Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH047.1225	**MISCELLANEOUS** **WEIGHT MANAGEMENT MEDICATIONS** See Table 1 for medications covered by policy
Effective Date: 2/1/2026	**Review/Revised Date**: 10/22, 03/23, 09/23, 03/24, 08/24, 12/24, 01/25, 04//25, 09/25, 01/26 (KN)
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Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA)-Approved Indications

REQUIRED MEDICAL INFORMATION:
For initiation of therapy:

1. For weight management:
    a. Member's benefit provides coverage for weight management medications
    b. Phentermine is covered for members with coverage for weight management medications
    c. For all other medications:
        i. For adults, one of the following:
            1) Body mass index (BMI) of at least 30
            2) BMI of at least 27 with the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, obstructive sleep apnea, cardiovascular disease)
            3) BMI of at least 25 for members of South Asian, Chinese, other Asian, Middle Eastern, Black African, or African-Caribbean, Native Hawaiian, Pacific Islanders, or American Indians/Alaska Natives descent
        ii. For pediatrics, one of the following:
            1) BMI of at least 30
            2) BMI in the 95th percentile or greater, standardized for age and sex

3) BMI in the 85th percentile or greater, standardized for age and sex with the presence of at least one weight-related comorbidity (e.g., hypertension, dyslipidemia, type 2 diabetes, obstructive sleep apnea)

2. For the reduction of major adverse cardiovascular (CV) events in patients with established cardiovascular disease (Wegovy only):
    a. Member's benefit provide coverage for weight management medication
    b. History of one of the following:
        i. Myocardial infarction
        ii. Stroke
        iii. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease
    c. Patient has a BMI of at least 27 (or BMI of at least 25 for members of South Asian, Chinese, other Asian, Middle Eastern, Black African, or African-Caribbean, Native Hawaiian, Pacific Islanders, or American Indians/Alaska Natives descent)
    d. The patient will use optimized pharmacotherapy for established cardiovascular disease in combination with the requested agent
3. For moderate to severe obstructive sleep apnea (Zepbound only):
    a. Member's benefit provide coverage for weight management medication
    b. Diagnosis of obesity as defined by body mass index (BMI) of at least 30
    c. Diagnosis of moderate to severe obstructive sleep apnea as defined by both of the following:
        i. Polysomnography (PSG) or home sleep apnea test
        ii. Apnea-hypopnea index (AHI; the number of apneas and hypopneas during an hour of sleep) greater than or equal to 15 events per hour prior to initiation of pharmacotherapy
4. For metabolic dysfunction associated steatohepatitis (MASH) (Wegovy injectable only):
    a. Stage F2, or F3 fibrosis as confirmed by both of the following prior to starting therapy:
        i. FIB-4 score consistent with stage F2, or F3 fibrosis adjusted for age
        ii. One of the following:
            1) Liver biopsy
            2) Vibration-controlled transient elastography (VCTE)
            3) Enhanced liver fibrosis (ELF) score
            4) Magnetic resonance elastography (MRE)
    b. One of the following:
        i. BMI greater than 25

ii. BMI greater than 23 for members of South Asian, Chinese, other Asian, Middle Eastern, Black African, or African-Caribbean, Native Hawaiian, Pacific Islanders, or American Indians/Alaska Natives descent

c. One of the following:
   i. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits)
   ii. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits)
d. Patient does not have any of the following:
   i. Decompensated cirrhosis
   ii. Moderate to severe hepatic impairment (Child-Pugh Class B or C)
   iii. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis

For continuation of therapy:

1. Patient has previous authorization for coverage with the plan or attestation from provider that coverage was provided through another health plan (new start to this plan)
   Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy
   a. For weight management: Patient achieved and maintained the following weight loss:
      i. Adult patients:
         1) For Qsymia, Wegovy, and Zepbound: at least a 5% weight loss from baseline body weight while on the requested medication
         2) For Saxenda: at least a 4% weight loss from baseline body weight while on the requested medication
      ii. Pediatric patients:
         1) For Qsymia, Wegovy, and Zepbound: at least a 5% BMI reduction from baseline while on the requested medication
         2) For Saxenda: at least a 1% BMI reduction from baseline while on the requested medication
2. For cardiovascular risk reduction:

   a. Patient has clinical benefit from medication
   b. Patient will use optimized pharmacotherapy for established cardiovascular disease in combination with the requested agent
3. For moderate to severe obstructive sleep apnea: Patient has clinical benefit from the requested agent (e.g., reduction in AHI, decrease in Epworth Sleepiness Scale)
4. For MASH:
   a. Patient has had clinical benefit
   b. One of the following:
      i. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits)
      ii. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits)
   c. Patient does not have any of the following:
      i. Decompensated cirrhosis
      ii. Moderate to severe hepatic impairment (Child-Pugh Class B or C)
      iii. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis

For Intel members: Wegovy, Zepbound, or Saxenda may be covered if the following criteria are met:

1. For initiation of therapy, member must meet clinical criteria outlined above and be enrolled in the group's designated behavioral modification program (BMP), Omada. Approval will be for six months.
2. For continuation of therapy (after six months), member must meet clinical criteria outlined above and have participated in the group's designated BMP program, Omada, defined as completion of 16 lessons over the six-month period (not to exceed more than four lessons per month)

EXCLUSION CRITERIA:

Concurrent use with another GLP-1 receptor agonist for any indication or another weight loss agent

AGE RESTRICTIONS:

Per FDA label for the requested medication

PRESCRIBER RESTRICTIONS:
For MASH: Must be prescribed by, or in consultation with, a hepatologist or gastroenterologist

COVERAGE DURATION:
Initial authorization and reauthorization will be approved for one year

QUANTITY LIMIT:
- Zepbound: Four injections per 28 days
- Saxenda: 15 mL per 30 days (up to 3 mg per day)
- Wegovy: Four injections per 28 days, one tablet per day
- Qsymia: One capsule per day

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Semaglutide (Wegovy) and liraglutide (Saxenda) are glucagon-like peptide-1 (GLP-1) receptor agonists. Tirzepatide (Zepbound) is a GLP-1 and gastric inhibitory polypeptide (GIP) receptor agonist. The active ingredients are also approved for use in diabetes mellitus (at lower does) and have been shown to promote weight loss in these patient populations. These medications increase satiety by delaying gastric emptying, thereby reducing hunger. GLP-1 agonists should not be used in patients with medullary thyroid cancer (MTC) history or multiple endocrine neoplasia type 2 (MEN 2) history.[1]

Phentermine is an amphetamine-like medication that suppresses appetite by action of catecholamines in the hypothalamus. It is available as monotherapy (generic) and in a combination product with topiramate (Qsymia). It is not completely understood how topiramate acts in weight management but is believed to be due to effects of appetite suppression and satiety enhancement. This agent should not be used in pregnant patients, those with glaucoma or hyperthyroidism, and used with caution

for patients with history of cardiovascular disease, uncontrolled hypertension or seizures.[1]

Setmelanotide (Imcivree) is approved for weight management for obesity due to specific genetic conditions. Due to the specific and complex diagnostic criteria required for the indicated genetic conditions, Imcivree is not included in this policy and is instead addressed in the "Medications for Rare Indications" clinical policy.

FDA APPROVED INDICATIONS:

Table 1. Medications Applicable to this Policy and their FDA-approved indications

Medication	FDA Indication
Tirzepatide (Zepbound)	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 • To treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity *Limitation of Use:* • Contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.

Semaglutide injectable (Wegovy)	In combination with a reduced calorie diet and increased physical activity:
	• To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV 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
	• For the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults
	The indication for MASH is approved under accelerated approval based on improvement of MASH and fibrosis. Continued approval for this indication may be contingent upon the verification and description of clinical benefit in a confirmatory trial
	
	Limitations of Use:
	• Concomitant use with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended

Semaglutide tablet (Wegovy)	In combination with a reduced calorie diet and increased physical activity: • To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV 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 *Limitations of Use:* Concomitant use with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended
Liraglutide (Saxenda)	In combination with a reduced calorie diet and increased physical activity for chronic weight management in: • Adults and pediatric patients aged 12 years and older with body weight greater than 60 kg and obesity • Adults with overweight in the presence of at least one weight-related comorbid condition *Limitation of Use:* • Contains liraglutide and should not be coadministered with other liraglutide-containing products or with any other GLP-1 receptor agonist • The safety and effectiveness in pediatric patients with type 2 diabetes have not been established
Phentermine/ topiramate (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 *Limitations of Use:* • The effect of QSYMIA on cardiovascular morbidity and mortality has not been established • The safety and effectiveness of QSYMIA in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established
Phentermine	A short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity for patients with an initial body mass index ≥30 kg/m2, or ≥27 kg/m2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). The limited usefulness of agents of this class, including phentermine should be measured against possible risk factors inherent in their use.

POSITION STATEMENT:

Obesity is a chronic condition that is associated with developing multiple health consequences, such as type 2 diabetes, metabolic dysfunction-associated steatohepatitis (MASH), and cardiovascular disease. Weight management is a complicated process without many effective pharmacotherapy options, until recent approvals for drugs like tirzepatide (Zepbound), liraglutide (Saxenda), and semaglutide (Wegovy).

The goal of managing weight is to lower the risk of weight-related complications, thereby improving health. Lifestyle and behavioral modifications are an integral aspect of weight management programs and are imperative for long-term success. Pharmacotherapy is used to supplement these lifestyle changes and should not be relied upon as monotherapy for weight management.

Weight Management Guidelines

Endocrine Society Pharmacological Management of Obesity (2016)[2] and Obesity Canada Clinical Practice Guidelines[3]

- Diet, exercise, and behavioral modification are essential components of obesity management and may result in 3-5% body weight reduction alone
- Pharmacological therapy should be considered for patients with BMI ≥30 or BMI ≥27 with comorbid medical conditions(s), such as hypertension, dyslipidemia, type 2 diabetes, and obstructive sleep apnea
- Patients with uncontrolled hypertension or a history of heart disease should not use sympathomimetic agents (e.g., phentermine)
- If response to medication is considered successful (at least 5% reduction in body weight at three months and safe for the patient), medication should be continued; medications do not change the underlying physiology of weigh regulation
- If response is deemed ineffective, medication should be discontinued, and alternative therapy tried

Weight Management in Children

The prevalence of obesity and severe obesity in the United States has increased to more than 4.5 million children and adolescents having severe obesity in 2017-2018. Body Mass Index (BMI) is used as a screening tool to identify possible weight concerns in children. A BMI equal to or greater than the 95th percentile for age and weight is considered obese. However, it is important to take into consideration factors that may affect an individual's results when compared to other children, such as parents' body size or the level of physical maturity.[7-9] The 2023 American Academy of Pediatrics (AAP) guidelines recommend use of weight loss medications in conjunction with lifestyle changes when appropriate. They also stress the importance of treating comorbidities to improve overall health.[9]

Wegovy, Saxenda and Qsymia are approved in children 12 years and older.

- Use of Wegovy is supported by a 68-week, double-blind, placebo-controlled clinical trial in 201 pediatric patients aged 12 years and older with a BMI corresponding to ≥95th percentile for age and sex and from studies in adult patients with obesity. There are insufficient data in pediatric patients with type 2 diabetes treated with Wegovy for obesity to determine if there is an increased risk of hypoglycemia with Wegovy treatment similar to that reported in adults.[1]
- The safety and effectiveness of Saxenda as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management have been established in pediatric patients aged 12 years and older with body weight above 60 kg and an initial BMI corresponding to 30 kg/m^2 or greater for adults (obese) by international cut-offs. Use of Saxenda for this indication is supported by a 56-week double-blind, placebo-controlled clinical trial in 251 pediatric patients aged 12 to 17 years, a pharmacokinetic study in pediatric patients, and studies in adults with obesity.[1]
- The safety and effectiveness of Qsymia as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients aged 12 years and older with a BMI in the 95th percentile or greater standardized for age and sex have been established. Use of Qsymia for this indication is supported by a 56-week, double-blind, placebo-controlled study in 223 pediatric patients aged 12 years and above, a pharmacokinetic study in pediatric patients, and studies in adults with obesity.[1]

Institute for Clinical and Economic Review (ICER)
"Medications for Obesity Management: Effectiveness and Value" Evidence Report[4] published August 2022 includes pharmacologic treatments: semaglutide, liraglutide, naltrexone/bupropion, and phentermine/topiramate extended-release.

All medications showed improved efficacy over lifestyle modification alone. A conducted network meta-analysis for patients with obesity alone (no comorbid diabetes) concluded that semaglutide showed the best efficacy for weight loss at one year; it is considered superior to all medications in the review when compared to placebo

Table 3.11. NMA Results of Medications for the Management of Obesity, Mean Percentage Weight Loss from Baseline at One Year (95% CI)

Semaglutide				
-4.6 (-2.4 to -7.2)	Phentermine/ Topiramate*			
-8.7 (-7.3 to -10.4)	-4.1 (-1.9 to -6.3)	Liraglutide		
-9.1 (-7.2 to -11.5)	-4.5 (-2.2 to -6.9)	-0.4 (-2.3 to +1.3)	Bupropion/ Naltrexone	
-13.7 (-12.6 to -15.1)	-9.1 (-7.1 to -11)	-5.0 (-3.9 to -6.1)	-4.6 (-3.0 to -6.0)	Placebo

Legend: Each cell represents estimated absolute differences in percentage weight loss and 95% credible interval for the combined direct and indirect comparisons between two medications or one medication and placebo. Estimates in bold indicate the 95% credible interval does not contain 1.

*High dose.

Discontinuation rates for these medications were also higher than placebo; semaglutide was found to have lower discontinuation rates than liraglutide, phentermine/topiramate, and bupropion/naltrexone (these results were not considered statistically significant).

Overall conclusions in the report are:

- Semaglutide is considered “comparable or incremental” (moderate certainty of a comparable or small net health benefit with high certainty of at least a comparable net health benefit) to liraglutide and phentermine/topiramate
- Semaglutide is considered “comparable or better” (moderate certainty of a comparable, small, or substantial net health benefit with high certainty of at least a comparable net health benefit) to bupropion/naltrexone

National Institute for Health and Care Excellence (NICE)

Technology Appraisal Guidance: Naltrexone–bupropion for managing overweight and obesity (2017, reaffirmed 2020)[5]

- “Naltrexone–bupropion is not recommended within its marketing authorization for managing overweight and obesity in adults alongside a reduced-calorie diet and increased physical activity.” This recommendation is due to unclear long-term effectiveness and uncertain cost-effectiveness

Technology Appraisal Guidance: Semaglutide for managing overweight and obesity (March 2023, updated September 2023)[6]

- Recommend as an option for adults for weight management that include diet and exercise
- Considered cost-effective for patients with one or more weight-related comorbidity and:

  - BMI of at least 35, or
  - BMI 30-34.9 who qualify for referral to a specialist weight management service through NICE
    Note: Recommended to use lower BMI thresholds (usually reduced by 2.5) for people with South Asian, Chinese, other Asian, Middle Eastern, and Black African or Caribbean backgrounds
- Maximum two years of utilization
- Considered ineffective if <5% body weight reduction within six months

Obstructive Sleep Apnea in Adults
Zepbound (tirzepatide) is approved to treat obstructive sleep apnea in adults with obesity, in combination with a reduced calorie diet and increased physical activity.

  - Use of Zepbound for this indication is supported by two 52-week, double-blind, randomized, controlled trials in adults with moderate-to-severe obstructive sleep apnea and obesity (SURMOUNT-OSA).[10]

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