

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 <i>For Anti-Obesity Weight Loss Mgmt Policy = Standard, see policy J-1389.</i> Healthcare Reform: Prior Authorization (1.): Anti-Obesity = Yes* <i>*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.</i>
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	Additional Restriction(s):
Version: J-1388-028	Original Date: 08/07/2024
Effective Date: 07/01/2026	Review Date: 09/16/2026

Drugs Product(s):	• Contrave (bupropion and naltrexone) • Qsymia (phentermine and topiramate extended-release) • Saxenda (liraglutide) • Wegovy (semaglutide) single-dose pen injector • Wegovy HD (semaglutide) single-dose pen injector
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	• Wegovy (semaglutide) oral tablet • Xenical (orlistat) • Zepbound (tirzepatide) • Foundayo (orforglipron)
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/m² or BMI ≥ 27 kg/m² 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/m² or BMI ≥ 27 kg/m² 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/m² or greater for adults (obese) by international cut-offs (Cole Criteria) • Wegovy injection (<i>including Wegovy HD</i>) ○ 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. • Wegovy oral tablets ○ 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 with obesity, or in 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/m² or ≥ 27 kg/m² 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. • Foundayo ○ Indicated in combination with a reduced-calorie diet and increased physical activity 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.
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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. • Foundayo, Saxenda (liraglutide), Wegovy, and Zepbound for Weight Loss ○ Saxenda (liraglutide) is an acylated human glucagon-like peptide-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. ○ 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
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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.

- Foundayo is a novel, orally administered, non-peptide GLP-1 receptor agonist. Unlike injectable GLP-1 receptor agonists, its small molecule structure allows for oral bioavailability and extended action.
- 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/m², 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 major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in patients with CVD. In the landmark Wegovy CV trial, 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/m² and concurrently received heart-healthy lifestyle interventions, including diet and exercise.

- Stroke, MI, peripheral arterial disease, and peripheral vascular disease are all manifestations of coronary artery disease/atherosclerotic cardiovascular disease.

- **Wegovy for MASH**

- Wegovy is a glucagon-like peptide-1 (GLP-1) receptor agonist previously approved to reduce excess body weight and reduce the risk of major adverse cardiovascular events in patients who are overweight and obese. It mimics GLP-1, regulating appetite and insulin secretion, reducing appetite, slowing gastric emptying, and improving glycemic control, resulting in weight loss. Wegovy also reduces fat in the liver by decreasing lipogenesis (the creation of new fat) and increasing lipolysis (the breakdown of existing fat), while also improving insulin sensitivity and glycemic control to reduce the influx of fatty acids into the liver. This has been shown to reduce steatohepatitis and liver fibrosis associated with MASH.
- Patients with MASH, particularly those with advanced fibrosis or cirrhosis, have a substantially increased risk of mortality, with studies indicating a 5-year mortality rate ranging from 10% to 25%. In clinical trials, Wegovy has been shown to slow progression of fibrosis and reverse fibrosis. Reversing fibrosis is associated with a reduced MASH mortality risk.

- **Zepbound for Obstructive Sleep Apnea (OSA)**

- Zepbound has been shown to reduce the apnea-hypopnea index (AHI) in patients with obesity (BMI ≥ 30 kg/m²) 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/m² 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. Respiratory distress index (RDI) includes the total number of apneas, hypopneas, and respiratory effort related arousals (RERAs) during sleep. A score greater than or equal to 15 indicates moderate to severe apnea. Clinical guidelines recommend that objective data from a sleep study should inform a diagnosis of OSA. Respiratory event index (REI) is reported from home studies and represents the number of apneas or hypopneas recorded during the sleep study per hour of recording time. Because the recording time is frequently more than the time spent asleep, sometimes the REI is an underestimate of the AHI. An AHI, RDI, or REI ≥ 15 indicates moderate to severe sleep apnea. (American Academy of Sleep Medicine).
- Home sleep apnea testing (HSAT) is recommended when administered by an accredited sleep center under the supervision of a board-certified sleep physician using a technically adequate device. HSAT is recommended for patients that have an increased risk of moderate to severe OSA that do not have the following: significant cardiopulmonary disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation or high risk of sleep related hypoventilation, history of stroke, chronic opioid medication use, severe insomnia, symptoms of other significant sleep disorder(s), or

environmental or personal factors that preclude the adequate acquisition and interpretation of data from HSAT. For patients that do not meet the previous criteria, a polysomnography (PSG) is recommended.

- OSA can cause disruption in sleep patterns, leading to excessive daytime 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.
- Uncontrolled OSA, especially when compounded by obesity, presents a significant and amplified mortality risk. Patients with severe, untreated OSA face a 2.6-fold increased risk of all-cause mortality, which is even higher for obese individuals. Decreasing the AHI controls OSA and likely lowers mortality risk associated with OSA.
- 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 ≥ 25 kg/m² (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.
 - The World Health Organization (WHO) Guideline on GLP-1 Therapies for Obesity in Adults states that counseling on behavioral and lifestyle changes should be provided as a first step to intensive behavioral therapy when prescribing GLP-1 receptor agonists or GIP/GLP-1 dual agonists.
 - The American Association of Clinical Endocrinology (AACE) Consensus Statement on Obesity/Adiposity-Based Chronic Disease supports the Lancet Commission definition of clinical obesity. They define that ≤ 5% weight loss is an incomplete response to obesity medications that is often insufficient to treat complications. A 5% to < 15% weight loss is a good response, and ≥ 15% weight loss is an excellent response that is sufficient to prevent a broad array of obesity related chronic diseases.
 - The AACE Consensus Statement also states that first generation obesity medications (for example, Contrave, Qsymia, Xenical) may be appropriate first line agents in patients with no obesity related comorbid diseases, or one mild obesity related comorbid disease. In patients with at least one severe obesity related comorbid disease, second generation obesity medications (for example, Wegovy, Zepbound) may be considered first line.
- **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
- Baseline BMI refers to the BMI of a patient within 6 months of initiating the requested medication and/or a GLP-1 medication.
 - In clinical trials for obesity GLP-1 medications, participants with significant weight change within 90 days of trial initiation were excluded. This underscores the importance of the recency of BMI to ensure appropriate use in patients with the FDA-approved indications for the medications.
- 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)

Age (in years)	Male		Female	
	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 95 th 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.
 - **Foundayo, Saxenda (liraglutide), 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 (liraglutide), Wegovy and Zepbound should not be co-administered with any other GLP-1 RA.
- The FDA approved indications for Wegovy differ for the single-dose pen injectors and oral tablets. The highest dose of Wegovy injection is branded as Wegovy HD. Wegovy oral tablets are not approved for use to treat MASH or pediatric obesity.
- The maintenance dosage of Wegovy injection is either 2.4 mg (recommended) or 1.7 mg once weekly for weight loss, cardiovascular risk reduction, and MASH. 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. Adult patients requiring additional weight loss may increase their dose to 7.2 mg once weekly. The 7.2 mg dose is available under the Wegovy HD branding. The 7.2 mg dose is only recommended in patients requiring additional weight loss; it is not a recommended maintenance dose for cardiovascular risk reduction or MASH.
- The recommended starting dosage of Wegovy oral tablets is 1.5 mg taken orally once daily for 30 days. The recommended dose escalation is as follows: for days 31 to 60, take 4 mg daily; for days 61 to 90, take 9 mg daily; for days 90 and beyond, take 25 mg daily. If patients do not tolerate a dose during dosage escalation, consider delaying dosage escalation. The recommended maintenance dosage of Wegovy tablets is 25 mg orally once daily. If patients do not tolerate the 25 mg once daily maintenance dosage, consider switching to Wegovy injection 1.7 mg once weekly.
- 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.
- Foundayo is available in 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, and 17.2 mg doses. Patients should initiate 0.8 mg daily and escalate dosing after at least 30 days to the recommended maintenance dosage of 5.5 mg. Dosage may be increased to the next dosage level (9 mg, 14.5 mg, or 17.5 mg) after at least 30 days on the current dosage, based on treatment response and tolerability. Maximum dosage is 17.2 mg once daily.
- Foundayo, Saxenda (liraglutide), 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 (liraglutide) 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.
- 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.
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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 (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - b. The member's baseline BMI is $\geq 95^{\text{th}}$ percentile standardized for age and sex (*Table 1, above*) (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
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 (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - b. Current age, height, weight, and BMI.
 - c. The member's baseline BMI is ≥ 95th percentile standardized for age and sex (*Table 1, above*) (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
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 (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - b. The member has a baseline BMI ≥ 35 kg/m² (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
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 (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - b. Current height, weight, and BMI.
 - c. The member has a baseline BMI ≥ 35 kg/m² (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
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 $\geq 5\%$ weight loss from baseline

III. Saxenda (liraglutide) or Wegovy injection for Adolescents, and Foundayo, Saxenda (liraglutide), Wegovy injection, Wegovy HD injection, Wegovy oral tablet, and Zepbound for Adults who Initiated Saxenda (liraglutide) or Wegovy as Adolescents

A. Initiation

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

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

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 (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
4. The member meets one (1) of the following criteria (**a. or b.**):
 - a. The member has a BMI ≥ 35 (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - b. The member has a BMI that is $\geq 120\%$ of the 95th percentile for age and sex (*Table 1, above*) (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
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 (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)
8. If the request is for brand Saxenda, the member has experienced therapeutic failure or intolerance to plan-preferred generic liraglutide.

B. Maintenance

- **≥ 7 months of previous therapy**

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

1. The member meets one (1) of the following criteria **(a. or b.)**:
 - a. If the request is for Wegovy injection or Saxenda (liraglutide), the member is 12 years of age or older.
 - b. If the request is for Foundayo, Wegovy HD injection, Wegovy oral tablet, or Zepbound, 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)
3. The prescriber provides documentation of all of the following **(a. and b.)**:
 - a. Baseline age, height, weight, and BMI (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - 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 BMI ≥ 35 (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - b. The member had a baseline BMI that is $\geq 120\%$ of the 95th percentile standardized for age and sex (*Table 1, above*) (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
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 activity
6. The member will not be using Saxenda (liraglutide), 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. The member has experienced and maintained at least a 5% BMI reduction from baseline.
8. The requested dose of the medication meets one (1) of the following criteria **(a. through e.)**:
 - a. If the request is for Saxenda (liraglutide), 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. If the request is for Wegovy injection, the member meets one (1) of the following criteria **(i., ii., or iii.)**:
 - i. If the member is 17 years of age or younger, the requested dose is 1.7 mg or 2.4 mg once weekly.
 - ii. If the member is 18 years of age or older, the requested dose is 1.7 mg, 2.4 mg, or 7.2 mg.
 - iii. The prescriber attests the member is titrating to one of the above age-appropriate maintenance doses.
 - c. If the request is for Wegovy oral tablet, the member meets one (1) of the following criteria **(i. or ii.)**:
 - i. The requested dose is 25 mg once daily.
 - ii. The prescriber attests that the member is titrating to a dose of 25 mg once daily.
 - d. If the request is for Foundayo, the member meets one (1) of the following criteria **(i. or ii.)**:
 - i. The requested dose is 5.5 mg, 9 mg, 14.5 mg, 17.5 mg.
 - ii. The prescriber attests the member is titrating to a dose of 5.5 mg, 9 mg, 14.5 mg, or 17.5 mg daily.
 - e. If the request is for Zepbound, 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 Foundayo, Saxenda (liraglutide), or Wegovy and 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 the requested agent) or contraindication (specifically, documented allergic reaction, hypersensitivity) to plan-preferred Zepbound.
- 10. If the request is for brand Saxenda, the member has experienced therapeutic failure or intolerance to plan-preferred generic liraglutide.

IV. Saxenda (liraglutide), Foundayo, Wegovy injection, Wegovy HD injection, Wegovy oral tablet, and Zepbound for Adults

A. Initiation

- **< 7 months of previous therapy**

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

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 (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - b. The member meets both of the following criteria **(i. and ii.)**:
 - i. The member has a baseline BMI $\geq 40 \text{ kg/m}^2$ (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - ii. The member meets one (1) of the following criteria **(A), (B), or (C))**:
 - A) The member has prediabetes, high triglycerides, and low high-density lipoprotein (HDL), demonstrated by all of the following tests (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*) **(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 $\geq 150 \text{ mg/dL}$
 - 3) HDL $< 40 \text{ mg/dL}$ for men, or HDL $< 50 \text{ mg/dL}$ for women
 - B) The member has one (1) of the following clinical manifestations of organ dysfunction directly caused by obesity **(1) through 7))**:
 - 1) Coronary artery disease
 - 2) Metabolic dysfunction-associated steatohepatitis with moderate to advanced (F2 to F3) liver fibrosis
 - 3) Myocardial infarction
 - 4) Stroke
 - 5) Peripheral arterial disease
 - 6) Peripheral vascular disease
 - 7) Moderate to severe obstructive sleep apnea
 - C) The member has at least two (2) of the following clinical manifestations of organ dysfunction directly caused by obesity **(1) through 10))**:
 - 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 f))**:
 - a) Atrial fibrillation

- b) Heart failure with preserved ejection fraction (HFpEF) with chronic fatigue or lower limb edema due to impaired diastolic dysfunction
 - c) Heart failure with reduced ejection fraction (HFrEF) with reduced left ventricular systolic function
 - d) Hypertension
 - e) Pulmonary arterial hypertension
 - f) Recurrent deep vein thrombosis or pulmonary thromboembolic disease
 - 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) Polycystic ovarian syndrome (PCOS), anovulation, or oligo-menorrhea
 - 8) Recurrent or chronic urinary incontinence
 - 9) Reduced lung and/or diaphragmatic compliance resulting in hypoventilation, breathlessness, or wheezing.
 - 10) 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 member will NOT be using Foundayo, 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. 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 Foundayo, Wegovy or Saxenda (liraglutide), 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 Foundayo, Wegovy or Saxenda (liraglutide)) or contraindication (specifically, documented allergic reaction, hypersensitivity) to plan-preferred Zepbound.
8. If the request is for brand Saxenda, the member has experienced therapeutic failure or intolerance to plan-preferred generic liraglutide.

B. Maintenance

- **≥ 7 months of previous therapy**

When a benefit, continuation therapy of Saxenda (liraglutide), Foundayo, Wegovy, or 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 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 (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - 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/m² (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - ii. The member meets one (1) of the following criteria **(A), (B), or (C)**):
 - A)** The member has prediabetes, high triglycerides, and low high-density lipoprotein (HDL), demonstrated by all of the following tests (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*). **(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 had one (1) of the following clinical manifestations of organ dysfunction directly caused by obesity at baseline **(1) through 7))**:
 - 1) Coronary artery disease
 - 2) Metabolic dysfunction-associated steatohepatitis with moderate to advanced (F2 to F3) liver fibrosis
 - 3) Myocardial infarction
 - 4) Stroke
 - 5) Peripheral arterial disease
 - 6) Peripheral vascular disease
 - 7) Moderate to severe obstructive sleep apnea
 - C)** The member had at least two (2) of the following clinical manifestations of organ dysfunction directly caused by obesity at baseline **(1) through 10))**:
 - 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 f))**:
 - a) Atrial fibrillation
 - b) Heart failure with preserved ejection fraction (HFpEF) with chronic fatigue or lower limb edema due to impaired diastolic dysfunction
 - c) Heart failure with reduced ejection fraction (HFrEF) with reduced left ventricular systolic function
 - d) Hypertension
 - e) Pulmonary arterial hypertension
 - f) Recurrent deep vein thrombosis or pulmonary thromboembolic disease
 - 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) Polycystic ovarian syndrome (PCOS), anovulation, or oligo-menorrhea
 - 8) Recurrent or chronic urinary incontinence
 - 9) Reduced lung and/or diaphragmatic compliance resulting in hypoventilation, breathlessness, or wheezing.
 - 10) 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 Foundayo, 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. The prescriber attests that the member does NOT have a diagnosis of type 2 diabetes mellitus (ICD-10: E11.9).
7. The member has experienced and maintained $\geq 7.5\%$ weight loss from baseline.
8. The requested dose of the medication meets one (1) of the following criteria **(a. through e.)**:
 - a. If the request is for Saxenda (liraglutide), 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. If the request is for Wegovy injection, the member meets one (1) of the following criteria **(i. or ii.)**:
 - i. The requested dose is 1.7 mg, 2.4 mg, or 7.2 mg.
 - ii. The prescriber attests the member is titrating to a dose of 1.7 mg, 2.4 mg, or 7.2 mg.
 - c. If the request is for Wegovy oral tablet, the member meets one (1) of the following criteria **(i. or ii.)**:
 - i. The requested dose is 25 mg once daily.
 - ii. The prescriber attests that the member is titrating to a dose of 25 mg once daily.
 - d. If the request is for Foundayo, the member meets one (1) of the following criteria **(i. or ii.)**:
 - i. The requested dose is 5.5 mg, 9 mg, 14.5 mg, 17.5 mg.
 - ii. The prescriber attests the member is titrating to a dose of 5.5 mg, 9 mg, 14.5 mg, or 17.5 mg daily.
 - e. If the request is for Zepbound, 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 Foundayo, Wegovy or Saxenda (liraglutide), 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 Foundayo, Wegovy or Saxenda (liraglutide)) or contraindication (specifically, documented allergic reaction, hypersensitivity) to plan-preferred Zepbound.
10. If the request is for brand Saxenda, the member has experienced therapeutic failure or intolerance to plan-preferred generic liraglutide.

V. Wegovy injection or Wegovy oral tablet 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 injection or Wegovy oral tablet 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 (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - b. The member has a baseline BMI ≥ 27 kg/m² (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
- 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 following 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 injection or Wegovy oral tablet may be approved when all of the following criteria are met **(1. through 11.)**:

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 at baseline **(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 (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - b. The member has a baseline BMI ≥ 27 kg/m² (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
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 following 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. If the request is for Wegovy injection, 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 the member is titrating to a dose of 1.7 mg or 2.4 mg once weekly.
- 11. If the request is for Wegovy oral tablet, the member meets one (1) of the following criteria (**a. or b.**):
 - a. The requested dose is 25 mg once daily.
 - b. The prescriber attests that the member is titrating to a dose of 25 mg once daily.

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, recording time, or home sleep apnea test (without use of positive airway pressure [PAP] or oral appliance during testing) demonstrating an apnea/hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI) ≥ 15 events per hour.
 - b. Baseline AHI, RDI, or REI 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 (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
 - b. The member has a baseline BMI ≥ 30 kg/m² (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
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. through d.)**:
 - a. Baseline polysomnography, recording time, or home sleep apnea test (without use of positive airway pressure [PAP] or oral appliance during testing) demonstrating an apnea/hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI) ≥ 15 events per hour, as documented by a sleep study.
 - b. The baseline AHI, RDI, or REI with use of PAP or oral appliance, as documented by a sleep study or device report.
 - c. The member meets one (1) of the following criteria **(i. or ii.)**:
 - i. A decrease of $\geq 25\%$ from baseline (specifically, the baseline with PAP or oral appliance use and prior to initiation of the requested therapy) in the AHI, RDI, or REI as documented by a PAP device report or sleep study.
 - ii. If the baseline AHI/RDI/REI with PAP or oral appliance use prior to the initiation of the requested therapy was 0, then the AHI/RDI/REI remained at 0, 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 AHI, RDI, or REI.
5. The prescriber provides documentation substantiating a baseline BMI ≥ 30 kg/m² (*specifically, within 6 months of the initial request date or the initiation date of a weight loss/GLP-1 medication used without a substantial gap in therapy*).
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. 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.
- II. 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.
- III. 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

References:

1. Qsymia [package insert]. Campbell, CA: Vivus, Inc.; September 2024.
2. Contrave [package insert]. La Jolla, CA: Nalpropion Pharmaceuticals LLC; April 2021.
3. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk; June 2022.
4. Wegovy [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S; March 2026.
5. Xenical [package insert]. Greifswald, Germany: Cheplapharm Arzneimittel GmbH; January 2018.
6. Zepbound [package insert]. Indianapolis, IN: Lilly USA, LLC; December 2024.
7. Foundayo [package insert]. Indianapolis, IN: Lilly USA, LLC; April 2026.
8. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2023.
9. Guidelines for the Management of Overweight and Obesity in Adults (2013). Accessed April 20, 2019.
10. Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: international survey. *BMJ*. 2000;320(7244):1240-1243.
11. Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for Comprehensive Medical Care

- of Patients with Obesity-Executive Summary. American Association of Clinical Endocrinologists. Published July 1, 2016. Accessed June 05, 2019.
12. 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.
 13. Seger JC, Horn DB, Westman EC, et al. Obesity Algorithm, presented by the American Society of Bariatric Physicians. Obesity Medicine Association. 2015. Accessed April 20, 2020.
 14. 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.
 15. Lincoff AM, Brown-Frandsen K, Colhoun HM, et al. Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. *N Engl J Med*. 2023 Dec 14;389(24):2221-2232.
 16. Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of obesity and severe obesity among adults: United States, 2017–2018. NCHS Data Brief, no 360. Hyattsville, MD: National Center for Health Statistics. 2020
 17. Kitahara CM, Flint AJ, Berrington de Gonzalez A, et al. Association between class III obesity (BMI of 40–59 kg/m²) and mortality: a pooled analysis of 20 prospective studies. *PLoS Med*. 2014 Jul 8;11(7):e1001673.
 18. Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity. *Pediatrics*. 2023 Feb 1;151(2):e2022060640.
 19. Drucker DJ. GLP-1 physiology informs the pharmacotherapy of obesity. *Mol Metab*. 2022 Mar;57:101351.
 20. 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.
 21. Dicker D, Greenland P, Leibowitz M, et al. All-Cause Mortality of Patients With and Without Diabetes Following Bariatric Surgery: Comparison to Non-surgical Matched Patients. *Obes Surg*. 2021 Feb;31(2):755-762.
 22. Dicker D, Sagy YW, Ramot N, et al. Bariatric Metabolic Surgery vs Glucagon-Like Peptide-1 Receptor Agonists and Mortality. *JAMA Netw Open*. 2024 Jun 3;7(6):e2415392.
 23. Stenberg E, Näslund E. Major adverse cardiovascular events among patients with type-2 diabetes, a nationwide cohort study comparing primary metabolic and bariatric surgery to GLP-1 receptor agonist treatment. *Int J Obes (Lond)*. 2023 Apr;47(4):251-256.
 24. Syn NL, Cummings DE, Wang LZ, et al. Association of metabolic-bariatric surgery with long-term survival in adults with and without diabetes: a one-stage meta-analysis of matched cohort and prospective controlled studies with 174 772 participants. *Lancet*. 2021 May 15;397(10287):1830-1841.
 25. Yan G, Wang J, Zhang J, et al. Long-term outcomes of macrovascular diseases and metabolic indicators of bariatric surgery for severe obesity type 2 diabetes patients with a meta-analysis. *PLoS One*. 2019 Dec 3;14(12):e0224828.
 26. Patil SP, Ayappa IA, Caples SM, et al. Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. 2019 Feb 15;15(2):335-343.
 27. Kim AM, Keenan BT, Jackson N, et al. Tongue fat and its relationship to obstructive sleep apnea. *Sleep*. 2014 Oct 1;37(10):1639-48.
 28. Pahkala R, Seppä J, Ikonen A, Smirnov G, Tuomilehto H. The impact of pharyngeal fat tissue on the pathogenesis of obstructive sleep apnea. *Sleep Breath*. 2014 May;18(2):275-82.
 29. Hudgel DW, Patel SR, Ahasic AM, et al. The Role of Weight Management in the Treatment of Adult Obstructive Sleep Apnea. An Official American Thoracic Society Clinical Practice Guideline. *Am J Respir Crit Care Med*. 2018 Sep 15;198(6):e70-e87.
 30. Epstein LJ, Kristo D, Strollo PJ Jr, et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. 2009 Jun 15;5(3):263-76.

31. Ramar K, Dort LC, Katz SG, et al. Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015. *J Clin Sleep Med*. 2015 Jul 15;11(7):773-827.
32. American Diabetes Association Professional Practice Committee. 10. Cardiovascular Disease and Risk Management: Standards of Care in Diabetes-2025. *Diabetes Care*. 2025 Jan 1;48(Supplement_1):S207-S238.
33. Rubino F, Cummings DE, Eckel RH, et al. Definition and diagnostic criteria of clinical obesity. *Lancet Diabetes Endocrinol*. 2025 Mar;13(3):221-262.
34. Kapur, VK, Auckley DH, Chowduri S, et al. Clinical Practice Guideline for the Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. 2017;13(3):479-504.
35. Young T, Finn L, Peppard PE, et al. Sleep disordered breathing and mortality: eighteen-year follow-up of the Wisconsin sleep cohort. *Sleep*. 2008 Aug;31(8):1071-8.
36. Estes C, Razavi H, Loomba R, et al. Modeling the epidemic of nonalcoholic fatty liver disease demonstrates an exponential increase in burden of disease. *Hepatology*. 2018 Jan;67(1):123-133.
37. Nadolsky K, Garvey WT, Agarwal M, et al. American Association of Clinical Endocrinology Consensus Statement: Algorithm for the Evaluation and Treatment of Adults with Obesity/Adiposity-Based Chronic Disease - 2025 Update. *Endocr Pract*. 2025 Nov;31(11):1351-1394. Celletti F, Farrar J, De Regil L. World Health Organization Guideline on the Use and Indications of Glucagon-Like Peptide-1 Therapies for the Treatment of Obesity in Adults. *JAMA*. 2025 Dec 1. doi: 10.1001/jama.2025.24288.

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.

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