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®, Mounjaro®) 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 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 for chronic weight management: six months
  - iii. Semaglutide (Wegovy) for Major Adverse Cardiovascular Events (MACE) risk reduction in patients with overweight or obesity: 12 months
  - iv. Tirzepatide (Zepbound) for Obstructive Sleep Apnea (OSA) in adults with obesity: 12 months
- Renewal:
  - i. Benzphetamine, phendimetrazine, and phendimetrazine ER: no renewal
  - ii. All other agents for chronic weight management: six months
  - iii. Semaglutide (Wegovy) for Major Adverse Cardiovascular Events (MACE) risk reduction in patients with overweight or obesity: 12 months
  - iv. Tirzepatide (Zepbound) for Obstructive Sleep Apnea (OSA) in adults with obesity: 12 months

Quantity Limits

Product Name	Indication	Dosage Form	Quantity Limit
tirzepatide (Zepbound)	Chronic weight management in patients ≥18 years of age Obstructive sleep apnea in adults with obesity	2.5mg/0.5mL vial	2mL/28 days (4 vials)
		5mg/0.5mL vial	
		2.5mg/0.5mL (0.5mL pre-filled pen)	2mL/28 days (4 pre-filled pens)
		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)	
tirzepatide (Mounjaro)	Type 2 diabetes mellitus	2.5mg/0.5mL vial	2mL/28 days (4 vials)
		5mg/0.5mL vial	
		2.5mg/0.5mL (0.5mL pre-filled pen)	2mL/28 days (4 pre-filled pens)
		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 Major adverse cardiovascular events (MACE) risk reduction in adults with established cardiovascular disease and obesity or overweight	0.25 mg/0.5 mL (0.5 mL pre-filled pen)	2mL/28 days (4 pre-filled pens)
		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)	3mL/28 days (4 pre-filled pens)
		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)	15mL/30 days (5 pre-filled pens)
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 equiv)	Short-term weight management in patients ≥17	37.5 mg capsule	30 capsules/30 days

phentermine (Lomaira)	years of age; chronic weight management in patients ≥12 years of age (off-label)	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	120 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

Weight Maintenance

Initial Evaluation

** Treatment of excess body weight and weight maintenance only (i.e., not MACE risk reduction and not treatment of OSA) is considered 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, 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, 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
            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, 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
        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, 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, 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, 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

Major Adverse Cardiovascular Events (MACE) risk reduction

Initial Evaluation

I. **Semaglutide (Wegovy)** may be considered medically necessary when the following criteria are met:

A. Member is 18 years of age or older; **AND**

B. The request is for **Major Adverse Cardiovascular Events (MACE) risk reduction; AND**

C. Chart note documentation of established cardiovascular disease defined by one of the following:

1. Prior myocardial infarction
2. Prior stroke (ischemic or hemorrhagic)
3. Symptomatic peripheral arterial disease (PAD), as confirmed by one or more of the following:
   i. Intermittent claudication with ankle-brachial index (ABI) <0.85 (at rest)
   ii. Peripheral arterial revascularization procedure
   iii. Amputation due to atherosclerotic disease; **AND**

D. Member's body mass index (BMI) is ≥27 kg/m^2 within the last three months; **AND**

E. Member does not have type 1 or type 2 diabetes; **AND**

F. Member does not have NYHA Class IV heart failure; **AND**

G. Provider attestation that medication is used in combination with a reduced calorie diet and increased physical activity; **AND**

H. Member does not currently use any tobacco products (e.g., cigarettes, chewing tobacco); **OR**

1. The member is being managed for tobacco cessation; **AND**

I. Documentation that member is optimizing all of the following standard of care pharmacologic treatments, unless ineffective, not tolerated, not indicated, or all are contraindicated:

1. Antihypertensive therapy (e.g., ACE inhibitor [e.g., lisinopril, ramipril], ARB [e.g., losartan, valsartan], beta-blocker [e.g., metoprolol, carvedilol])
2. Lipid lowering therapy (e.g., statins [atorvastatin, simvastatin], ezetimibe)
3. Antiplatelet therapy (e.g., aspirin, clopidogrel, ticagrelor)

II. Semaglutide (Wegovy) is considered not medically necessary when criteria above are not met and/or when used for:
   A. Major Adverse Cardiovascular Events (MACE) risk reduction in patients with type 2 diabetes mellitus and overweight or obesity

III. Semaglutide (Wegovy) is considered investigational when used for all other conditions, including but not limited to:
   A. Major Adverse Cardiovascular Events (MACE) risk reduction in patients without prior myocardial infarction, prior stroke, or symptomatic peripheral artery disease (PAD)
   B. Major Adverse Cardiovascular Events (MACE) risk reduction in patients with NYHA stage IV heart failure
   C. Heart failure symptom reduction in patients with overweight or obesity

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. The request is for **Major Adverse Cardiovascular Events (MACE) risk reduction; AND**
IV. Chart note documentation of established cardiovascular disease defined by one of the following:
   A. Prior myocardial infarction
   B. Prior stroke (ischemic or hemorrhagic)
   C. Symptomatic peripheral arterial disease (PAD), as evidenced by ≥1 of the following:
      1. Intermittent claudication with ankle-brachial index (ABI) <0.85 (at rest)
      2. Peripheral arterial revascularization procedure
      3. Amputation due to atherosclerotic disease; **AND**
V. Member does not have type 1 or type 2 diabetes; **AND**
VI. Member does not have NYHA Class IV heart failure; **AND**
VII. Provider attestation that medication is used in combination with a reduced calorie diet and increased physical activity; **AND**
VIII. Member does not currently use any tobacco products (e.g., cigarettes, chewing tobacco); **OR**
   E. The member is being managed for tobacco cessation; **AND**
IX. Documentation that member is optimizing all of the following standard of care pharmacologic treatments, unless ineffective, not tolerated, not indicated, or all are contraindicated:
   A. Antihypertensive therapy (e.g., ACE inhibitor [e.g., lisinopril, ramipril], ARB [e.g., losartan, valsartan], beta-blocker [e.g., metoprolol, carvedilol])
   B. Lipid lowering therapy (e.g., statins [atorvastatin, simvastatin], ezetimibe)

C. Antiplatelet therapy (e.g., aspirin, clopidogrel, ticagrelor)

Obstructive Sleep Apnea (OSA)

Initial Evaluation

I. **Tirzepatide (Zepbound)** may be considered medically necessary when the following criteria are met:
   A. Member is 18 years of age or older; **AND**
   B. Medication is prescribed by, or in consultation with a sleep medicine specialist, pulmonologist, or otolaryngologist; **AND**
   C. Sleep study was completed within the last 5 years; **AND**
   D. The member has a diagnosis of **Obstructive Sleep Apnea (OSA); AND**
   E. Chart note documentation of moderate to severe disease defined by an apnea-hypopnea index (AHI) or obstructive respiratory disturbance index (RDI) ≥15; **AND**
   F. Provider attestation that the member had an adequate trial of primary obstructive sleep apnea (OSA) therapy (e.g. CPAP, mandibular advancement device, etc) and the member was unable to achieve their goal (e.g. at least 50% reduction in AHI, AHI<15, reduced health risk, etc); **OR**
      1. Provider attestation that the member was unable to tolerate primary OSA therapy (e.g. CPAP, mandibular advancement device, etc) despite proper education and adjustments; **AND**
   F. Member will continue to use primary obstructive sleep apnea (OSA) therapy (e.g. CPAP, mandibular advancement device, etc) in combination with **tirzepatide; OR**
      1. Provider attestation that the member was unable to tolerate primary OSA therapy (e.g. CPAP, mandibular advancement device, etc) despite proper education and adjustments; **AND**
   G. Documentation that the member's body mass index (BMI) ≥30 kg/m^2 within the last three months; **AND**
   H. Provider attestation that medication is used in combination with a reduced calorie diet and increased physical activity

II. **Tirzepatide (Mounjaro)** may be considered medically necessary when the following criteria are met:
   A. The request is for treatment of **Type 2 Diabetes Mellitus** and **Obstructive Sleep Apnea (OSA); AND**
      1. Criteria I(A)-I(H) above are met; **OR**
      2. Treatment with all of the following have been ineffective, contraindicated, or not tolerated
         i. Dulaglutide (Trulicity)

ii. Liraglutide
iii. Dapagliflozin (generic Farxiga)
iv. Ertugliflozin (Steglatro); **OR**

B. The member has a diagnosis of **Type 2 Diabetes Mellitus; AND**
1. Treatment with all of the following have been ineffective, contraindicated, or not tolerated
i. Dulaglutide (Trulicity)
ii. Liraglutide
iii. Dapagliflozin (generic Farxiga)
iv. Ertugliflozin (Steglatro)

III. Tirzepatide (Zepbound) is considered investigational when used for all other conditions, including but not limited to:
A. Obstructive sleep apnea (OSA) in patients without obesity
B. Metabolic dysfunction-associated steatohepatitis (MASH), or formerly nonalcoholic steatohepatitis (NASH)
C. Heart failure with preserved ejection fraction
D. Chronic kidney disease

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this 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**
XI. Member has exhibited improvement or stability of disease symptoms [e.g., improved A1c, reduction in excessive daytime sleepiness, improved sleep-related quality of life, etc); **AND**
XII. The request is for treatment of **tirzepatide (Zepbound)**; **AND**
A. Member will continue to use primary obstructive sleep apnea (OSA) therapy (e.g. CPAP, mandibular advancement device, etc) in combination with **tirzepatide; OR**
1. Provider attestation that the member was unable to tolerate primary OSA therapy (e.g. CPAP, mandibular advancement device, etc) despite proper education and adjustments; **AND**
B. Provider attestation that medication is used in combination with a reduced calorie diet and increased physical activity; **OR**
II. The request is **tirzepatide (Mounjaro)**

Supporting Evidence

Chronic Weight Management

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 greater 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. Diethylpropion was additionally studied in two low quality trials in patients <17 years, however, there's insufficient evidence to recommend this as treatment

option for chronic weight management in children and adolescents. Diethylpropion can be recommended for chronic weight management in adults 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.

XII. 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.

MACE risk reduction

I. Semaglutide (Wegovy) has not been studied in patients <18 years of age for the indication of Major Adverse Cardiovascular Events (MACE) risk reduction in those affected by overweight or obesity; therefore, the net health benefit in a younger patient population has not been established at this time.

II. Semaglutide (Wegovy) for MACE risk reduction in patients with overweight or obesity was studied in one Phase 3, randomized, double-blind, placebo-controlled trial (SELECT). Patients were included if they were ≥45 years of age, had a body mass index (BMI) ≥27kg/m^2, and had preexisting cardiovascular disease as evidenced by one of the following: prior myocardial infarction (MI), prior stroke (ischemic or hemorrhagic), or symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease. At baseline, the majority of patients had prior MI (68%), followed by stroke (18%), and symptomatic PAD (4%), and about 8% had two or more of these events. After a mean of 33 months of treatment, results demonstrated a 20% risk reduction (HR 0.80; 95% CI 0.72-0.90; p<0.001) in the composite of death from cardiovascular causes, nonfatal MI, and nonfatal stroke in favor of semaglutide (Wegovy) vs placebo. Efficacy (i.e., MACE risk reduction) has not been established in patients without these major cardiovascular events at baseline, as such, use in primary prevention of MACE is considered experimental and investigational.

III. Documentation of patient's body mass index (BMI) within the last three months is required to assess medical necessity for use. The safety and efficacy of semaglutide (Wegovy) for MACE reduction has not been established in those with BMI <27mg/kg^2.

IV. Semaglutide (Wegovy) has not been adequately studied in patients with diabetes and overweight or obesity and established cardiovascular disease for MACE risk reduction. The pivotal study (SELECT) excluded patients with type 1 and type 2 diabetes (history of gestational diabetes was allowed). Patients affected by diabetes type 2 or those that develop diabetes type 2 while on treatment with semaglutide (Wegovy) may benefit from treatment with anti-diabetic medications with established cardioprotective benefits in patients with diabetes (e.g., semaglutide [Ozempic]).

V. Semaglutide (Wegovy) has not been adequately studied in patients with NYHA Class IV heart failure symptoms for MACE risk reduction. The pivotal trial (SELECT) excluded patients with NYHA Class IV heart failure symptoms. Semaglutide (Wegovy) has been studied in a smaller subset of patients with NYHA Class IV heart failure with obesity in a different trial called STEP-HFpEF which showed improved heart failure symptoms in those taking semaglutide (Wegovy), however, MACE outcomes were not evaluated. As such, efficacy of semaglutide (Wegovy) in patients with NYHA Class IV HF for risk reduction of MACE has not been established and use in this population is considered experimental and investigational at this time.

VI. For MACE risk reduction, semaglutide (Wegovy) has been evaluated on top of standard of care which includes healthy lifestyle guidance (recommendations on improved diet and physical

activity, tobacco cessation) and standard of care pharmacologic therapy for cardiovascular disease (e.g., post-MI, post-stroke, PAD therapies). Overweight and obesity are major risk factors for development of future CV events, as such, first-line therapies for overweight and obesity which includes lifestyle counseling should be maximized. Tobacco use is an additional risk factor for development of CV events; therefore, concurrent tobacco use is not allowed unless patients are actively undergoing tobacco cessation. Additionally, SELECT trial studied semaglutide (Wegovy) in combination with drugs that treat or prevent CV disease (e.g., anti-hypertensives, lipid-lowering agents, anticoagulants, aspirin), for maximal benefit, standard of care agents for CVD should be optimized.

OSA with Obesity

I. Tirzepatide (Zepbound) was FDA for treatment of moderate to severe obstructive sleep apnea in adults with obesity on December 20,2024. Tirzepatide (Zepbound) has not been studied in patients <18 years of age for treatment of obstructive sleep apnea (OSA) with obesity, therefore, the net health benefit in a younger patient population has not been established at this time.

II. Given the complexity of diagnosis and management of OSA, the treatment of OSA must be initiated by, or in consultation with a sleep medicine specialist, pulmonologist, or otolaryngologist.

III. Tirzepatide (Zepbound) in treatment of OSA in adults with obesity was studied in one Phase 3, randomized, double-blinded, placebo-controlled trial (SURMOUNT-OSA). Participants were 18 years or older, had a diagnosis of moderate-to-severe OSA, defined by an apnea-hypopnea index (AHI) ≥15, and had a BMI ≥30 kg/m2. Weight loss medications were not permitted during enrollment. The study split participants into two groups. Those that did not receive prior continuous positive airway pressure (CPAP) were placed in cohort 1 and those that did receive prior PAP were placed in cohort 2. The primary endpoint was change in AHI at week 52 and secondary endpoints included change in hypoxic burden and patient-reported sleep impairment and disturbance. At baseline, the mean AHI was 51.5 in cohort 1 and 49.5 in cohort 2, and mean BMI 39.1 and 38.7, respectively. After 52 weeks, cohort 1 had a mean change in AHI of −25.3 events with tirzepatide (95% CI, −29.3 to −21.2) and −5.3 events with placebo (95% CI, −9.4 to −1.1), p <0.001. This correlates to an AHI lowering of about 50%. Cohort 2 had a mean change in AHI of −29.3 events with tirzepatide (95% CI, −33.2 to −25.4) and −5.5 events with placebo (95% CI, −9.9 to −1.2), p <0.001. This correlates to an AHI lowering of about 57%.

IV. There was a significant change in sleep-apnea-specific hypoxic burden between active and placebo arms, difference of -70.1% min/hr (95% CI, -90.9 to -49.3) and -61.3% (95% CI, -84.7 to -37.9) in trials 1 and 2, respectively. The Patient-Reported Outcomes Measurement Information (PROMIS) score difference between tirzepatide and placebo were -3.9 (95% CI, -5.7 to -2.2) and -3.1 (-4.5 to -1.5) in trials 1 and 2, respectively. There is moderate to high confidence that tirzepatide (Zepbound) reduces AHI as well as AHI burden when compared to placebo in treatment of OSA.

XIII. The 2019 American Academy of Sleep Medicine Clinical Practice guideline, 2018 American Thoracic Society Clinical Practice Guideline, and Cleveland Clinic Journal of Medicine Treatments for Obstructive Sleep Apnea guidelines support the use of reduction in AHI scores and oxygen desaturation levels to support efficacy in treatment OSA. While there is no set time to repeat a sleep apnea test, sleep specialists recommended an updated test every 5 years to account for returning symptoms, changes in lifestyle, or re-evaluation of primary OSA treatment.

V. Documentation of patient's body mass index (BMI) within the last three months is required to assess medical necessity for use. The safety and efficacy of tirzepatide (Zepbound) for OSA in adults has not been established in those with BMI <30mg/kg^2.

VI. The most frequently reported adverse events were generally gastrointestinal and occurred more frequently in the participants who received tirzepatide. These events were generally mild-to-moderate in severity and occurred most frequently during the dose-escalation phase. Serious adverse events were reported by 35 participants (7.5%) overall. Similar percentages of participants in the tirzepatide and placebo groups experienced adverse events. There were two confirmed cases of acute pancreatitis in the trial 2 tirzepatide group.

VII. Participants in SURMOUNT-OSA were permitted to continue CPAP while enrolled in the study. CPAP has been shown to reduce AHI by 72.5% in patients with OSA (compared to tirzepatide's reduction in AHI of 50% as monotherapy and 57% when used combination with CPAP). The 2019 American Academy of Sleep Medicine Clinical Practice guideline, 2018 American Thoracic Society Clinical Practice Guideline, and Cleveland Clinic Journal of Medicine Treatments for Obstructive Sleep Apnea guidelines note that CPAP is the gold standard therapy for adult patients with moderate to severe OSA. Moderate to severe OSA is defined by an AHI score of >15. Mild OSA is defined by an AHI score of 5 to 15. Guidelines note that the use of primary OSA therapy (e.g. CPAP) in this population may improve quality of life and reduce OSA-related excessive daytime sleepiness, fatigue, insomnia, uncontrolled hypertension, and heart disease.

VIII. Weight loss interventions and lifestyle modifications may be used in addition to PAP to treat OSA. Therefore, requiring PAP in treatment of OSA is clinically appropriate. For maximum benefit, standard of care agents for OSA should be optimized.

IX. Tirzepatide (Mounjaro) is FDA for treatment of type 2 diabetes mellitus. The 2024 ADA guidelines support the use of Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors and glucagon-like peptide-1 receptor agonists (GLP-1) as options for glycemic management and categorize these medications as a "high" likelihood of achieving glycemic goals. Guidelines do not make a recommendation of one agent over the other and requiring treatment with dulaglutide (Trulicity), liraglutide, dapagliflozin, and ertugliflozin (Steglatro) is clinically appropriate and cost effective.

X. While Mounjaro and Zepbound carry different FDA-approved indications, they are both available in all the same doses and dosage forms. Mounjaro and Zepbound can deliver the right amount of tirzepatide to treat both type 2 diabetes mellitus and OSA. OSA is a common comorbidity in patients with type 2 diabetes.

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
   E. Major Adverse Cardiovascular Events (MACE) risk reduction in patients with type 2 diabetes mellitus and overweight or obesity
      1. For this indication, semaglutide (Wegovy) is considered not medically necessary over available anti-diabetic drugs with established MACE risk reduction outcomes (e.g., semaglutide (Ozempic)).
   F. Major Adverse Cardiovascular Events (MACE) risk reduction in patients without prior myocardial infarction, prior stroke, or symptomatic peripheral artery disease (PAD)
      1. Primary prevention of MACE in patients with cardiovascular risk factors or CVD other than prior MI, prior stroke, or symptomatic PAD has not been established and is considered experimental and investigational at this time when the request is for semaglutide (Wegovy).
   G. Major Adverse Cardiovascular Events (MACE) risk reduction in patients with NYHA stage IV heart failure
      1. MACE risk reduction in patients with NYHA stage IV HF and overweight or obesity has not been adequately studied and is considered experimental or investigational when the request is for semaglutide (Wegovy).
   H. Heart failure symptom reduction in patients with overweight or obesity
      1. Semaglutide (Wegovy) is being studied in multiple trials (e.g., STEP HFpEF, STEP HFpEF DM) in patients with heart failure to evaluate its effects on heart failure symptoms. At this time, requests for this indication are considered experimental and investigational.
   I. Obstructive sleep apnea (OSA) in patients without obesity

1. The safety and efficacy of tirzepatide (Zepbound) for OSA in adults has not been established in those with BMI <30mg/kg^2

J. Metabolic dysfunction-associated steatohepatitis (MASH), or formerly nonalcoholic steatohepatitis (NASH)
K. Heart failure with preserved ejection fraction
L. Chronic kidney disease

Appendix

I. Table 1

Medication Class	Medication Names
Angiotensin-converting enzyme (ACE) inhibitors	Lisinopril, captopril, enalapril, benazepril, fosinopril, quinapril, ramipril, perindopril, trandolapril
Angiotensin II receptor blockers (ARB)	Losartan, olmesartan, valsartan, telmisartan, irbesartan, candesartan, azilsartan, eprosartan.
Beta-blockers	Propranolol, timolol, nadolol, metoprolol, carvedilol, bisoprolol, atenolol, nebivolol, acebutolol, pindolol, sotalol, bucindolol
Lipid lowering therapies	Atorvastatin, rosuvastatin, simvastatin, pravastatin, lovastatin, fluvastatin, pitavastatin, ezetimibe, bempedoic acid (Nexletol), bempedoic acid and ezetimibe (Nexlizet)
Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors	Evolocumab (Repatha), praluent (Alirocumab)
Antiplatelet therapy	Aspirin, clopidogrel, ticagrelol, prasugrel, cangrelor

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Policy Implementation/Update:

Action and Summary of Changes	Date
Added criteria II.A.2 to OSA criteria and reworded renewal criteria to improve flow	06/2025
Mounjaro updated to require prior authorization. Criteria added to support medical necessity review for Type 2 Diabetes Mellitus. In the setting of OSA: updated required specialists to include pulmonologist and otolaryngologist. Updated criteria for moderate to severe OSA and added criteria requiring a sleep study within the last 5 years. Access limited moderate to severe disease defined by an apnea-hypopnea index (AHI) or obstructive respiratory disturbance index (RDI) ≥15.	05/2025
Live 1/1/2025 - Added tirzepatide (Zepbound)'s new indication, treatment of obstructive sleep apnea (OSA) in adults with obesity	11/2024
Updated the supporting evidence section and references as a result of pediatric and adolescent chronic weight management class review	06/2024
Added semaglutide (Wegovy)'s new indication, major adverse cardiovascular events (MACE) risk reduction in patients affected by overweight and obesity.	05/2024
Statement regarding prioritized list and EPSDT included on top, criteria requiring provider attestation of condition severity included.	01/2024
Policy created	12/2023