Pharmacy Policy Bulletin: J-1388 Anti-Obesity (Enhanced) – Commercial and Healthcare Reform	
Number: J-1388	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial Fully Insured:** **Prior Authorization (1. and 2.):** **1.** Anti-Obesity = Yes*,† **2.** Other Managed Drugs = Yes w/ Prior Authorization **Commercial Administrative Services Only (ASO):** **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 = Enhanced *For Anti-Obesity Weight Loss Mgmt Policy = Standard, see policy J-1389.* **Healthcare Reform:** **Prior Authorization (1.):** Anti-Obesity = Yes* **Wegovy (semaglutide) and Zepbound (tirzepatide) may be eligible for coverage for members with a Delaware Commercial fully-insured or Healthcare Reform plan without the anti-obesity benefit if the criteria in Section V or Section VI are met.* *†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.*
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):**
Version: J-1388-013	**Original Date:** 08/07/2024
Effective Date: 08/26/2025	**Review Date:** 06/25/2025

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
	  ○ 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. Maintenance refers to a member that has been using a chronic weight loss agent for more than the number of defined months in the below approval criteria. • Members that have a substantial gap in therapy should be evaluated using the initiation criteria. • **Contrave, Qsymia, and Xenical** ○ 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 (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. ○ 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. ○ BMI percentiles for obesity standardized by age and sex for pediatrics can be calculated using Table 1. • **Saxenda, Wegovy, and Zepbound for Weight Loss** ○ Saxenda 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 does not increase 24-hour energy expenditure. ○ Wegovy (semaglutide) is a GLP-1 RA that activates GLP-1 receptors, thus regulating appetite and caloric intake. ○ 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. ○ 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. ○ 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). Examples glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 RA approved for type II diabetes include Mounjaro. These products are only approved for use in type II diabetes and should not be used to treat obesity in patients without type II diabetes.
    - While the FDA has approved some GLP-1 RAs for individuals with a BMI ≥ 30 kg/m^2, not all individuals with this BMI are at increased risk for obesity-related health complications. BMI fails to account for muscle mass, fat distribution, and other crucial metabolic factors that are more closely associated with future health risk. Using BMI alone as a determinate for the clinical appropriateness of these drugs can lead to misdiagnosis and inappropriate treatment decisions. However, BMIs associated with morbid obesity (≥ 40 kg/m²) are more closely correlated with increased risks of serious health complications.
    - 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.
    - GLP-1 RAs have shown promise in weight management and improving glycemic control, but long-term safety and effectiveness data are still emerging. Most studies evaluating GLP-1 RAs have been conducted for a duration of 2-5 years. Other medical interventions, like bariatric surgery, offer significant benefits for individuals struggling with severe obesity and related health conditions. Bariatric surgery leads to substantial and lasting weight loss, often exceeding the results achievable with other interventions. On average, patients undergoing bariatric surgery lose 50 pounds more than patients taking GLP-1 RAs. Bariatric surgery is generally safe, with serious complications estimated to be between 1 to 4%. GLP-1 RAs are also known to also cause adverse events. In clinical trials, nearly three-quarters of patients taking a GLP-1 RA for weight loss experienced gastrointestinal events, and these events were considered severe in 4% of patients.
- **Wegovy for Cardiovascular Disease**
    - Wegovy has been shown to reduce the risk of MACE in patients with CVD. 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.
- **Zepbound for Obstructive Sleep Apnea (OSA)**
    - Zepbound has been shown to reduce the apnea-hypopnea index (AHI) in patients with obesity (BMI ≥ 30 kg/m^2) and moderate to severe obstructive sleep apnea (baseline AHI ≥ 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.
    - AHI is a measure of how many times a patient stops breathing (apnea) or experiences shallow breathing (hypoapnea) during sleep. An AHI of < 5 events per hour is considered normal, and OSA is diagnosed at an AHI ≥ 5 in the presence of other symptoms/comorbidities and at an AHI ≥ 15 regardless of symptoms/comorbidities. Clinical guidelines recommend that objective data from a sleep study should inform a diagnosis of OSA (American Academy of Sleep Medicine).

- OSA can cause disruption in sleep patterns, leading to excessive day-time sleepiness and impaired sleep-related quality of life. OSA is also associated with other comorbidities, such as hypertension. Clinical guidelines recommend that positive airway pressure devices (PAP), such as continuous PAP (CPAP) or automatic PAP (APAP), be used in patients with excessive daytime sleepiness (strong recommendation), impaired sleep-related quality of life (conditional recommendation), or hypertension (conditional recommendation, American Academy of Sleep Medicine). These guidelines have not yet been updated to include Zepbound.
- Oral appliances (OAs) are devices intended to protrude and stabilize the mandible to maintain a patent airway during sleep. The 2015 AASM Clinical Practice Guideline for the Treatment of OSA and Snoring with Oral Appliance Therapy recommends the consideration of OAs for adults with OSA who are intolerant of CPAP therapy or prefer alternate therapy. The guideline states that CPAP should generally still be used first-line as it has been found to be superior to OAs in reducing AHI, arousal index, and oxygen desaturation index and improving oxygen saturation. The guideline recommends that a custom, titratable appliance be used. A custom OA is created using impressions and models of a patient's oral structures. Titratable OAs have a mechanism that allows for varying amounts of mandibular protrusion. A tongue retaining device is not considered to be an OA.
- Provigil (modafinil), Nuvigil (armodafinil), and Sunosi (solriamfetol) are FDA-approved to treat excessive daytime sleepiness in patients with OSA. These agents produce stimulant-like effects and are controlled substances. While these agents target the symptoms of OSA, they do not treat the underlying disease. Excess weight, particularly excess oral-pharyngeal fat, may contribute to OSA by obstructing the airway during sleep. Research has shown that weight loss can lead to reductions in AHI (with a reduction of 50% considered clinically significant), and guidelines recommend that need for PAP be re-evaluated after a 10% weight loss (American Academy of Sleep Medicine). Clinical guidelines recommend participation in a comprehensive lifestyle modification program that includes a reduced-calorie diet, exercise/increased physical activity, and behavioral counseling (related to dietary and physical activity changes) for patients with OSA and a BMI $\geq$ 25 kg/m^2 (American Thoracic Society). Zepbound can treat the underlying etiology of OSA by causing weight loss, which can lead to reductions in oral-pharyngeal fat.
- Clinical guidelines also recommend avoidance of alcohol before bed and avoidance of sleeping in a supine position (American Academy of Sleep Medicine).

- **Clinical Obesity**
  - The Lancet Diabetes and Endocrinology Commission defines clinical obesity as a chronic, systemic illness resulting from excessive adiposity that alters the function of tissues and organs. This can lead to significant end-organ damage and life-threatening complications such as heart attacks, strokes, and renal failure. Clinical obesity is characterized by the presence of both excess adiposity and associated signs, symptoms, or limitations in daily activities. Preclinical obesity is the presence of confirmed excess adiposity without current, demonstrable organ dysfunction or significant limitations in daily activities.
  - Excess adiposity can be determined through several methods: Direct measurement of body fat, using techniques like DEXA or bioimpedance analysis; anthropometric criteria, such as waist circumference or waist-

to-hip ratio, used in addition to BMI, applying age-, gender-, and ethnicity-appropriate cut-offs; or, in individuals with a BMI greater than 40 kg/m², excess adiposity can be pragmatically assumed without further confirmation.
    - In adults, clinical manifestations of obesity may include raised intracranial pressure, respiratory issues, reduced left ventricular systolic function, chronic fatigue, and lower limb edema. Additional indicators are hyperglycemia, high triglycerides, low HDL cholesterol, nonalcoholic fatty liver disease, microalbuminuria, recurrent urinary incontinence, menstrual irregularities in women, male hypogonadism, chronic joint pain, and mobility limitations. Children and adolescents can exhibit raised intracranial pressure, sleep problems, elevated liver function tests (LFTs) due to metabolic dysfunction-associated fatty liver disease, and recurrent urinary incontinence. The presence of confirmed excess adiposity is also needed before these can be labeled as clinical obesity.
    - Significant impairment in activities of daily living (ADLs) would involve notable difficulty or the inability to perform essential self-care tasks, such as bathing, dressing, toileting, or eating, without substantial assistance. It also includes significant limitations in mobility, such as difficulty walking a short distance, climbing stairs, or rising from a seated position.
- **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
    - The CDC recognizes that obesity is associated with health risks, and that severe obesity further increases the risk of obesity related complications, such as coronary heart disease and end-stage renal disease.
    - Class III obesity (severe obesity) is associated with a lower life expectancy than class I or class II obesity. Many of these deaths are due to obesity related health complications, such as heart disease.
    - BMI for pediatrics can be calculated using the CDC BMI Percentile Calculator for Child and Teen: https://www.cdc.gov/bmi/child-teen-calculator/index.html
    - BMI percentiles for pediatrics can be calculated using the CDC Extended BMI-for-Age Growth Charts: https://www.cdc.gov/growthcharts/Extended-BMI-Charts.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**	**120% of the 95th Percentile BMI**	**95th Percentile BMI**	**120% of the 95th Percentile BMI**
12	24.2	29.0	25.2	30.3

12.5	24.7	29.6	25.7	31.0
13	25.1	30.2	26.3	31.5
13.5	25.6	30.7	26.8	32.1
14	26.0	31.2	27.2	32.7
14.5	26.4	31.8	27.7	33.3
15	26.8	32.1	28.1	33.6
15.5	27.2	32.6	28.5	34.2
16	27.5	33.0	28.9	34.6
16.5	27.9	33.5	29.3	35.2
17	28.2	33.9	29.6	35.5
17.5	28.6	34.3	30.0	36.0

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 Categories	
Percentile Range/BMI	**Weight Status**
< 5th percentile	Underweight
5th percentile to < 85th percentile	Normal or Healthy Weight
85th percentile to less < 95th percentile	Overweight
≥ 95th percentile	Obese
≥ 120% of the 95th percentile, OR ≥ 35 kg/m^2	Severe Obesity

Table 4: Adult BMI Categories

Adult BMI Categories	
Adult BMI	**Weight Status**
Below 18.5	Underweight
18.5 to 24.9	Normal or Healthy Weight
25.0 to 29.9	Overweight
30.0 to < 35.0	Class I Obesity
35.0 to < 40.0	Class II Obesity
≥ 40	Class III Obesity (Severe Obesity)

- Prescribing Considerations:
  - **Contrave, Qsymia, and Xenical**
    - Response to Contrave 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. ▪ 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. ▪ When taking Xenical, patients should be on a nutritionally balanced, reduced-calorie diet that contains approximately 30% of calories from fat. ○ **Saxenda, Wegovy, and Zepbound** ▪ Concomitant use with an insulin secretagogue, insulin may increase risk of hypoglycemia. Reducing the dose of the insulin secretagogue or insulin may be necessary. ▪ Saxenda, Wegovy and Zepbound should not be co-administered with any other GLP-1 RA. ▪ 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. 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 recommended maintenance dosages for Zepbound are 5 mg, 10 mg, or 15 mg once weekly. Consider treatment response and tolerability when selecting the maintenance dosage. If patients do not tolerate a maintenance dosage, consider a lower maintenance dosage such as 7.5 mg or 12.5 mg. The 2.5 mg dosage is for treatment initiation and is not intended for maintenance use. ▪ Saxenda, Wegovy, and Zepbound are all contraindicated in patients with a personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2. Saxenda has an additional contraindication for pregnancy. All agents are contraindicated in patients who had a previous allergic reaction or hypersensitivity to the medication. If pancreatitis occurs while taking any of these agents, members should not attempt to switch to another agent.

Approval Criteria

Table A. Documentation Requirements for Lifestyle Modifications

Acceptable Documentation	
Physical Activity	**Diet**
Provider chart notes specifying type, duration, and frequency of physical activity	Provider chart notes detailing specific dietary adjustments and/or calorie deficit

Recurring receipts for a gym membership (for example monthly, provided for each month) and notes specifying type, duration, and frequency of physical activity	Recurring receipts for a subscription to a lifestyle modification program, such as Noom, Weight Watchers, Vida, Lark, Signos, Wondr, Livongo, Omada, Newtopia, Virta, plan sponsored coaching programs (for example My Weight Management Journey; Penn State Health obesity medicine institute) (for example monthly, provided for each month)
Summary report from a wearable device specifying frequency of physical activity (for example elevated heart rate for over 20 minutes for at least 3 times a week for a month)	Dietary log maintained by member detailing specific diet and/or calorie deficit
Recurring appointments with a personal trainer (for example receipt provided monthly) and notes specifying type, duration, and frequency of physical activity	Recurring appointments for private nutritional counseling or medical nutrition therapy (for example receipt or chart documentation provided monthly)

For approval, one piece of documentation must be provided from each column.

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

A. Initiation

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

When a benefit, initiation of Qsymia or Xenical may be approved when all of the following criteria are met **(1. through 4.)**:

1. The member is 12 to 18 years of age.
2. The member is using Qsymia or Xenical for chronic weight management. (ICD-10: E66.0)
3. The prescriber provides documentation 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 provides documentation according to Table A. supporting all of the following criteria **(a. through d.)**:
  a. The member maintained healthy dietary changes for at least 6 months prior to initiation of the requested therapy
  b. The member maintained increased physical activity for at least 6 months prior to initiation of the requested therapy
  c. The member will use the requested therapy in combination with healthy dietary changes
  d. The member will use the requested therapy in combination with increased physical activity

B. Maintenance

- **≥ 7 months of previous therapy**

When a benefit, maintenance therapy of Qsymia or Xenical 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 or Xenical for chronic weight management. (ICD-10: E66.0)
3. The prescriber provides documentation 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 provides documentation according to Table A. supporting all of the following criteria **(a. and b.)**:
  a. The member is using the requested therapy in combination with healthy dietary changes

b. The member is using the requested therapy in combination with increased physical activity

5. The member has experienced and maintained a BMI reduction of ≥ 3 percentile points standardized for age and sex from baseline.

II. Contrave, Qsymia, or Xenical in Adults

A. Initiation

- **< 7 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 4.):**

1. The member is 18 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 provides documentation of both of the following **(a. and b.)**:

a. Baseline height, weight, and BMI.

b. The member has a baseline BMI ≥ 35 kg/m^2

4. The prescriber provides documentation according to Table A. supporting all of the following criteria **(a. through d.)**:

a. The member maintained healthy dietary changes for at least 6 months prior to initiation of the requested therapy

b. The member maintained increased physical activity for at least 6 months prior to initiation of the requested therapy

c. The member will use the requested therapy in combination with healthy dietary changes

d. The member will use the requested therapy in combination with increased physical activity

B. Maintenance

- **≥ 7 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 is 18 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 provides documentation of all of the following **(a., b., and c.)**:

a. Baseline height, weight, and BMI.

b. Current height, weight, and BMI.

c. The member has a baseline BMI ≥ 35 kg/m^2

4. The prescriber provides documentation according to Table A. supporting all of the following criteria **(a. and b.)**:

a. The member is using the requested therapy in combination with healthy dietary changes

b. The member is using the requested therapy in combination with increased physical activity

5. The member has experienced and maintained ≥ 5% weight loss from baseline

III. Saxenda or Wegovy for Adolescents, and Saxenda, Wegovy, and Zepbound for Adults who Initiated Saxenda or Wegovy as Adolescents

A. Initiation

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

When a benefit, initiation of Saxenda or Wegovy may be approved when all of the following criteria are met **(1. through 7.)**:

1. The member is 12 to 18 years of age.

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

3. The prescriber provides documentation of baseline age, height, weight, and BMI.

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

a. The member has a BMI ≥ 35
b. The member has a BMI that is ≥ 120% of the 95th percentile for age and sex (*Table 1, above*).

5. The prescriber provides documentation according to Table A. supporting all of the following criteria **(a. through d.)**:
a. The member maintained healthy dietary changes for at least 6 months prior to initiation of the requested therapy
b. The member maintained increased physical activity for at least 6 months prior to initiation of the requested therapy
c. The member will use the requested therapy in combination with healthy dietary changes
d. The member will use the requested therapy in combination with increased physical activity

6. The prescriber attests that the member does NOT have a diagnosis of type 2 diabetes mellitus (ICD-10: E11.9).

7. The member will not be using Saxenda 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)

B. Maintenance

- **≥ 7 months of previous therapy**

When a benefit, maintenance therapy of Saxenda, Wegovy, or Zepbound 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 provides documentation of all of the following **(a. and b.)**:
a. Baseline age, height, weight, and BMI.
b. Current age, height, weight, and BMI.

4. The member meets one (1) of the following criteria **(a. or b.)**:
a. The member had a baseline a BMI ≥ 35
b. The member had a baseline BMI that is ≥ 120% of the 95th percentile standardized for age and sex (*Table 1, above*).

5. The prescriber provides documentation according to Table A. supporting all of the following criteria **(a. and b.):**
a. The member is using the requested therapy in combination with healthy dietary changes
b. The member is using the requested therapy in combination with increased physical activityThe member will not be using Saxenda, Wegovy, and 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)

7. If the request is for Saxenda, the member meets all of the following criteria **(a., b., and c.):**
a. The member has experienced and maintained a at least a5% 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. If the member is 18 years of age or older, the member has experienced therapeutic intolerance (specifically, documented severe side effects not resolved by diet modification or dose de-escalation and not anticipated to occur with Wegovy or Saxenda) or contraindication (specifically, documented allergic reaction, hypersensitivity) to plan-preferred Zepbound.

8. If the request is for Wegovy, the member meets all of the following criteria **(a., b., and c.):**
a. The member has experienced and maintained at least a 5% BMI reduction 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.

c. If the member is 18 years of age or older, the member has experienced therapeutic intolerance (specifically, documented severe side effects not resolved by diet modification or dose de-escalation and not anticipated to occur with Wegovy or Saxenda) or contraindication (specifically, documented allergic reaction, hypersensitivity) to plan-preferred Zepbound.

IV. Saxenda, Wegovy, and Zepbound for Adults

A. Initiation

- **< 7 months of previous therapy**

When a benefit, initiation of Saxenda, Wegovy, or Zepbound may be approved when all of the following criteria are met **(1. through 7.)**:

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 provides documentation of all of the following **(a. and b.)**:

a. Baseline height, weight, and BMI.

b. The member meets both of the following criteria **(i. and ii.)**:

i. The member has a baseline BMI ≥ 40 kg/m^2

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

A.) The member has prediabetes, high triglycerides, and low high-density lipoprotein (HDL), demonstrated by all of the following tests within the past six (6) months **(1)., 2)., and 3).):**

1.) Prediabetes demonstrated by one (1) of the following **(a)., b)., or c).):**

a.) A1C of 5.7% to 6.4%

b.) Fasting plasma glucose (FPG) of 100 mg/dL to 125 mg/dL

c.) Oral glucose tolerance test (OGTT) of 140 to 199 mg/dL

2.) Triglycerides ≥ 150 mg/dL

3.) HDL < 40 mg/dL for men, or HDL < 50 mg/dL for women

B.) The member has at least two (2) of the following clinical manifestations of organ dysfunction directly caused by obesity **(1). through 11.).):**

1). Chronic, severe knee or hip pain with joint stiffness and reduced range of motion.

2). One (1) or more of the following cardiovascular diseases *[presence of two separate cardiovascular diseases constitutes two clinical manifestations of organ dysfunction]* **(a). through k).)**:

a). Atrial fibrillation

b). Coronary artery disease

c). Heart failure with preserved ejection fraction (HFpEF) with chronic fatigue or lower limb edema due to impaired diastolic dysfunction

d). Heart failure with reduced ejection fraction (HFrEF) with reduced left ventricular systolic function

e). Hypertension

f). Myocardial infarction

g). Peripheral arterial disease

h). Peripheral vascular disease

i). Pulmonary arterial hypertension

j). Recurrent deep vein thrombosis or pulmonary thromboembolic disease

k). Stroke

3). Idiopathic intracranial hypertension

4). Lower limb lymphedema causing chronic pain and/or reduced range of motion.

5). Male hypogonadism

6). Microalbuminuria with reduced estimated glomerular filtration rate (eGFR)

7). Obstructive sleep apnea

8). Polycystic ovarian syndrome (PCOS), anovulation, or oligo-menorrhea
9). Recurrent or chronic urinary incontinence
10). Reduced lung and/or diaphragmatic compliance resulting in hypoventilation, breathlessness, or wheezing.
11). Significant, age-adjusted limitations of mobility (for example, inability to walk without assistive devices) and/or other basic activities of daily living (for example, dressing and bathing).

4. The prescriber provides documentation according to Table A. supporting all of the following criteria **(a. through d.)**:
   a. The member maintained healthy dietary changes for at least 6 months prior to initiation of the requested therapy
   b. The member maintained increased physical activity for at least 6 months prior to initiation of the requested therapy
   c. The member will use the requested therapy in combination with healthy dietary changes
   d. The member will use the requested therapy in combination with increased physical activity
5. The prescriber attests that the member does NOT have a diagnosis of type 2 diabetes mellitus (ICD-10: E11.9).
6. If the request is for Wegovy or Saxenda, the member has experienced therapeutic intolerance (specifically, documented severe side effects not resolved by diet modification or dose de-escalation and not anticipated to occur with Wegovy or Saxenda) or contraindication (specifically, documented allergic reaction, hypersensitivity) to plan-preferred Zepbound.
7. The member will NOT be using Saxenda, 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)

B. Maintenance

- ≥ **7 months of previous therapy**

When a benefit, continuation therapy of Saxenda, 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 provides documentation 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 both of the following criteria **(i. and ii.)**:
      i. The member has a baseline BMI ≥ 40 kg/m^2
      ii. The member meets one (1) of the following criteria **(A) or B))**:
         A). The member has prediabetes, high triglycerides, and low high-density lipoprotein (HDL), demonstrated by all of the following tests within the past six (6) months **(1)., 2)., and 3).)**:
            1). Prediabetes demonstrated by one (1) of the following **(a)., b)., or c).)**:
               a). A1C of 5.7% to 6.4%
               b). Fasting plasma glucose (FPG) of 100 mg/dL to 125 mg/dL
               c). Oral glucose tolerance test (OGTT) of 140 to 199 mg/dL
            2). Triglycerides ≥ 150 mg/dL
            3). HDL < 40 mg/dL for men, or HDL < 50 mg/dL for women
         B). The member has at least two (2) of the following clinical manifestations of organ dysfunction directly caused by obesity **(1). through 11).)**:
            1). Chronic, severe knee or hip pain with joint stiffness and reduced range of motion.
            2). One (1) or more of the following cardiovascular diseases *[presence of two separate cardiovascular diseases constitutes two clinical manifestations of organ dysfunction]* **(a). through k).)**:
               a). Atrial fibrillation

b). Coronary artery disease
c). Heart failure with preserved ejection fraction (HFpEF) with chronic fatigue or lower limb edema due to impaired diastolic dysfunction
d). Heart failure with reduced ejection fraction (HFrEF) with reduced left ventricular systolic function
e). Hypertension
f). Myocardial infarction
g). Peripheral arterial disease
h). Peripheral vascular disease
i). Pulmonary arterial hypertension
j). Recurrent deep vein thrombosis or pulmonary thromboembolic disease
k). Stroke

3). Idiopathic intracranial hypertension
4). Lower limb lymphedema causing chronic pain and/or reduced range of motion.
5). Male hypogonadism
6). Microalbuminuria with reduced estimated glomerular filtration rate (eGFR)
7). Obstructive sleep apnea
8). Polycystic ovarian syndrome (PCOS), anovulation, or oligo-menorrhea
9). Recurrent or chronic urinary incontinence
10). Reduced lung and/or diaphragmatic compliance resulting in hypoventilation, breathlessness, or wheezing.
11). Significant, age-adjusted limitations of mobility (for example, inability to walk without assistive devices) and/or other basic activities of daily living (for example, dressing and bathing).

4. The prescriber provides documentation according to Table A. supporting all of the following criteria **(a. and b.)**:
- **a.** The member is using the requested therapy in combination with healthy dietary changes
- **b.** The member is using the requested therapy in combination with increased physical activity

5. The member will NOT be using Saxenda, 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. The prescriber attests that the member does NOT have a diagnosis of type 2 diabetes mellitus (ICD-10: E11.9).

7. If the request is for Saxenda, the member meets all of the following criteria **(a., b., and c.)**:
- **a.** The member has experienced and maintained ≥ 7.5% 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.
- **c.** The member has experienced therapeutic intolerance (specifically, documented severe side effects not resolved by diet modification or dose de-escalation and not anticipated to occur with Saxenda) or contraindication (specifically, documented allergic reaction, hypersensitivity) to plan-preferred Zepbound.

8. If the request is for Wegovy, the member meets all of the following criteria **(a., b., and c.)**:
- **a.** The member has experienced and maintained ≥ 7.5% 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.
- **c.** The member has experienced therapeutic intolerance (specifically, documented severe side effects not resolved by diet modification or dose de-escalation and not anticipated to occur with Wegovy) or contraindication (specifically, documented allergic reaction, hypersensitivity) to plan-preferred Zepbound.

9. If the request is for Zepbound, the member meets all of the following criteria **(a. and b.):**
    a. The member has experienced and maintained ≥ 7.5% 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.

V. Wegovy for major adverse cardiovascular events risk reduction

Applies to members with a DE Commercial fully-insured or Healthcare Reform plan without the anti-obesity benefit only

A. Initiation

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

When a benefit, initiation of Wegovy 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 major adverse cardiovascular event risk reduction.
3. The member has a pre-existing diagnosis of at least one (1) of the following **(a., b., or c.)**:
    a. Myocardial infarction (ICD-10: I21)
    b. Stroke (ICD-10: I63)
    c. Peripheral arterial disease (ICD-10: I73.9) with documentation of at least one (1) of the following **(i., ii., or iii.)**:
        i. Intermittent claudication with ankle-brachial index (ABI) less than 0.85 at rest
        ii. Peripheral arterial revascularization procedure
        iii. Amputation due to atherosclerotic disease
4. The prescriber provides documentation substantiating all of the following **(a. and b.)**:
    a. Baseline height, weight, and BMI.
    b. The member has a baseline BMI ≥ 27 kg/m^2
5. The member meets one (1) of the following criteria **(a. or b.)**:
    a. The member will be using Wegovy as an adjunct to all of the following **(i. and ii)**:
        i. Maximally-tolerated statin therapy.
        ii. ezetimibe
    b. The member meets all of the following criteria **(i. and ii)**:
        i. The member is statin intolerant defined as one (1) of the following **(A). or B))**:
            A) While receiving at least two (2) separate trials of different statins, the member experienced one (1) of the following **(1) or 2))**:
                1) Statin related rhabdomyolysis, which resolved upon discontinuation of the statins
                2) Skeletal-related muscle symptoms, which resolved upon discontinuation of the statins
            B) The member experienced one (1) of the following during any course of statin therapy **(1), 2), or 3))**:
                1) Creatinine kinase (CK) increase to 10 times ULN
                2) Liver function tests (LFTs) increase to 3 times ULN
                3) Hospitalization due to severe statin-related adverse event (for example, rhabdomyolysis)
        ii. The member has experienced therapeutic failure, contraindication, or intolerance to ezetimibe monotherapy.
6. The member meets one (1) of the follow criteria **(a. or b.)**:
    a. The member will be using Wegovy as an adjunct to a PCSK9 inhibitor (for example Praluent, Repatha).
    b. The member has experienced therapeutic failure, contraindication, or intolerance to a PCSK9 inhibitor (for example Praluent, Repatha).
7. The prescriber provides documentation according to Table A. supporting all of the following criteria **(a. through d.)**:
    a. The member maintained healthy dietary changes for at least 6 months prior to initiation of the requested therapy

b. The member maintained increased physical activity for at least 6 months prior to initiation of the requested therapy
c. The member will use the requested therapy in combination with healthy dietary changes
d. The member will use the requested therapy in combination with increased physical activity

8. If the member has a diagnosis of Type 2 diabetes (ICD-10: E11.9), the member has experienced therapeutic failure to a preferred GLP-1 RA that is FDA-approved to treat diabetes and FDA-approved for cardiovascular risk reduction (for example Ozempic).
9. The member will not be using 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)

B. Maintenance

- **Maintenance: ≥ 7 months of previous therapy**

When a benefit, continuation and maintenance of Wegovy may be approved when all of the following criteria are met **(1. through 10.)**:
1. The member is 18 years of age or older.
2. The drug is being used for major adverse cardiovascular event risk reduction.
3. The member has a pre-existing diagnosis of at least one (1) of the following **(a., b., or c.)**:
a. Myocardial infarction (ICD-10: I21)
b. Stroke (ICD-10: I63)
c. Peripheral arterial disease (ICD-10: I73.9) with documentation of at least one (1) of the following **(i., ii., or iii.)**:
i. Intermittent claudication with ankle-brachial index (ABI) less than 0.85 at rest
ii. Peripheral arterial revascularization procedure
iii. Amputation due to atherosclerotic disease
4. The prescriber provides documentation substantiating all of the following **(a. and b.)**:
a. Baseline height, weight, and BMI.
b. The member has a baseline BMI ≥ 27 kg/m^2
5. The member meets one (1) of the following criteria **(a. or b.)**:
a. The member will be using Wegovy as an adjunct to all of the following **(i. and ii.)**:
i. Maximally-tolerated statin therapy.
ii. ezetimibe
b. The member meets all of the following criteria **(i. and ii)**:
i. The member is statin intolerant defined as one (1) of the following **(A) or B))**:
A) While receiving at least two (2) separate trials of different statins, the member experienced one (1) of the following **(1) or 2))**:
1) Statin related rhabdomyolysis, which resolved upon discontinuation of the statins
2) Skeletal-related muscle symptoms, which resolved upon discontinuation of the statins
B) The member experienced one (1) of the following during any course of statin therapy **(1), 2), or 3))**:
1) Creatinine kinase (CK) increase to 10 times ULN
2) Liver function tests (LFTs) increase to 3 times ULN
3) Hospitalization due to severe statin-related adverse event (for example, rhabdomyolysis)
ii. The member has experienced therapeutic failure, contraindication, or intolerance to ezetimibe monotherapy.
6. The member meets one (1) of the follow criteria **(a. or b.)**:
a. The member is using Wegovy as an adjunct to a PCSK9 inhibitor (for example Praluent, Repatha).
b. The member has experienced therapeutic failure, contraindication, or intolerance to a PCSK9 inhibitor (for example Praluent, Repatha).

7. The prescriber provides documentation according to Table A. supporting all of the following criteria **(a. and b.)**:
   - **a.** The member is using the requested therapy in combination with healthy dietary changes
   - **b.** The member is using the requested therapy in combination with increased physical activity
8. If the member has a diagnosis of Type 2 diabetes (ICD-10: E11.9), the member has experienced therapeutic failure to a preferred GLP-1 RA that is FDA-approved to treat diabetes and FDA-approved for cardiovascular risk reduction (for example Ozempic).
9. The member will not be using 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)
10. The member meets one (1) of the following criteria **(a. or b.):**
    - **a.** The requested dose is 1.7 mg or 2.4 mg once weekly.
    - **b.** The prescriber attests that the member is titrating to a dose of 1.7 mg or 2.4 mg once weekly.

VI. Zepbound for obstructive sleep apnea

Applies to members with a DE Commercial fully-insured or Healthcare Reform plan without the obesity benefit only

A. Initiation

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

When a benefit, initiation of Zepbound may be approved when all of the following criteria are met **(1. through 10.)**:

1. The member is 18 years of age or older.
2. The medication is prescribed by or in consultation with a sleep specialist.
3. The member has a diagnosis of moderate to severe obstructive sleep apnea/hypopnea syndrome (OSAHS) (ICD-10: G47.33).
4. The prescriber provides documentation substantiating all of the following **(a. and b.):**
   - **a.** Baseline polysomnography or recording time (without use of positive airway pressure [PAP] or oral appliance during testing) demonstrating an apnea/hypopnea index (AHI) ≥ 15 events per hour.
   - **b.** Baseline apnea/hypopnea index (AHI) with use of PAP or oral appliance, as documented by a device report or sleep study.
5. The prescriber provides documentation substantiating all of the following **(a. and b.)**:
   - **a.** Baseline height, weight, and BMI.
   - **b.** The member has a baseline BMI ≥ 30 kg/m^2
6. The member meets one (1) of the following **(a. or b.):**
   - **a.** The prescriber provides documentation substantiating that the member is currently receiving and is compliant with PAP, as documented by a device report demonstrating that the device was used for 70 percent of nights for four or more hours per night, for two or more months.
   - **b.** The member meets all of the following **(i. through iv.):**
     - **i.** The member has experienced therapeutic failure, intolerance, or contraindication to PAP.
     - **ii.** The member is using a custom, titratable, oral appliance.
     - **iii.** The oral appliance is prescribed by, or in consultation with a sleep specialist.
     - **iv.** The prescriber documents that the member has been adherent to the oral appliance.
7. The prescriber provides documentation according to Table A. supporting all of the following criteria **(a. through d.)**:
   - **a.** The member maintained healthy dietary changes for at least 6 months prior to initiation of the requested therapy
   - **b.** The member maintained increased physical activity for at least 6 months prior to initiation of the requested therapy

c. The member will use the requested therapy in combination with healthy dietary changes
d. The member will use the requested therapy in combination with increased physical activity

8. The prescriber provides documentation (specifically, chart notes) supporting both of the following **(a. and b.)**:
a. The member practiced sleep hygiene modifications (for example, sleep positioning to avoid a supine position, avoidance of alcohol and sedatives before bed) for at least 6 months prior to initiation of the requested therapy.
b. The member will use sleep hygiene modifications (for example, sleep positioning to avoid a supine position, avoidance of alcohol and sedatives before bed) in combination with the requested therapy.

9. The member will NOT be using 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)

10. If the member has a diagnosis of Type 2 diabetes (ICD-10: E11.9), the member has experienced therapeutic failure to a preferred GLP-1 RA that is FDA-approved to treat diabetes (for example, Ozempic, Mounjaro).

B. Maintenance

- **Maintenance: ≥ 7 months of previous therapy**

When a benefit, maintenance of Zepbound may be approved when all of the following criteria are met **(1. through 10.)**:

1. The member is 18 years of age or older.
2. The medication is prescribed by or in consultation with a sleep specialist.
3. The member had a diagnosis of moderate to severe obstructive sleep apnea/hypopnea syndrome (OSAHS) (ICD-10: G47.33) prior to initiation of the requested therapy.
4. The prescriber provides documentation substantiating all of the following **(a., b., and c.):**
a. Baseline polysomnography or recording time (without use of positive airway pressure [PAP] or oral appliance during testing) demonstrating an apnea/hypopnea index (AHI) ≥ 15 events per hour, as documented by a sleep study.
b. The baseline apnea/hypopnea index (AHI) with use of PAP or oral appliance, as documented by a sleep study or device report.
c. A decrease of ≥ 25% from baseline (specifically, the baseline with PAP or oral appliance use and prior to initiation of the requested therapy) in the apnea/hypopnea index (AHI), as documented by a PAP device report or sleep study.
d. The member requires additional therapy with the requested agent to maintain the decrease in the apnea/hypopnea index (AHI).
5. The prescriber provides documentation substantiating a baseline BMI ≥ 30 kg/m^2.
6. The prescriber provides documentation according to Table A. supporting all of the following criteria **(a. and b.)**:
a. The member is using the requested therapy in combination with healthy dietary changes
b. The member is using the requested therapy in combination with increased physical activity
7. The prescriber provides documentation (specifically, chart notes) that the member is practicing sleep modifications (for example, sleep positioning to avoid a supine position, avoidance of alcohol and sedatives before bed) in combination with the requested therapy.
8. The member meets one (1) of the following criteria **(a. or b.):**
a. The requested dose is 10 mg, 12.5 mg, or 15 mg once weekly.
b. The prescriber attests the member is titrating to a dose of 10 mg once weekly.
9. The member will NOT be using 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)

10. If the member has a diagnosis of Type 2 diabetes (ICD-10: E11.9), the member has experienced therapeutic failure to a preferred GLP-1 RA that is FDA-approved to treat diabetes (for example, Mounjaro, Ozempic).

VII. 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 or HCR 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 and HCR Plans: If approved, up to the following authorization duration may be granted.

I. **Initiation**: 7 months

II. **Maintenance**: 12 months

Automatic Approval Criteria

None

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