Medications for Weight Management

EOCCO POLICY

Policy Type:PA/SP Pharmacy Coverage Policy: EOCCO288

Description

Semaglutide (Wegovy®) and liraglutide (Saxenda®) are glucagon-like peptide-1 (GLP-1) receptor agonists. Tirzepatide (Zepbound™) is a dual gastric inhibitory polypeptide (GIP) and GLP-1 receptor agonist. Phentermine and topiramate extended-release (Qsymia®) is a combination of a sympathomimetic amine anorectic (phentermine) and neuronal voltage-dependent sodium channel inhibitor (topiramate). Phentermine (Adipex-P®, Lomaira™) is a sympathomimetic amine anorectic. Orlistat (Xenical®) is a reversible inhibitor of gastrointestinal lipases. Naltrexone and bupropion extended-release (ER) (Contrave®) is a combination of an opioid antagonist (naltrexone) and an aminoketone antidepressant (bupropion). Diethylpropion, diethylpropion ER, benzphetamine, and phendimetrazine are sympathomimetic amines with pharmacologic properties similar to the amphetamines.

Length of Authorization

- Initial
  - i. Benzphetamine, phendimetrazine, and phendimetrazine ER: three months
  - ii. All other agents: six months
- Renewal:
  - i. Benzphetamine, phendimetrazine, and phendimetrazine ER: no renewal
  - ii. All other agents: six months

Quantity Limits

Product Name	Indication	Dosage Form	Quantity Limit
tirzepatide (Zepbound)	Chronic weight management in patients ≥18 years of age	2.5mg/0.5mL (0.5mL pre-filled pen)	4 pre-filled pens (2mL/28 days)
		5mg/0.5mL (0.5mL pre-filled pen)	
		7.5mg/0.5mL (0.5mL pre-filled pen)	
		10mg/0.5mL (0.5mL pre-filled pen)	
		12.5mg/0.5mL (0.5mL pre-filled pen)	
		15mg/0.5mL (0.5mL pre-filled pen)	
semaglutide (Wegovy)	Chronic weight management in patients ≥12 years of age	0.25 mg/0.5 mL (0.5 mL pre-filled pen)	4 pre-filled pens (2mL)/28 days
		0.5 mg/0.5 mL	

		(0.5 mL pre-filled pen)	
		1 mg/0.5 mL (0.5 mL pre-filled pen)	
		1.7 mg/0.75 mL (0.75 mL pre-filled pen)	4 pre-filled pens (3mL)/28 days
		2.4 mg/0.75 mL (0.75 mL pre-filled pen)	
liraglutide (Saxenda)	Chronic weight management in patients ≥12 years of age	6 mg/mL (3 mL pre-filled pen)	5 pre-filled pens (15mL)/30 days
phentermine and topiramate ER (Qsymia)	Chronic weight management in patients ≥12 years of age	3.75 mg/23 mg capsule	30 capsules/30 days
		7.5 mg/46 mg capsule	
		11.25 mg/69 mg capsule	
		15 mg/92 mg capsule	
orlistat (Xenical)	Chronic weight management in patients ≥12 years of age	120 mg capsule	90 capsules/30 days
phentermine (Adipex-P)	Short-term weight management in patients ≥17 years of age; chronic weight management in patients ≥12 years of age (off-label)	37.5 mg capsule	30 capsules/30 days
phentermine (Lomaira)		8 mg tablets	90 tablets/30 days
phentermine		15 mg capsule	30 capsules/30 days
		30 mg capsule	
naltrexone and bupropion ER (Contrave)	Chronic weight management in patients ≥18 years of age	8 mg/90 mg tablet	60 tablets/30 days
diethylpropion	Short-term weight management in patients ≥17 years of age; chronic weight management in patients ≥17 years of age (off-label)	25 mg tablet	120 tablets/30 days
diethylpropion ER		75 mg ER tablet	30 tablets/30 days
benzphetamine	Short-term weight management in patients ≥17 years of age	25 mg tablet	90 tablet/30 days
		50 mg tablet	90 tablets/30 days
phendimetrazine	Short-term weight management in patients ≥17 years of age	35 mg tablet	180 tablets/30 days
phendimetrazine ER		105 mg capsule	30 capsules/30 days

Initial Evaluation

** Medications included in this policy are used to treat obesity or overweight in the presence of weight related comorbidities, a non-funded condition according to the Oregon Health Plan Prioritized List of Healthcare Services.

However, under The Early and Periodic Screening, Diagnostic and Treatment (EPSDT), if the request is determined to be medically necessary and medically appropriate, regardless of the prioritized list status, coverage must be provided for enrolled children and youth until their 21st birthday.

Requests for medications included in this policy may be considered medically necessary and appropriate when meeting the following criteria:

I. **Tirzepatide (Zepbound), semaglutide (Wegovy), liraglutide (Saxenda), phentermine and topiramate ER (Qsymia), orlistat (Xenical), phentermine (e.g., Adipex-P, Lomaira) bupropion and naltrexone ER (Contrave)**, **diethylpropion, diethylpropion ER, benzphetamine, phendimetrazine, and phendimetrazine ER** may be considered medically necessary when the following criteria are met:
   A. Medication is requested for weight management; **AND**
   B. Provider attestation that the condition is of sufficient severity that it impacts the member's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.); **AND**
   C. Medication is not being used in combination with other medications intended for weight management; **AND**
   D. Documentation of member's body mass index (BMI) or weight and height within the last three months; **AND**
   E. Provider attestation that medically supervised intensive health behavior and lifestyle treatment program for at least three months has been ineffective in attainment of a healthy weight status or amelioration of weight-related comorbidities (e.g., diabetes mellitus, hypertension, dyslipidemia); **AND**
   F. Medication is being used as an adjunct to medically supervised intensive health behavior and lifestyle treatment program as supported by current and active enrollment in a comprehensive program; **AND**
      1. If approved, provider agrees to respond in a timely manner to additional information requests, including confirmation that member remains an active participant in intensive health behavior and lifestyle treatment program; **AND**
   G. Member is 12 to 17 years of age; **AND**
      1. Member's body mass index (BMI) is in the 95th percentile or greater for age and sex (obesity); **AND**

2. The request is for phentermine (e.g., Adipex-P, Lomaira), phentermine and topiramate ER (Qsymia), or orlistat (Xenical); **OR**
3. The request is for semaglutide (Wegovy) or liraglutide (Saxenda); **AND**
    i. Treatment with <u>one</u> of the following has been ineffective, contraindicated, or not tolerated:
        a. Phentermine (Adipex-P, Lomaira)
        b. Phentermine and topiramate ER (Qsymia)
        c. Orlistat (Xenical); **OR**

H. Member is 18 to 20 years of age; **AND**
1. Member's body mass index (BMI) is 30 kg/m^2 or greater (obesity); **OR**
    i. Member's body mass index (BMI) is 27 kg/m2 or greater (overweight) in the presence of at least one of the following weight-related comorbid conditions:
        a. Prediabetes
        b. Metabolic syndrome
        c. Type 2 diabetes
        d. Dyslipidemia
        e. Hypertension
        f. Cardiovascular disease
        g. Nonalcoholic fatty liver disease
        h. Polycystic ovary syndrome
        i. Female infertility
        j. Male hypogonadism
        k. Obstructive sleep apnea
        l. Asthma/reactive airway disease
        m. Osteoarthritis
        n. Urinary stress incontinence
        o. Gastroesophageal reflux disease
        p. Depression; **AND**
2. The request is for phentermine (e.g., Adipex-P, Lomaira), diethylpropion, diethylpropion ER, phentermine and topiramate ER (Qsymia), bupropion and naltrexone ER (Contrave) or orlistat (Xenical); **OR**
3. The request is for benzphetamine, phendimetrazine, and phendimetrazine ER; **AND**
    i. Medication use is limited to a total of three months of therapy; **OR**
4. The request is for tirzepatide (Zepbound), semaglutide (Wegovy) or liraglutide (Saxenda); **AND**
    i. Treatment with two of the following has been ineffective, contraindicated, or not tolerated:

a. Phentermine (Adipex-P, Lomaira)
b. Phentermine and topiramate (Qsymia)
c. Bupropion and naltrexone (Contrave)
d. Orlistat (Xenical)

II. Tirzepatide (Zepbound), semaglutide (Wegovy), liraglutide (Saxenda), phentermine and topiramate ER (Qsymia), phentermine (e.g., Adipex-P, Lomaira), orlistat (Xenical), naltrexone and bupropion ER (Contrave®, diethylpropion, diethylpropion ER, benzphetamine, phendimetrazine, and phendimetrazine ER are considered investigational when used for all other conditions, including but not limited to:
   A. All agents
      1. Chronic weight management in members <12 years of age
      2. Chronic treatment of overweight in members <18 years of age
   B. Diethylpropion, and diethylpropion ER, benzphetamine, phendimetrazine, and phendimetrazine ER
      1. Short-term or chronic weight management in members ≤16 years of age
   C. Benzphetamine, phendimetrazine, and phendimetrazine ER
      1. Chronic weight management longer than three months
   D. Tirzepatide (Zepbound) and naltrexone and bupropion ER (Contrave)
      1. Chronic weight management in members <18 years of age

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Medication is requested for weight management; **AND**
IV. Provider attestation that the condition is of sufficient severity that it impacts the member's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.); **AND**
V. Medication is not being used in combination with other medications intended for weight management; **AND**
VI. Documentation that medically supervised intensive health behavior and lifestyle treatment program for at least three months has been ineffective in attainment of a healthy weight status or amelioration of weight-related comorbidities (e.g., diabetes mellitus, hypertension, dyslipidemia); **AND**

VII. Medication is being used as an adjunct to medically supervised intensive health behavior and lifestyle treatment as supported by current and active enrollment in a comprehensive program; **AND**
- If approved, provider agrees to respond in a timely manner to additional information requests, including confirmation that member remains an active participant in intensive health behavior and lifestyle treatment; **AND**

VIII. Documentation of member's body weight within the last 3 months; **AND**

IX. Member has completed 6 to 12 months of initial therapy; **AND**
- The request is for semaglutide (Wegovy), liraglutide (Saxenda), phentermine (Adipex-P, Lomaira), phentermine and topiramate ER (Qsymia), or orlistat (Xenical); **AND**
    i. Member is 12 to 20 years of age; **AND**
    ii. Member has experienced weight loss or weight has remained stable; **OR**
- The request is for tirzepatide (Zepbound), diethylpropion, diethylpropion ER, or naltrexone and bupropion ER (Contrave); **AND**
    i. Member is 18 to 20 years of age; **AND**
    ii. Member has experienced weight loss or weight has remained stable; **OR**

X. Member has completed 12 months or more of initial therapy; **AND**
a. The request is for semaglutide (Wegovy), liraglutide (Saxenda), phentermine (Adipex-P, Lomaira), phentermine and topiramate ER (Qsymia), or orlistat (Xenical); **AND**
    i. Member is 12 to 20 years of age; **AND**
    ii. Member has achieved ≥5% weight loss from baseline body weight; **OR**
b. The request is for tirzepatide (Zepbound), diethylpropion, diethylpropion ER, or naltrexone and bupropion extended-release (Contrave); **AND**
    iii. Member is 18 to 20 years of age; **AND**
    iv. Member has achieved ≥5% weight loss from baseline body weight

Supporting Evidence

I. Semaglutide (Wegovy), and phentermine and topiramate ER (Qsymia) are FDA approved as adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients aged ≥12 years with a BMI in the 95th percentile or greater standardized for age and sex. Both agents are also approved in adults ≥18 years of age with an initial body mass index (BMI) of ≥30 kg/m^2 (obesity), or ≥27 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia). Orlistat (Xenical) is FDA approved for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet in patients aged ≥12 years. Orlistat (Xenical) is also indicated to reduce the risk for weight regain after prior weight loss. The safety and efficacy of orlistat (Xenical) in adolescents was studied in participants affected by obesity, all had baseline BMI that was two units great than the US weighted mean for the 95th

percentile based on age and gender. Liraglutide (Saxenda) is FDA approved as adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients aged ≥12 years with body weight above 60 kg and an initial BMI corresponding to 30 kg/m^2 for adults (obesity) by international cut-offs. Although liraglutide (Saxenda) is specifically FDA approved in pediatric patients above 60 kg with BMI corresponding to 30 kg/m^2 for adults, this correlates with a BMI in the 95th percentile or greater for age and sex (obesity) using the Centers for Disease Control and Prevention (CDC) chart below. Liraglutide is also FDA approved in adults ≥18 years of age affected by obesity or overweight with weight-related complications. Tirzepatide (Zepbound) and naltrexone and bupropion ER (Contrave) are FDA approved in adults affected by obesity or overweight.

II. Phentermine (e.g., Adipex-P, Lomaira), diethylpropion, diethylpropion ER, benzphetamine, phendimetrazine, and phendimetrazine ER are FDA approved in patients ≥17 years of age as a short-term (a few weeks) regimen for weight reduction based on exercise, behavioral modification, and caloric restriction in the management of exogenous obesity for patients with an BMI ≥30 kg/m^2, or ≥27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). Due to extensive clinical practice experience with phentermine (e.g., Adipex-P, Lomaira), which was FDA approved in 1959, a well-established safety profile, as well as data available from use in combination with topiramate (Qsymia), in both children and adults, there is a path to coverage for patients ≥12 years of age and for those seeking chronic treatment beyond a few weeks. Diethylpropion, benzphetamine, and phendimetrazine were studied in adults aged 17 years and older and path to coverage is restricted to adults only at this time, corresponding to 18 years of age in this policy. Exceptions to allow coverage of these agents in patients 17 years of age and older (per label age requirement) may be allowed. Additionally, diethylpropion can be recommended for chronic weight management as supported by clinical guidelines.

Centers for Disease Control and Prevention (CDC) 95th Percentile BMI

	Male	Female
Age (years)	95th Percentile BMI Value	95th Percentile BMI Value
12	24.2	25.3
12.5	24.7	28.5
13	25.2	26.3
13.5	25.6	26.8
14	26.0	27.3
14.5	26.5	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.6	28.9
16.5	27.9	29.3

17	28.3	29.6
17.5	28.6	30.0

III. The safety and efficacy of tirzepatide (Zepbound), semaglutide (Wegovy), liraglutide (Saxenda), phentermine and topiramate ER (Qsymia), orlistat (Xenical), phentermine (Adipex-P, Lomaira), naltrexone and bupropion ER (Contrave), diethylpropion, diethylpropion ER, benzphetamine, phendimetrazine, and phendimetrazine ER have not been established in patients <12 years of age. The use of these agents in patients <12 years of age is considered experimental and investigational. The American Academy of Pediatrics (AAP) Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents with Obesity note that there is insufficient evidence to provide recommendations for pharmacotherapy for children younger than 12 years for the sole indication of obesity. There are, however, specific conditions for which use of certain medications may be indicated in children <12 years. An example of this is the use of metformin when other indications are also present (e.g., type 2 diabetes mellitus). The data for safety and efficacy of diethylpropion, diethylpropion ER, benzphetamine, phendimetrazine, and phendimetrazine ER are additionally limited to patients 17 years or older, and the data for naltrexone and bupropion ER (Contrave) is limited to patients aged ≥18 years.

IV. There is currently no path to coverage to tirzepatide (Zepbound), semaglutide (Wegovy), liraglutide (Saxenda), phentermine and topiramate ER (Qsymia), orlistat (Xenical), phentermine (e.g., Adipex-P, Lomaira), naltrexone and bupropion ER (Contrave), diethylpropion, diethylpropion ER, benzphetamine, phendimetrazine, and phendimetrazine ER in patients aged ≥21 years. Weight loss is in the category of indications that are excluded from the health plan's benefit when used in members aged ≥21 years.

V. Intensive health behavior and lifestyle treatment (IHBLT) is the first line recommended intervention to achieve body mass reduction in children and adolescents according to AAP. IHBLT typically involves participation of families in the discussion of necessary treatment. The most effective IHBLT programs deliver 26 or more hours face-to-face, family-based counseling on nutrition and physical activity over at least a three-to-12-month period, for children aged six years and older with overweight and obesity, with more limited evidence for children two to five years of age. Various IHBLT programs are currently available in the U.S., some are housed in academic medical centers or community hospitals, some are in primary care offices or obesity treatment specialty clinics, and others are delivered through partnerships with local community entities such as YMCA or parks and recreation departments.

VI. Current evidence does not support weight loss medication use as monotherapy; thus, prescribers who prescribe weight loss medications to children, adolescents, and young adults should provide or refer to intensive behavioral interventions for patients and families as an adjunct to medication therapy.

VII. The safety and efficacy of tirzepatide (Zepbound), semaglutide (Wegovy), liraglutide (Saxenda), phentermine and topiramate ER (Qsymia), orlistat (Xenical), phentermine (e.g., Adipex-P, Lomaira), naltrexone and bupropion ER (Contrave), diethylpropion, diethylpropion ER,

benzphetamine, phendimetrazine, and phendimetrazine ER in combination with other drugs intended for weight loss, including prescription and over-the-counter drugs have not been established.

VIII. Body mass index (BMI) is the person's weight in kilograms divided by the square of height in meters. For children and adolescents aged two to 20 years, BMI is age- and sex- specific and is often referred to BMI-for-age. After BMI is calculated for children and adolescents, the percentile can be obtained from the charts or a percentile calculator available on the Centers for Disease Control and Prevention (CDC) web page. Obesity is defined as BMI at or above the 95th percentile for children and teens of the same age and sex. Overweight is defined as a BMI at or above the 85th percentile and below the 95th percentile for children and adolescents of the same age and sex. Medications in this policy are restricted for children and adolescents whose BMI falls in the weight status consistent with obesity.

IX. Medications FDA approved for weight management in adults may be authorized for those 17 (select agents with an FDA approval in those aged ≥17 years) or 18 to 20 years of age when BMI is consistent with obesity (BMI ≥30 kg/m^2) or overweight (BMI ≥27 kg/m^2). When BMI is categorized as overweight, authorization of medications is permitted when weight-related complications are present. The American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) Guidelines for Medical Care of Patients with Obesity define weight-related complications as the following: prediabetes, metabolic syndrome, type 2 diabetes, dyslipidemia, hypertension, cardiovascular disease, nonalcoholic fatty liver disease, polycystic ovary syndrome, female infertility, male hypogonadism, obstructive sleep apnea, asthma/reactive airway disease, osteoarthritis, urinary stress incontinence, gastroesophageal reflux disease, and depression.

X. Use of benzphetamine, phendimetrazine, and phendimetrazine ER is limited to three months. These agents are FDA approved for no more than 12 weeks. There's lack of data to support longer-term safety and efficacy, therefore, renewal or continuation of therapy for longer than 12 weeks is not permitted. If patients are undergoing a new, distinct period of engagement in a weight loss program requiring use of benzphetamine, phendimetrazine, and phendimetrazine ER, initial criteria must be met.

XI. Medications included in this policy have not been studied in head-to-head clinical trials to inform comparative safety and efficacy. All products have unique safety profiles; therefore, the ultimate treatment selection must take individual patient characteristics into consideration. In the absence of contraindications, treatment with phentermine (e.g., Adipex-P, Lomaira), phentermine and topiramate ER (Qsymia), or orlistat (Xenical) is required for authorizing coverage of semaglutide (Wegovy) or liraglutide (Saxenda) in patients aged 12 to 17 years old. For adults, similar requirements are in place including for tirzepatide (Zepbound), with naltrexone and bupropion ER (Contrave) as an additional treatment option. When compared to placebo, significantly more patients were able to achieve clinically meaningful reductions in body weight (≥5% body weight) when treated with phentermine (data in adults), phentermine

and topiramate ER (Qsymia), bupropion and naltrexone ER (Contrave) (data in adults) and orlistat (Xenical). There's lack of high-quality clinical trials comparing these agents to semaglutide (Wegovy), liraglutide (Saxenda), or tirzepatide (Zepbound), therefore, superiority of one agent over the other is not established. The off-label use of phentermine (e.g., Adipex-P, Lomaira) in the treatment of overweight and obesity is supported by extensive clinical practice experience given its FDA approval in 1959, a well-established safety profile, as well as data available from its use in combination with topiramate (Qsymia) in both children and adults. Selection of medications for the treatment of chronic weight management in children, adolescents, and adults depends on individual patient factors, such as comorbidities, contraindications, historical response, and potential drug–drug interactions. All products have unique safety profiles; therefore, ultimate treatment selection must take individual patient characteristics into consideration. Consult product drug information for a full list of contraindications and warnings and precautions associated with each therapy.
Initial and renewal authorization of medications included in this policy are limited to six months to confirm ongoing participation in an intensive health behavior and lifestyle treatment program. Additionally, after 12 months of continued treatment with pharmacotherapy and lifestyle engagement, subsequent renewal authorization is contingent upon verification of benefit on BMI and/or weight parameters. The AGA clinical guidelines for the treatment of overweight and obesity define a minimally clinically important difference for efficacy of pharmacotherapy in the management of obesity that corresponds to important patient benefits as 5% total body weight loss from baseline.

Investigational or Not Medically Necessary Uses

I. Tirzepatide (Zepbound), semaglutide (Wegovy), liraglutide (Saxenda), phentermine and topiramate ER (Qsymia), phentermine (e.g., Adipex-P, Lomaira), orlistat (Xenical), naltrexone and bupropion ER (Contrave), diethylpropion, diethylpropion ER, benzphetamine, phendimetrazine, and phendimetrazine ER are considered investigational when used for all other conditions, including but not limited to:
   A. All agents
      1. Chronic weight management in members <12 years of age
      2. Chronic treatment of overweight in members <18 years of age
   B. Diethylpropion, diethylpropion ER, benzphetamine, phendimetrazine, and phendimetrazine ER
      1. Short-term or chronic weight management in members ≤16 years of age
   C. Benzphetamine, phendimetrazine, and phendimetrazine ER
      1. Chronic weight management longer than three months
   D. Tirzepatide (Zepbound) and naltrexone and bupropion extended-release (Contrave)
      1. Chronic weight management in members <18 years of age

References

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13. Phentermine (Lomaira) [Prescribing Information]. Newton, PA; KVK Tech, Inc., September 2016.
14. Naltrexone and bupropion ER (Contrave) [Prescribing Information]. Brentwood, TN; Currax Pharmaceuticals LLC., April 2021.
15. Phendimetrazine extended-release (Fendique ER). Langhorne, PA; Virtus Pharmaceuticals., November 2020.
16. Benzphetamine (Didrex) [Prescribing Information]. New York, NY; Pfizer Inc., April 2020.
17. Tirzepatide (Zepbound) [Prescribing Information]. Indianapolis, IN; Eli Lilly Inc., November 2023.

Policy Implementation/Update:

Action and Summary of Changes	Date
Statement regarding prioritized list and EPSDT included on top, criteria requiring provider attestation of condition severity included.	01/2024
Policy created	12/2023