Pharmacy Policy Bulletin: J-1389 Anti-Obesity (Standard) – Commercial	
Number: J-1389	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☐ Healthcare Reform ☐ Medicare	**Benefit(s):** **Prior Authorization (1., 2., and 3.):** **1.** Anti-Obesity = Yes* **2.** Other Managed Drugs = Yes w/ Prior Authorization **3.** Anti-Obesity Weight Loss Mgmt Policy = Standard *For Anti-Obesity Weight Loss Mgmt Policy = Enhanced, see policy J-1388.* **This policy only applies to Wegovy when used for treatment of obesity. For treatment of metabolic-dysfunction associated steatohepatitis (MASH, formerly known as NASH), see policy J-1379.*
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1389-010	**Original Date:** 08/07/2024
Effective Date: 10/02/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Contrave (bupropion and naltrexone) • Qsymia (phentermine and topiramate extended-release) • Saxenda (liraglutide) • Wegovy (semaglutide) • Xenical (orlistat) • Zepbound (tirzepatide)

FDA-Approved Indication(s):	• Contrave
	  ○ 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) ≥ 30 kg/m^2 or BMI ≥ 27 kg/m^2 in the presence of at least one weight-related comorbidity (for example, hypertension, dyslipidemia, type 2 diabetes)
	• Qsymia
	  ○ In combination with a reduced-calorie diet and increased physical activity 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.
	• Saxenda (liraglutide)

	○ As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in: ▪ Adults with an initial BMI ≥ 30 kg/m^2 or BMI ≥ 27 kg/m^2 in the presence of at least one weight-related comorbidity (for example, hypertension, dyslipidemia, type 2 diabetes) ▪ Pediatric patients aged 12 years and older with body weight ≥ 60 kg and an initial BMI corresponding to ≥ 30 kg/m^2 or greater for adults (obese) by international cut-offs (Cole Criteria) • Wegovy ○ 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. • Xenical ○ For obesity management including weight loss and weight maintenance when used in conjunction with a reduced-caloric diet in adult patients and adolescents 12 years of age and older with an initial BMI ≥ 30 kg/m^2 or ≥ 27 kg/m^2 in the presence of other risk factors (for example, hypertension, diabetes, dyslipidemia) ○ To reduce the risk for weight regain after prior weight loss • Zepbound ○ To reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition, in combination with a reduced-calorie diet and increased physical activity. ○ To treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

Background:	• Initiation refers to members who are new to therapy. Continuation refers to the period after the initiation phase when a member that has been using a chronic weight loss agent. Maintenance refers to a member that has been using a chronic weight loss agent for more than 12 months. • Members that have a substantial gap in therapy should be evaluated using the initiation criteria. • Some individuals may not lose weight while taking a GLP-1 RA. This may be due to polymorphisms in the GLP-1 receptor. There is limited evidence to inform how to manage GLP-1 non-responders, and there is no evidence to suggest that a patient who fails to lose weight on one GLP-1 RA would lose weight on another GLP-1 RA. • **Contrave** ○ Contrave (bupropion/naltrexone) regulates energy balance and decreases appetite by working in the hypothalamus (appetite regulatory center) and the mesolimbic dopamine circuit (the reward system) addressing the behavioral and physiological aspects of obesity. • **Qsymia** ○ Qsymia (phentermine/topiramate) is a combination medication containing phentermine and topiramate extended release. The effect of phentermine on chronic weight management is likely mediated by release of catecholamines in the hypothalamus, resulting in reduced appetite and decreased food

consumption. The exact mechanism of action of topiramate on chronic weight management is unknown. Topiramate augments the activity of the neurotransmitter GABA, modulates voltage-gated ion channels, inhibits AMPA/kainite excitatory glutamate receptors, and inhibits carbonic anhydrase. While topiramate is typically used to treat seizures and migraines, it also causes decreased appetite and satiety enhancement.
    - BMI percentiles for obesity standardized by age and sex for pediatrics can be calculated using Table 1.
- **Saxenda (liraglutide)**
    - Saxenda (liraglutide) is an acylated human glucagon-like pepetide-1 receptor agonist (GLP-1 RA) which binds to the GLP-1 receptor ultimately leading to a decrease in caloric intake resulting in lower body weight. Saxenda (liraglutide) does not increase 24-hour energy expenditure.
    - Other GLP-1 RAs approved for use in diabetes include Bydureon (exenatide), Byetta (exenatide), Trulicity (dulaglutide), Victoza (liraglutide), Ozempic (semaglutide), and Rybelsus (semaglutide). Example insulin/GLP-1 RA combinations include Soliqua (insulin glargine/lixisenatide) and Xultophy (insulin degludec/liraglutide).
    - The Cole Criteria (Table 2) should be used to determine appropriateness of Saxenda (liraglutide) in the treatment of pediatric patients.
- **Wegovy**
    - Wegovy (semaglutide) is a GLP-1 RA that activates GLP-1 receptors, thus regulating appetite and caloric intake.
    - Table 1 (CDC criteria) should be used to determine appropriateness of Wegovy in the treatment of pediatric patients.
    - Wegovy has been shown to reduce the risk of MACE in patients with CVD. CVD was defined as stroke, 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.
- **Xenical**
    - Xenical (orlistat) is a reversible inhibitor of gastrointestinal lipases.
    - Xenical forms a covalent bond with the serine residue site of gastric acid and pancreatic lipases, thus rendering pancreatic lipase from hydrolyzing dietary fat into absorbable free fatty acids (FFA) and monoglycerides. As undigested FFA and monoglycerides are not absorbed, the resulting caloric deficit may have a positive effect on weight control.
- **Zepbound**
    - Zepbound is a GIP receptor and GLP-1 receptor agonist. It is an amino acid sequence including a C20 fatty diacid moiety that enables albumin binding and prolongs the half-life. Zepbound selectively binds to and activates both the GIP and GLP-1 receptors, the targets for native GIP and GLP-1, thus regulating appetite and caloric intake. Nonclinical studies suggest the addition of GIP may further contribute to the regulation of food intake.
    - Examples glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 RA approved for type II diabetes include Mounjaro.
    - Zepbound has been shown to reduce the apnea-hypopnea index (AHI) in patients with obesity (BMI $\geq$ 30 kg/m^2) and moderate to severe obstructive sleep apnea (baseline AHI $\geq$ 15 events per hour). Patients in these studies also participated in lifestyle modifications including a 500 calorie daily deficit and 150 minutes a week of physical activity. Zepbound has not been studied in patients with a BMI < 30 kg/m^2 nor an AHI < 15 events per hour.

- Zepbound single-dose vials are only available for self-pay patients with an on-label prescription. Vials are not able to be billed through insurance coverage.

- **Body mass index (BMI)**:
  - BMI is a screening method for weight category—underweight, healthy weight, overweight, and obesity.
  - Pediatric BMI covers those up to 19 years of age. The BMI-for-age percentile growth charts are the most commonly used indicator to measure the size and growth patterns of children and teens in the US. These percentiles express a child's BMI relative to US children who participated in national surveys.
  - Adult BMI covers those 20 years of age or older. BMI is interpreted using standard weight status categories and is the same for men and women of all body types and ages.
  - BMI for pediatrics can be calculated using the CDC BMI Percentile Calculator for Child and Teen: https://www.cdc.gov/healthyweight/bmi/calculator.html.
  - BMI for adults can be calculated using the CDC Adult BMI Calculator: https://www.cdc.gov/healthyweight/assessing/bmi/adult_BMI/english_bmi_calculator/bmi_calculator.html.

Table 1: BMI Percentile Values by Age and Sex for Pediatric Patients Aged 12 Years and Older (CDC criteria)

	Male	Female
Age (in years)	**95th Percentile BMI**	**95th Percentile BMI**
12	24.2	25.2
12.5	24.7	25.7
13	25.1	26.3
13.5	25.6	26.8
14	26.0	27.2
14.5	26.4	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.5	28.9
16.5	27.9	29.3
17	28.2	29.6
17.5	28.6	30.0

Table 2: International Obesity Task Force BMI Cut-offs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (Cole Criteria)

Age (years)	**BMI corresponding to adult BMI of 30 kg/m^2**	
	Males	**Females**
12	26.02	26.67
12.5	26.43	27.24
13	26.84	27.76
13.5	27.25	28.20
14	27.63	28.57
14.5	27.98	28.87
15	28.30	29.11
15.5	28.60	29.29
16	28.88	29.43
16.5	29.14	29.56
17	29.41	29.69
17.5	29.70	29.84

Table 3: Pediatric BMI-for-Age Weight

Pediatric BMI-for-age Weight	
Weight Status Category	**Percentile Range**
Underweight	Less than the 5th percentile
Normal or Healthy Weight	5th percentile to less than the 85th percentile
Overweight	85th percentile to less than the 95th percentile
Obese	Equal to or greater than the 95th percentile

Table 4: Adult BMI Categories

Adult BMI	Weight Status
Below 18.5	Underweight
18.5 – 24.9	Normal or Healthy Weight
25.0 – 29.9	Overweight
30.0 and above	Obese

- **Weight Related Comorbidities**
  - Evidence suggests that the following are weight-related comorbidities:
    - Cardiovascular disease (CVD)
    - Coronary artery disease (CAD)
    - Heart failure with preserved ejection fraction (HFpEF)
    - Hypertension
    - Dyslipidemia
    - Sleep apnea
    - Osteoarthritis
    - Type II diabetes
    - Polycystic ovarian syndrome (PCOS)
    - Non-alcoholic steatohepatitis/non-alcoholic fatty liver disease (NASH/NAFLD)
    - Asthma
    - Chronic obstructive pulmonary disease (COPD)
- Prescribing Considerations:
  - **Contrave**
    - Response to therapy should be evaluated after 12 weeks at the maintenance dosage (or after 16 weeks of starting therapy). If a patient has not lost at least 5% of baseline body weight, discontinue Contrave, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.
    - Contrave can be discontinued immediately and does not require a tapered dose reduction.
  - **Qsymia**
    - Evaluate weight loss following dose escalation to Qsymia 15 mg/92 mg after an additional 12 weeks of treatment (or after 28 weeks of starting therapy). If a patient has not lost at least 5% of baseline body weight on Qsymia 15 mg/92 mg, discontinue Qsymia as directed, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.
    - Discontinue Qsymia 15 mg/92 mg gradually by taking Qsymia 15 mg/92 mg once daily every other day for at least 1 week prior to stopping treatment altogether, due to the possibility of precipitating a seizure.
  - **Saxenda (liraglutide)**
    - While the 3 mg daily dose is the only dose of Saxenda (liraglutide) that should be used in adult patients, pediatric patients who do not tolerate 3 mg daily may have their maintenance dose reduced to 2.4

mg daily. Saxenda (liraglutide) should be discontinued in adults who do not tolerate 3 mg daily or pediatric patients who do not tolerate 2.4 mg daily.
    - Saxenda (liraglutide) has a warning for serious hypoglycemia when used with a sulfonylurea or insulin. The dose of anti-diabetic drugs should be reduced to lower the risk of hypoglycemia when Saxenda (liraglutide) is given with a sulfonylurea or insulin.
    - Saxenda (liraglutide) should not be co-administered with any other GLP-1 RA.
    - **Adults**: Evaluate the change in body weight 16 weeks after initiating Saxenda (liraglutide) and discontinue Saxenda (liraglutide) if the patient has not lost at least 4% of baseline body weight, since it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.
    - **Pediatrics**: Dose escalation for pediatric patients may take up to 8 weeks. Evaluate the change in BMI after 12 weeks on the maintenance dose and discontinue Saxenda (liraglutide) if the patient has not had a reduction in BMI of at least 1% from baseline, since it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.
    - Liraglutide 3 mg/0.5 mL, delivering a maximum dose of 3 mg, is a generic of Saxenda approved for treatment of obesity. Liraglutide 3 mg/0.5 mL is also available in a device delivering a maximum dose of 1.8 mg and is only approved for treatment of diabetes.
- **Wegovy**
    - Wegovy lowers blood glucose and can cause hypoglycemia.
    - The incidence of cholelithiasis and cholecystitis was higher in pediatric patients aged 12 years and older than in adults.
    - 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.
    - **Adults**: 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 for chronic weight management.
    - **Pediatrics**: If patients do not tolerate the maintenance 2.4 mg once-weekly dosage, the maintenance dosage may be reduced to 1.7 mg once weekly. Discontinue if the patient cannot tolerate the 1.7 mg dose. 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 for chronic weight management.
- **Xenical**
    - Patients should be on a nutritionally balanced, reduced-calorie diet that contains approximately 30% of calories from fat.
- **Zepbound**
    - Concomitant use with an insulin secretagogue or insulin may increase risk of hypoglycemia. Reducing the dose of the insulin secretagogue or insulin may be necessary.
    - Zepbound should not be used in combination with any other GLP-1 RA. The safety and efficacy of coadministration with other products for weight management have not been established.
    - Zepbound has not been studied in patients with a history of pancreatitis.

	▪ Zepbound is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia syndrome type 2. ▪ The recommended maintenance dosages are 5 mg, 10 mg, or 15 mg once weekly. The 2.5 mg dosage is for treatment initiation and is not intended for chronic weight management.

Approval Criteria

I. Qsymia for Adolescents or Adults who Initiated Qsymia as Adolescents

A. Initiation

- **0 to < 7 months of previous therapy**

When a benefit, initiation of Qsymia may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is 12 years of age or older.
2. The member is using Qsymia for chronic weight management. (ICD-10: E66.0)
3. The prescriber submits attestation of both of the following **(a. and b.)**:
  a. Baseline age, height, weight, and BMI.
  b. The member's baseline BMI is ≥ 95th percentile standardized for age and sex (*Table 1, above*).
4. The prescriber attests that the member will use the product in combination with a lifestyle modification program that encourages reduced calorie diet and increased physical activity (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).
5. The prescriber attests to the member's active participation for at least 3 months prior to initiation of the requested therapy in a lifestyle modification program that encourages reduced calorie diet and increased physical activity (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).

B. Maintenance

- **≥ 7 months of previous therapy**

When a benefit, maintenance therapy of Qsymia may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is 12 years of age or older.
2. The member is using Qsymia for chronic weight management. (ICD-10: E66.0)
3. The prescriber submits attestation of all of the following **(a., b., and c.)**:
  a. Baseline age, height, weight, and BMI.
  b. Current age, height, weight, and BMI.
  c. The member's baseline BMI is ≥ 95th percentile standardized for age and sex (*Table 1, above*).
4. 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 (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).
5. The member meets all of the following criteria **(a. and b.)**:
  a. The member has experienced ≥ 5% weight loss from baseline
  b. The member has maintained ≥ 5% weight loss from baseline.

II. Contrave or Qsymia in Adults, or Xenical (for chronic weight management)

A. Initiation

- **Contrave: 0 to < 4 months of previous therapy**
- **Qsymia: 0 to < 7 months of previous therapy**
- **Xenical: 0 to < 6 months of previous therapy**

When a benefit, initiation of Contrave, Qsymia or Xenical may be approved when all of the following criteria are met **(1. through 5.):**

1. The member meets one (1) of the following criteria **(a. or b.)**:
   a. If the request is for Contrave or Qsymia, the member is 18 years of age or older.
   b. If the request is for Xenical, the member is 12 years of age or older.
2. The member is using the requested product for chronic weight management. (ICD-10: E66.0, E66.3)
3. The prescriber submits attestation of both of the following **(a. and b.)**:
   a. Baseline height, weight, and BMI.
   b. The member meets (1) one of the following **(i. or ii.)**:
      i. The member has a baseline BMI ≥ 30 kg/m^2
      ii. The member has a baseline BMI ≥ 27 kg/m^2 and has a weight related comorbidity (for example hypertension, cardiovascular disease, dyslipidemia, obstructive sleep apnea).
4. The prescriber attests that the member will be using the product in combination with a lifestyle modification program that encourages reduced calorie diet and increased physical activity (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).
5. The prescriber attests to the member's active participation for at least 3 months prior to initiation of the requested therapy in a lifestyle modification program that encourages reduced calorie diet and increased physical activity (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).

B. Continuation

- **Contrave: 4 to < 12 months of previous therapy**
- **Qsymia: 7 to < 12 months of previous therapy**
- **Xenical: 6 to < 12 months of previous therapy**

When a benefit, continuation therapy of Contrave, Qsymia or Xenical may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member meets one (1) of the following criteria **(a. or b.)**:
   a. If the request is for Contrave or Qsymia, the member is 18 years of age or older.
   b. If the request is for Xenical, the member is 12 years of age or older.
2. The member is using the requested product for chronic weight management. (ICD-10: E66.0, E66.3)
3. The prescriber submits attestation of all of the following **(a, b., and c.)**:
   a. Baseline height, weight, and BMI.
   b. Current height, weight, and BMI.
   c. The member meets (1) one of the following **(i. or ii.)**:
      i. The member has a baseline BMI ≥ 30 kg/m^2
      ii. The member has a baseline BMI ≥ 27 kg/m^2 and has a weight related comorbidity (for example hypertension, cardiovascular disease, dyslipidemia, obstructive sleep apnea) at baseline.
4. 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 (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).
5. The member has experienced ≥ 5% weight loss from baseline.

C. Maintenance

- **Contrave, Qsymia, or Xenical: ≥ 12 months of previous therapy**

When a benefit, maintenance therapy of Contrave, Qsymia or Xenical may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member meets one (1) of the following criteria **(a. or b.)**:
   a. If the request is for Contrave or Qsymia, the member is 18 years of age or older.
   b. If the request is for Xenical, the member is 12 years of age or older.

2. The member is using the requested product for chronic weight management. (ICD-10: E66.0, E66.3)
3. The prescriber submits attestation of all of the following **(a., b., and c.)**:
   - **a.** Baseline height, weight, and BMI.
   - **b.** Current height, weight, and BMI.
   - **c.** The member meets (1) one of the following **(i. or ii.)**:
     - **i.** The member has a baseline BMI ≥ 30 kg/m^2
     - **ii.** The member has a baseline BMI ≥ 27 kg/m^2 and has a weight related comorbidity (for example hypertension, cardiovascular disease, dyslipidemia, obstructive sleep apnea) at baseline.
4. 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 (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).
5. The member has maintained ≥ 5% weight loss from baseline.

III. Xenical (to reduce risk of weight regain after weight loss)

A. Initiation

- **< 12 months of previous therapy**

When a benefit, initiation of Xenical may be approved when all of the following are met **(1. through 6.)**:

1. The member is 12 years of age or older.
2. The member is using Xenical to reduce the risk of weight regain after initial weight loss. (ICD-10: E66.0, E66.3)
3. The prescriber submits attestation of all of the following **(a., b., and c.)**:
   - **a.** Baseline height, weight, and BMI.
   - **b.** Current height, weight, and BMI.
   - **c.** The member meets one (1) of the following criteria **(i. or ii.)**:
     - **i.** The member has a baseline BMI ≥ 30 kg/m^2
     - **ii.** The member has a baseline BMI ≥ 27 kg/m^2 and has a weight related comorbidity (for example hypertension, cardiovascular disease, dyslipidemia, obstructive sleep apnea).
4. The prescriber attests that the member will use the product in combination with a lifestyle modification program that encourages reduced calorie diet and increased physical activity (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).
5. The prescriber attests to the member's active participation for at least 3 months prior to initiation of the requested therapy in a lifestyle modification program that encourages reduced calorie diet and increased physical activity (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).
6. The member has experienced ≥ 8% weight loss using non-pharmacologic weight loss therapy alone.

B. Maintenance

- **≥ 12 months of previous therapy**

When a benefit, initiation of Xenical may be approved when all of the following are met **(1. through 5.)**:

1. The member is 12 years of age or older.
2. The member is using Xenical to reduce the risk of weight regain after initial weight loss. (ICD-10: E66.0, E66.3)
3. The prescriber submits attestation of all of the following **(a., b., and c.)**:
   - **a.** Baseline height, weight, and BMI.
   - **b.** Current height, weight, and BMI.
   - **c.** The member meets one (1) of the following criteria **(i. or ii.)**:
     - **i.** The member has a baseline BMI ≥ 30 kg/m^2

ii. The member has a baseline BMI ≥ 27 kg/m^2 and has a weight related comorbidity (for example hypertension, cardiovascular disease, dyslipidemia, obstructive sleep apnea) at baseline.

4. 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 (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).

5. The member has maintained the ≥ 8% weight loss from using non-pharmacologic weight loss therapy alone..

IV. Saxenda (liraglutide) or Wegovy for Adolescents, or Adults who Initiated Saxenda (liraglutide) or Wegovy as Adolescents

A. Initiation

- **0 to < 5 months of previous therapy**

When a benefit, initiation of Saxenda (liraglutide) or Wegovy may be approved when all of the following criteria are met **(1. through 6.)**:

1. The member is 12 years of age or older.

2. The member is using the requested product for chronic weight management. (ICD-10: E66.0)

3. The prescriber submits attestation of all of the following **(a. through c.)**:

a. Baseline age, height, weight, and BMI.

b. If the request is for Saxenda (liraglutide), the member meets all of the following **(i. and ii.):**

i. The member has a baseline body weight ≥ 60 kg.

ii. The member has a baseline BMI corresponding to ≥ 30 kg/m^2 or greater for adults based on the Cole Criteria (*Table 2, above*).

c. If the request is for Wegovy, the member meets the following criterion **(i.):**

i. The member has a baseline BMI corresponding to ≥ 95th percentile for age and sex based on the CDC Criteria (*Table 1, above*).

4. The prescriber attests to both of the following criteria **(a. and b.)**:

a. The member actively participated for at least 3 months prior to initiation of the requested therapy in a lifestyle modification program that encourages reduced calorie diet and increased physical activity (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).

b. The member will use the requested therapy in combination with a lifestyle modification program that encourages reduced calorie diet and increased physical activity.

5. The member will not be using Saxenda (liraglutide) or Wegovy in combination with any of the following products **(a. and b.)**:

a. GLP-1 RA

b. GLP-1 RA combinations (for example, with insulin, GIP RA)

6. If the request is for brand Saxenda, the member has experienced therapeutic failure or intolerance to plan-preferred generic liraglutide.

B. Maintenance

- **≥ 5 months of previous therapy**

When a benefit, maintenance therapy of Saxenda (liraglutide) or Wegovy may be approved when all of the following criteria are met **(1. through 8.)**:

1. The member is 12 years of age or older.

2. The member is using the requested product for chronic weight management. (ICD-10: E66.0)

3. The prescriber submits attestation of all of the following **(a. through d.)**:

a. Baseline age, height, weight, and BMI.

b. Current age, height, weight, and BMI.

c. If the request is for Saxenda (liraglutide), the member meets all of the following **(i. and ii.):**

i. The member has a baseline body weight ≥ 60 kg.

ii. The member has a baseline BMI corresponding to ≥ 30 kg/m^2 or greater for adults based on the Cole Criteria (*Table 2, above*).

d. If the request is for Wegovy, the member meets the following criterion **(i.):**

i. The member has a baseline BMI corresponding to ≥ 95th percentile for age and sex based on the CDC Criteria (*Table 1, above*).

4. 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 (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).

5. The member will not be using Saxenda (liraglutide) or Wegovy in combination with any of the following products **(a. and b.)**:

a. GLP-1 RA

b. GLP-1 RA combinations (for example, with insulin, GIP RA)

6. If the request is for Saxenda (liraglutide), the member meets all of the following criteria **(a., b., and c.):**

a. The member has experienced ≥ 1% BMI reduction from baseline.

b. The member meets one (1) of the following criteria **(i. or ii.):**

i. The requested dose is 2.4 mg or 3 mg daily.

ii. The prescriber attests that the member is titrating to a dose of 2.4 mg or 3 mg daily.

c. The member has maintained ≥ 1% BMI reduction from baseline.

7. If the request is for Wegovy, the member meets all of the following criteria **(a., b., and c.):**

a. The member has experienced ≥ 5% BMI reduction from baseline.

b. The member has maintained ≥ 5% BMI reduction from baseline.

c. The member meets one (1) of the following criteria **(i. or ii.):**

i. The requested dose is 1.7 mg or 2.4 mg once weekly.

ii. The prescriber attests the member is titrating to a dose of 1.7 mg or 2.4 mg once weekly.

8. If the request is for brand Saxenda, the member has experienced therapeutic failure or intolerance to plan-preferred generic liraglutide.

V. Saxenda (liraglutide), Wegovy, and Zepbound for Adults

A. Initiation

- **Saxenda (liraglutide): 0 to < 4 months of previous therapy**
- **Wegovy: 0 to < 6 months of previous therapy**
- **Zepbound: 0 to < 7 months of previous therapy**

When a benefit, initiation of Saxenda (liraglutide), Wegovy, or Zepbound may be approved when all of the following criteria are met **(1. through 6.)**:

1. The member is 18 years of age or older.

2. The drug is being used for chronic weight management. (ICD-10: E66.0, E66.3)

3. The prescriber submits attestation substantiating all of the following **(a. and b.)**:

a. Baseline height, weight, and BMI.

b. The member meets (1) one of the following **(i. or ii.)**:

i. The member has a baseline BMI ≥ 30 kg/m^2

ii. The member has a baseline BMI ≥ 27 kg/m^2 and has a weight related comorbidity (for example hypertension, cardiovascular disease, dyslipidemia, obstructive sleep apnea).

4. The prescriber attests to both of the following criteria **(a. and b.)**:

a. The member actively participated for at least 3 months prior to initiation of the requested therapy in a lifestyle modification program that encourages reduced calorie diet and increased physical activity (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).

b. The member will use the requested therapy in combination with a lifestyle modification program that encourages reduced calorie diet and increased physical activity.

5. The member will not be using Saxenda (liraglutide), Wegovy, or Zepbound in combination with any of the following products **(a. and b.)**:
   - **a.** GLP-1 RA
   - **b.** GLP-1 RA combinations (for example, with insulin, GIP RA)
6. If the request is for brand Saxenda, the member has experienced therapeutic failure or intolerance to plan-preferred generic liraglutide.

B. Continuation

- **Saxenda (liraglutide): 4 to < 12 months of previous therapy**
- **Wegovy: 6 to < 12 months of previous therapy**
- **Zepbound: 7 to < 12 months of previous therapy**

When a benefit, continuation therapy of Saxenda (liraglutide), Wegovy, or Zepbound may be approved when all of the following criteria are met **(1. through 9.)**:

1. The member is 18 years of age or older.
2. The drug is being used for chronic weight management. (ICD-10: E66.0, E66.3)
3. The prescriber submits attestation of all of the following **(a., b., and c.)**:
   - **a.** Baseline height, weight, and BMI.
   - **b.** Current height, weight, and BMI.
   - **c.** The member meets (1) one of the following **(i. or ii.)**:
     - **i.** The member has a baseline BMI ≥ 30 kg/m^2
     - **ii.** The member has a baseline BMI ≥ 27 kg/m^2 and has a weight related comorbidity (for example hypertension, cardiovascular disease, dyslipidemia, obstructive sleep apnea) at baseline.
4. 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 (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).
5. The member will not be using Saxenda (liraglutide), Wegovy, or Zepbound in combination with any of the following products **(a. and b.)**:
   - **a.** GLP-1 RA
   - **b.** GLP-1 RA combinations (for example, with insulin, GIP RA)
6. If the request is for Saxenda (liraglutide), the member meets all of the following criteria **(a. and b.):**
   - **a.** The member has experienced ≥ 4% weight loss from baseline.
   - **b.** The member meets one (1) of the following criteria **(i. or ii.):**
     - **i.** The requested dose is 2.4 mg or 3 mg daily.
     - **ii.** The prescriber attests that the member is titrating to a dose of 2.4 mg or 3 mg daily.
7. If the request is for Wegovy, the member meets all of the following criteria **(a. and b.):**
   - **a.** The member has experienced ≥ 5% weight loss from baseline.
   - **b.** The member meets one (1) of the following criteria **(i. or ii.):**
     - **i.** The requested dose is 1.7 mg or 2.4 mg once weekly.
     - **ii.** The prescriber attests the member is titrating to a dose of 1.7 mg or 2.4 mg once weekly.
8. If the request is for Zepbound, the member meets all of the following criteria **(a. and b.):**
   - **a.** The member has experienced ≥ 5% weight loss from baseline.
   - **b.** The member meets one (1) of the following criteria **(i. or ii.):**
     - **i.** The requested dose is 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg once weekly.
     - **ii.** The prescriber attests the member is titrating to a dose of 5 mg once weekly.
9. If the request is for brand Saxenda, the member has experienced therapeutic failure or intolerance to plan-preferred generic liraglutide.

C. Maintenance

- **Saxenda (liraglutide), Wegovy, and Zepbound: ≥ 12 months of previous therapy**

When a benefit, maintenance therapy of Saxenda (liraglutide), Wegovy, or Zepbound may be approved when all of the following criteria are met **(1. through 9.)**:

1. The member is 18 years of age or older.
2. The drug is being used for chronic weight management. (ICD-10: E66.0, E66.3)
3. The prescriber submits attestation of all of the following **(a., b., and c.)**:
   - **a.** Baseline height, weight, and BMI.
   - **b.** Current height, weight, and BMI.
   - **c.** The member meets (1) one of the following **(i. or ii.)**:
     - **i.** The member has a baseline BMI ≥ 30 kg/m^2
     - **ii.** The member has a baseline BMI ≥ 27 kg/m^2 and has a weight related comorbidity (for example hypertension, cardiovascular disease, dyslipidemia, obstructive sleep apnea) at baseline.
4. 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 (for example, increased physical activity, nutritional counseling, participation in a comprehensive weight management program).
5. The member will not be using Saxenda (liraglutide), Wegovy, or Zepbound in combination with any of the following products **(a. and b.)**:
   - **a.** GLP-1 RA
   - **b.** GLP-1 RA combinations (for example, with insulin, GIP RA)
6. If the request is for Saxenda (liraglutide), the member meets all of the following criteria **(a. and b.):**
   - **a.** The member meets one (1) of the following criteria **(i. or ii.):**
     - **i.** The requested dose is 2.4 mg or 3 mg daily.
     - **ii.** The prescriber attests that the member is titrating to a dose of 2.4 mg or 3 mg daily.
   - **b.** The member has maintained ≥ 4% weight loss from baseline.
7. If the request is for Wegovy, the member meets all of the following criteria **(a. and b.):**
   - **a.** The member meets one (1) of the following criteria **(i. or ii.):**
     - **i.** The requested dose is 1.7 mg or 2.4 mg once weekly.
     - **ii.** The prescriber attests the member is titrating to a dose of 1.7 mg or 2.4 mg once weekly.
   - **b.** The member has maintained ≥ 5% weight loss from baseline.
8. If the request is for Zepbound, the member meets all of the following criteria **(a. and b.):**
   - **a.** The member meets one (1) of the following criteria **(i. or ii.):**
     - **i.** The requested dose is 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg once weekly.
     - **ii.** The prescriber attests the member is titrating to a dose of 5 mg once weekly.
   - **b.** The member has maintained ≥ 5% weight loss from baseline.
9. If the request is for brand Saxenda, the member has experienced therapeutic failure or intolerance to plan-preferred generic liraglutide.

VI. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations

Limitations of Coverage

I. This policy only applies to Wegovy when used for treatment of obesity and treatment of cardiovascular disease in patients who are overweight or obese. For treatment of metabolic-dysfunction associated steatohepatitis (MASH, formerly known as NASH), see policy J-1379.
II. Members established on samples or by paying out-of-pocket for drugs addressed in this policy will only be granted a continuation of therapy if the criteria within this policy is met.
III. Coverage of drugs addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
IV. For Commercial members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial Plans: If approved, up to the following authorization duration may be granted.

I. Initiation
- **A. Saxenda (liraglutide) for Adults, or Contrave:** 4 months
- **B. Saxenda (liraglutide) for Adolescents, or Wegovy for Adolescents**: 5 months
- **C. Wegovy for Adults, or Xenical:** 6 months
- **D. Zepbound, or Qsymia**: 7 months

II. Continuation: 12 months

III. Maintenance: 12 months

Automatic Approval Criteria

None

References:

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4. Wegovy [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S; March 2024.
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6. Zepbound [package insert]. Indianapolis, IN: Lilly USA, LLC; December 2024.
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11. 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. *J Am Coll Cardiol*. 2014;63(25 Pt B):2985-3023.
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13. Apovian CM, Aronne LJ, Bessesen DH, et al. Endocrine Society. Pharmacological management of obesity: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2015;100 (2):342-362.
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16. Brown E, Wilding JPH, Barber TM, Alam U, Cuthbertson DJ. Weight loss variability with SGLT2 inhibitors and GLP-1 receptor agonists in type 2 diabetes mellitus and obesity: Mechanistic possibilities. *Obes Rev*. 2019 Jun;20(6):816-828.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.