be approved when used for a medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS).

Limitations of Coverage

I. Coverage of Wegovy to reduce excess body weight and maintain weight reduction without preexisting cardiovascular disease will not be approved.

Authorization Duration

Initial Authorization

- Medicare Part D Plans: If approved, a 6 month authorization will be granted.

Reauthorization

- Medicare Part D Plans: If approved, a 12 month authorization will be granted.

Automatic Approval Criteria

None

References:

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4. Marso SP, Bain SC, Consoli A, et al. Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes. *N Engl J Med*. 2016 Nov 10;375(19):1834-1844
5. Look AHEAD Research Group. Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes. *N Engl J Med*. 2013 Jul 11;369(2):145-54.
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7. Heart.org. Atherosclerotic Cardiovascular Disease. Available at: https://www.heart.org/en/professional/quality-improvement/ascvd. Accessed March 19, 2024.
8. 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 Aug 29;148(9):e9-e119.
9. Medicare Prescription Drug Benefit Manual: Chapter 6- Part D Drugs and Formulary
10. Requirements. Revised January 15, 2016.