

Weight Management Drugs

Goal(s):

- To provide guidance for the use of weight management therapies to ensure they are used in the most appropriate patient populations in which evidence supports efficacy and safety.
- Allow case-by-case review for members covered under the EPSDT program. Recommend use of GLP-1 receptor agonists only for FDA-approved indications supported by the evidence.
- To provide guidance for the use of weight management drugs, like semaglutide (WEGOVY), to ensure coverage for the most appropriate patient populations in which evidence supports efficacy and safety for reduction in cardiovascular (CV) outcomes and nonalcoholic steatohepatitis (NASH, also called metabolic dysfunction-associated steatohepatitis [MASH]).

Length of Authorization:

- Up to 6 months
- Renewal up to 12 months

Requires PA:

- All drugs used for weight management.
- Refer to the Glucagon-like Peptide-1 (GLP-1) Receptor Agonists and Glucose Dependent Insulinotropic Polypeptide (GIP) Receptor Agonist PA Criteria for approval of Semaglutide (OZEMPIC and RYBELSUS) for type 2 diabetes.

Note: Semaglutide is not currently covered for adults who do not have established cardiovascular disease, non-alcoholic steatohepatitis (NASH), or type 2 diabetes.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. Drugs FDA Approved for Weight Management

Drug	Adults	Pediatrics
Liraglutide (SAXENDA)	Yes	Yes – 12 years and older
Naltrexone/bupropion (CONTRAVE)	Yes	No
Phentermine/topiramate (QSYMIA)	Yes	Yes – 12 years and older
Semaglutide (WEGOVY)	Yes	Yes – 12 years and older
Tirzepatide (ZEPBOUND)	Yes	No
Setmelanotide (IMCIVREE)	Yes	Yes – 6 years and older
Orlistat (Xenical)	Yes	Yes – 12 years and older

Table 2. BMI Cutoffs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (CDC Criteria)

Age (years)	Body mass index (kg/m ²) at 95% percentile	
	Males	Females
12	24.2	25.2
12.5	24.7	25.7
13	25.1	26.3
13.5	25.6	26.8
14	26.0	27.2
14.5	26.4	27.7
15	26.8	28.1
15.5	27.2	28.5

16	27.5	28.9
16.5	27.9	29.3
17	28.2	29.6
17.5	28.6	30

Table 3. Evidence-Supported Indications

Drug	Indications
Liraglutide	<ul style="list-style-type: none"> Non-alcoholic steatohepatitis (NASH) with stage 2 or 3 fibrosis in adults 18 years and older*
Semaglutide	<ul style="list-style-type: none"> Established cardiovascular disease (e.g., history of myocardial infarction, stroke, or symptomatic peripheral arterial disease) Non-alcoholic steatohepatitis (NASH) with stage 2 or 3 fibrosis in adults 18 years and older*

* NASH Requirements:

- Diagnosis by liver biopsy OR all of the following:
 - documentation that the patient does NOT have ongoing or recent (within 2 years) significant alcohol use or chronic or active viral hepatitis. Significant alcohol use can be patient-specific but is typically defined as greater than 21 drinks/week (or >30 g/day) in men and greater than 14 drinks/week (or >20 g/day) in women.
 - provider attestation or documentation that other causes of hepatic steatosis are not suspected based on patient history/presentation or have been ruled out. Examples of other secondary causes of hepatic steatosis include, but are not limited to, Wilson's disease, lipodystrophy, abetalipoproteinemia, medications (e.g., amiodarone, methotrexate, tamoxifen, corticosteroids).
 - documentation that the patient has, or is receiving drug treatment for, at least 3 of the 5 metabolic risk factors associated with MASH. Risk factors include:
 - Overweight or obesity or increased waist circumference (BMI \geq 25 kg/m² or ethnicity adjusted equivalent)
 - Hypertension
 - Type 2 diabetes mellitus
 - Hypertriglyceridemia
 - Decreased level of high density lipoprotein (HDL)
- fibrosis stage 2 or 3 as shown by appropriate diagnostic test within past 24 month [appropriate tests may include biopsy, vibration controlled transient elastography (VCTE), magnetic resonance elastography (MRE), enhanced liver fibrosis test (ELF)]
- medication being ordered by, or in consultation with, a hepatologist or gastroenterologist

Approval Criteria

1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this a request for continuation of therapy after an initial approval by FFS?	Yes: Go to Renewal Criteria	No: Go to #3

Approval Criteria

<p>3. Does the patient have a BMI corresponding to one of the following:</p> <ol style="list-style-type: none"> 1) ≥ 30 kg/m² or 2) ≥ 25 kg/m² and comorbid conditions [e.g., diabetes mellitus, hypertension, dyslipidemia, fatty liver disease, or cardiovascular disease] or 3) a BMI at the 95th percentile or greater for age and sex (Table 2 above)? 	<p>Yes: Go to #4</p> <p>Record baseline BMI</p>	<p>No: Deny; medical appropriateness</p>
<p>4. Will the patient be engaged in a weight management lifestyle modification program in addition to pharmacotherapy?</p> <p>See clinical notes below</p>	<p>Yes: Go to #5</p>	<p>No: Deny; medical appropriateness. All drugs approved for weight loss are indicated as an adjunct to diet and exercise.</p>
<p>5. Is the requested for a patient less than 21 years of age AND is the requested medication FDA-approved for their age (Table 1)?</p>	<p>Yes: Go to #6</p>	<p>No: Go to #11</p>
<p>6. Is the request for setmelanotide?</p>	<p>Yes: Go to #7</p>	<p>No: Go to #9</p>
<p>7. Does the patient have obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance OR does the patient have Bardet—Biedl syndrome (BBS)?</p>	<p>Yes: Go to #8</p>	<p>No: Deny; medical appropriateness.</p>
<p>8. Does the patient have a history of depression and/or suicidal ideation?</p>	<p>Yes: Deny; medical appropriateness.</p>	<p>No: Approve for up to 6 months.</p>
<p>9. Does the patient have comorbidities (e.g., hypertension, dyslipidemia, diabetes, fatty liver disease, depression, or sleep apnea)?</p>	<p>Yes: Approve for 6 months</p>	<p>No: Go to #10</p>

Approval Criteria

<p>10. Has the patient previously tried a weight loss treatment plan administered by a health care provider (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet) for a time period of at least 3 months within the previous 6 month timeframe*?</p> <p>* See Clinical Notes Below</p>	<p>Yes: Approve for 6 months.</p>	<p>No: Deny; medical appropriateness. Lifestyle modifications are recommended by guidelines.</p>
<p>11. Is the request for a FDA-approved or compendia-supported indication as defined in Table 3?</p>	<p>Yes: Go to #12</p>	<p>No: Pass to RPh. Deny; drugs are not covered by OHP for adults when indicated for weight loss.</p>
<p>12. Has the patient previously tried a weight loss treatment plan administered by a health care provider (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet) for a time period of at least 3 months within the previous 6 month timeframe?</p>	<p>Yes: Go to #13</p>	<p>No: Deny; medical appropriateness</p>
<p>13. Is there documentation of a type 2 diabetes diagnosis?</p>	<p>Yes: Go to #15</p>	<p>No: Go to #14</p>
<p>14. Has the patient been screened for diabetes within the past year and do screening results indicate they do not have diabetes (e.g., HbA1c <6.5% or fasting blood glucose <126 mg/dl (7 mmol/L)?</p>	<p>Yes: Go to #15</p>	<p>No: Pass to RPh; Deny; medical appropriateness.</p> <p>Recommend screening and if positive recommend a GLP-1 RA indicated for glucose lowering (see GLP-1 RA/GIP RA PA criteria)</p>
<p>15. Is the request for semaglutide?</p>	<p>Yes: Go to #16</p>	<p>No: Approve for up to 6 months</p>
<p>16. Is the patient currently taking semaglutide (Ozempic) 2.0 mg weekly and is able to tolerate the medication and is still desiring additional weight loss?</p>	<p>Yes: Approve for up to 6 months</p>	<p>No: Go to #17</p>
<p>17. Will the patient try semaglutide (Ozempic) for at least 4 months to ensure tolerability/compliance?</p>	<p>Yes: Approve Ozempic for up to 6 months</p>	<p>No: Pass to RPh. Deny; medical appropriateness.</p>

Renewal Criteria		
1. Is this a request for continuation of therapy with a weight loss medication previously approved by FFS?	Yes: Go to #2	No: Go to Approval Criteria above
2. Is the person requesting the medication less than 21 years of age?	Yes: Go to #3	No: Go to #4
3. Has the patient lost at least 1% of BMI from baseline or maintained at least a 1% BMI weight loss?	Yes: Go to #7	No: Deny; medical appropriateness
4. Is the request for ongoing treatment for someone with established cardiovascular disease (e.g., history of myocardial infarction, stroke, or symptomatic peripheral arterial disease) or NASH?	Yes: Go to #5	No: Pass to RPh. Deny; drugs are not covered by OHP for adults when indicated for weight loss.
5. Has the patient lost or maintained a BMI reduction of 5% or more?	Yes: Go to #6	No: Deny; medical appropriateness
6. Has the patient been adherent to therapy based on provider attestation?	Yes: Go to #7	No: Deny; medical appropriateness
7. Is the patient continuing with a weight loss treatment plan (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet)?	Yes: Approve for up to 12 months.	No: Deny; medical appropriateness. All drugs approved for weight loss are indicated as an adjunct to diet and exercise.

***Clinical Notes**

Adapted from the following guideline on the treatment of adolescents with obesity:

- American Academy of Pediatrics. *Pediatrics*. 2023;151(2): e2022060640. Available at: <https://publications.aap.org/pediatrics/article/151/2/e2022060640/190443/Clinical-Practice-Guideline-for-the-Evaluation-and?autologincheck=redirected>

Recommended Behavior Strategies

Strategy	Description
1. Reduction in sugar-sweetened beverages (SSBs)	Higher intake of sugar-sweetened beverages (carbonated beverages, sweetened beverages, soda, sports drinks, and fruit drinks) is associated with greater weight gain in adults and children. The American Heart Association (AHA) recommends not more than 25 g (6 tsp) each day of added sugar and not more than 1, 8-oz serving of SSB per week. The AAP discourages the consumption of sports drinks and energy drinks for children and adolescents. The AAP statement on fruit juice notes that it is a poor substitute for whole fruit because of its high sugar and calorie content and pediatricians should advocate for elimination of fruit juice in children with excessive weight gain.

2. Choose My Plate	<p>MyPlate is the US Department of Agriculture's (USDA) broad set of recommendations for healthy eating for Americans. These recommendations include multiple healthy diet goals: low in added sugar, low in concentrated fat, nutrient dense but not calorie dense, within an appropriate calorie range without defined calorie restriction, and with balanced protein and carbohydrate. The principles can be adapted to different food cultures. There is a surprising dearth of literature on the impact of these guidelines on health and BMI outcomes and on the most effective education practices.</p> <p>Available at: USDA choose my plate.gov</p>
3. 60 minutes daily of moderate to vigorous physical activity	<p>Aerobic exercise, especially for 60 min at a time, is associated with improved body weight in youth although its effect may be small and variable. It is also associated with better glucose metabolism profiles. High-intensity interval training in youth with obesity may improve body fat, weight, and cardiometabolic risk factors, although the effect is variable. The Physical Activity Guidelines for Americans recommends 60 min per day for children and adolescents.</p>
4. Reduction in sedentary behavior	<p>Reduction in sedentary behavior, generally defined as reduced screen time, has consistently shown improvement in BMI measures, although impact is small. Early studies focused on reduced television, a discrete activity that is simpler than current multifunctional electronic devices. The AAP recommends no media use under age 18 month, a 1-hour limit for ages 2–5 years, and a parent- monitored plan for media use in older children, with a goal of appropriate, not- excessive use but without a defined upper limit.</p>
<p>The activities most commonly associated with positive behavior change are: parental involvement in goal setting, problem solving, social support, demonstrating desired behaviors, and home environment modifications to support positive change.</p>	
<p>Abbreviations: AAP – American Academy of Pediatrics; BMI = body mass index; oz = ounce; tsp = teaspoon; USDA = United States Department of Agriculture</p>	

*P&T/DUR Review: 8/24 (SS/SF); 6/24 (KS)
Implementation: 9/1/24; 7/1/24*