

Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCEND092.0626	ENDOCRINE AND METABOLIC DRUGS GLP-1 RECEPTOR AGONISTS AND RELATED MEDICATIONS FOR NON- DIABETES INDICATIONS See Table 1 for medications covered by policy
Effective Date: 7/1/2026	Review/Revised Date: 09/23, 03/24, 08/24, 12/24, 4/25, 09/25, 01/26, 03/26, 06/26 (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:

Medicaid

POLICY CRITERIA:

COVERED USES:

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services when all applicable indication-specific criteria below are met or if the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit applies.

REQUIRED MEDICAL INFORMATION:

For initiation of therapy:

1. For weight management, must meet all the following criteria (a and b):
 - a. Patient is eligible for EPSDT review with documentation that condition is of sufficient severity that it impacts the patient’s health (such as quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.)
 - b. Documentation of current height and weight (measured within the previous month) indicating one of the following:
 - i. For adults, one of the following:
 - 1) Body mass index (BMI) of at least 30 (or 25 for patients of Asian, Middle Eastern, Black African, African-Caribbean, Native Hawaiian, Pacific Islander, or American Indian/Alaskan Native descent)
 - 2) BMI of at least 27 with at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus,

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- dyslipidemia, obstructive sleep apnea, cardiovascular disease)
- 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 at least one weight-related comorbidity (e.g., hypertension, dyslipidemia, type 2 diabetes, obstructive sleep apnea)
 2. For reduction of cardiovascular (CV) risk in patients with established CV disease (Wegovy only), must meet all the following criteria (a-c):
 - a. 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
 - b. Patient has a BMI of at least 27 (or 25 for patients of Asian, Middle Eastern, Black African, African-Caribbean, Native Hawaiian, Pacific Islander, or American Indian/Alaskan Native descent)
 - c. The patient will use optimized pharmacotherapy for established cardiovascular disease in combination with the requested agent
 3. For obstructive sleep apnea (OSA) (Zepbound only), must meet all the following criteria (a, b, and c):
 - a. Diagnosis of moderate to severe obstructive sleep apnea confirmed by polysomnography (PSG) or home sleep apnea test
 - b. 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
 - c. Current BMI (within the last 30 days) of at least 30
 4. For metabolic dysfunction-associated steatohepatitis (MASH) (formerly known as nonalcoholic steatohepatitis [NASH]) (Wegovy regular [non-HD] injectable only), must meet all the following criteria (a-c):
 - a. Stage F2 or F3 fibrosis as confirmed by one of the following prior to starting therapy with the requested agent:
 - i. Liver biopsy
 - ii. Vibration-controlled transient elastography (VCTE)

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- iii. Enhanced liver fibrosis (ELF) score
- iv. Magnetic resonance elastography (MRE)
- b. One of the following:
(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)
 - i. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day
 - ii. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day
- 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)
- 5. For Zepbound injection or vial: Medical rationale to support not using the preferred formulation, Zepbound KwikPen

For continuation of therapy:

(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)

- 1. For weight management:
 - a. Patient remains eligible for EPSDT review
 - b. Patient achieved and maintained the following weight loss:
 - i. Adult patients:
 - 1) For Foundayo, 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 Wegovy regular (non-HD) injectable: 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 had clinical benefit from medication

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- b. Patient will use optimized pharmacotherapy for established cardiovascular disease in combination with the requested agent
- 3. For obstructive sleep apnea:
 - a. Patient has had clinical benefit from the requested agent as evidenced by one of the following:
 - i. Reduction in AHI
 - ii. Improvement in validated sleep apnea score (such as sleep apnea-specific hypoxia burden [SASHB], Epworth Sleepiness Scale, Calgary)
 - iii. Improvement in OSA symptoms
- 4. For MASH:
 - a. Patient has had clinical benefit
 - b. One of the following:

(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)

 - i. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day
 - ii. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day
 - 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)
- 5. For Zepbound injection or vial: Medical rationale to support not using the preferred formulation, Zepbound KwikPen

EXCLUSION CRITERIA:

- 1. Type 2 diabetes
- 2. Concurrent use with another GLP-1 receptor agonist for any indication, another weight loss agent, or resmetirom (Rezdiffra)
- 3. For OSA: central or mixed apnea

AGE RESTRICTIONS:

Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTIONS:

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For noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH): Must be prescribed by, or in consultation with, a hepatologist or gastroenterologist

COVERAGE DURATION:

Initial authorization will be approved for six months. Reauthorization will be approved for one year.

QUANTITY LIMIT:

- Foundayo: One tablet per day
- Saxenda: 15 mL per 30 days (up to 3 mg per day)
- Wegovy/Wegovy HD: Four injections per 28 days, one tablet per day
- Zepbound: Four injections per 28 days

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 for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

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:

Orforglipron (Foundayo), 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 diabetes mellitus (at lower doses) 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.

FDA APPROVED INDICATIONS:

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

Medication	FDA Indication
Liraglutide (Saxenda)	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 body weight greater than 60 kg and obesity - Adults with overweight in the presence of at least one weight-related comorbid condition <i>Limitation of Use:</i> - 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
Orforglipron (Foundayo)	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 <i>Limitations of Use:</i> Concomitant use with another GLP-1 receptor agonist is not recommended
Semaglutide regular (non-HD) 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. <i>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.</i> <i>Limitations of Use:</i>

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	Concomitant use with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended
Semaglutide HD injectable (Wegovy HD)	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 overweight in the presence of at least one weight-related comorbid condition <i>Limitations of Use:</i> - 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 adults with overweight in the presence of at least one weight-related comorbid condition <i>Limitations of Use:</i> - Concomitant use with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended
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 <i>Limitation of Use:</i> - Contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended

HD = High-Dose

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

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approvals for drugs like orforglipron (Foundayo), 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 Guidelines³

- 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 weight 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.^{7,8}

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.

Wegovy regular (non-HD) injectable and Saxenda are approved in children 12 years and older.

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- 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 ≥ 95 th percentile for age and sex and from studies in adult patients with obesity. There is 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/m² 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

Institute for Clinical and Economic Review (ICER)

2022 “Medications for Obesity Management: Effectiveness and Value” Evidence Report⁴ 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 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.

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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

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Zepbound 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).

Early and Periodic Screening Diagnostic and Treatment (EPSDT) Review

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit includes comprehensive preventative health care services for Medicaid members until they turn age 21 and for members with qualifying special health care needs (Youth with Special Healthcare Needs (YSHCN)) as they turn 21. This benefit applies when a condition is determined to impact the ability to grow, develop or participate in school and the applicable criteria above are met.

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