
5.99.027

Section:	Prescription Drugs	Effective Date:	October 1, 2024
Subsection:	Miscellaneous Products	Original Policy Date:	September 9, 2022
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Last Review Date: September 6, 2024

Weight Loss Medications

Description

Adipex-P* (phentermine), Lomaira (phentermine), phentermine
Benzphetamine
Contrave (naltrexone and bupropion)
Diethylpropion
Phendimetrazine
Plenity* (carboxymethylcellulose-cellulose-citric acid)
Qsymia (phentermine and topiramate extended-release)
Saxenda (liraglutide)
Wegovy (semaglutide)
Xenical (orlistat)
Zepbound (tirzepatide)

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

Background

Obesity rates have increased dramatically in the 21st century and obesity contributes to increased morbidity, mortality, and the burden of healthcare costs. There are anti-obesity medications approved by the FDA for the long and short-term treatment of obesity. These medications for weight loss are indicated in combination with lifestyle modification for the management of obesity, and some are indicated for use in children as young as 12 years of age (1-3).

Regulatory Status

FDA-approved indications: (4-17)

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- Adipex-P, Contrave, Lomaira, phentermine, Qsymia, Saxenda, Wegovy, Xenical, and Zepbound are indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in patients with an initial body mass index (BMI) of:
 - 30 kg/m² or greater (obese) or
 - 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)
- Qsymia and Wegovy are indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients 12 years and older with an initial BMI in the 95th percentile or greater standardized for age and sex.
- Benzphetamine, diethylpropion and phendimetrazine are indicated in the management of exogenous obesity in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of 30 kg/m² or higher and who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone.
- Plenity is indicated to aid in weight management in adults with excess weight or obesity, a body mass index (BMI) of 25-40 kg/m², when used in combination with diet and exercise.
- Adipex-P, benzphetamine, diethylpropion, Lomaira, phendimetrazine, and generic phentermine are only indicated for short-term use (a few weeks).

Limitations of Use:

- The effect of Weight Loss Management Medications on cardiovascular morbidity and mortality has not been established (5,12).
- The safety and effectiveness of Weight Loss Management Medications in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established (5, 12-13, 17).

Patients should be periodically assessed for response to therapy. Evaluate decrease in BMI after 12-16 weeks of treatment. If a patient has not shown an appropriate decrease in BMI, discontinue the medication as it is unlikely that the patient will achieve and sustain clinically meaningful decrease in BMI with continued treatment (4-17).

The safety and effectiveness of Contrave, diethylpropion, phentermine products, phendimetrazine capsules, Plenity, and Zepbound in pediatric patients less than 17 years of age have not been established. The safety and effectiveness of benzphetamine, phendimetrazine tablets, Qsymia, Saxenda, Wegovy and Xenical in pediatric patients less than 12 years of age have not been established (4-17).

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Related policies

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Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Weight Loss Management Medications may be considered **medically necessary** if the conditions indicated below are met.

Weight Loss Management Medications may be considered **investigational** for all other indications.

Prior-Approval Requirements

*Prior authorization for *Adipex-P and *Plenity applies only to formulary exceptions due to being a non-covered medication.*

Age

17 years of age or older: *Adipex-P, Contrave, diethylpropion, Lomaira, phendimetrazine capsules, phentermine, Plenity, Zepbound

12 years of age or older: benzphetamine, phendimetrazine tablets, Qsymia, Saxenda, Wegovy, Xenical

Diagnosis

Patient must be using for the following:

Chronic weight management

AND ALL of the following:

1. Patient has **ONE** of the following:
 - a. Age 18+, must have **ONE** of the following:
 - i. Body mass index (BMI) ≥ 30 kg/m²
 - ii. Body mass index (BMI) ≥ 27 kg/m² **AND ONE** of the following:
 1. Patient has established cardiovascular disease (i.e., congenital heart disease, cerebrovascular disease, peripheral artery disease, or coronary heart disease)

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2. Patient has at least one weight related comorbid condition (i.e., type 2 diabetes mellitus, dyslipidemia, or hypertension)
 - b. Age 12-17 only: Body mass index (BMI) \geq 95th percentile for their age
2. Patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity with continuing follow-up for at least 3 months prior to using this medication
3. Patient will use this medication in combination with lifestyle changes and reduced calorie diet
4. Saxenda, Wegovy, or Zepbound **ONLY: NO** dual therapy with other glucagon-like peptide-1 (GLP-1) receptor agonists (e.g., Mounjaro, Rybelsus, Soliqua, Xultophy, etc.)
5. **Zepbound only:** Patient **MUST** have tried **BOTH** of the preferred products (Saxenda and Wegovy) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
6. **NO** dual therapy with another Prior Authorization (PA) medication for weight loss (see Appendix 1)

Prior – Approval *Renewal* Requirements

*Prior authorization for *Adipex-P and *Plenity applies only to formulary exceptions due to being a non-covered medication.*

Age

17 years of age or older: *Adipex-P, Contrave, diethylpropion, Lomaira, phendimetrazine capsules, phentermine, Plenity, Zepbound

12 years of age or older: benzphetamine, phendimetrazine tablets, Qsymia, Saxenda, Wegovy, Xenical

Diagnosis

Patient must be using for the following:

Chronic weight management

AND ALL of the following:

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1. Patient has had a clinically significant improvement in weight and/or patient has maintained their weight loss while on this medication
2. Patient will use this medication in combination with lifestyle changes and reduced calorie diet
3. Saxenda, Wegovy, or Zepbound **ONLY: NO** dual therapy with other glucagon-like peptide-1 (GLP-1) receptor agonists (e.g., Mounjaro, Rybelsus, Soliqua, Xultophy, etc.)
4. **Zepbound only:** Patient **MUST** have tried **BOTH** of the preferred products (Saxenda and Wegovy) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
5. **NO** dual therapy with another Prior Authorization (PA) medication for weight loss (see Appendix 1)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Medication	Quantity Limit
Benzphetamine	270 tablets per 90 days OR
Contrave	360 tablets per 90 days OR
Diethylpropion 25mg	270 tablets per 90 days OR
Diethylpropion 75mg	90 tablets per 90 days OR
Lomaira	270 tablets per 90 days OR
Phendimetrazine 35mg	270 tablets per 90 days OR
Phendimetrazine 105mg	90 capsules per 90 days OR
Phentermine	90 units per 90 days OR
Qsymia	90 capsules per 90 days OR
Saxenda	15 pre-filled pens per 90 days OR
Wegovy	12 single-dose pens per 84 days OR
Xenical	270 capsules per 90 days OR
Zepbound	12 single-dose pens per 84 days

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Medication <u>with approved formulary exception</u> <u>only</u>	Quantity Limit
Adipex-P	90 units per 90 days OR
Plenity	504 capsules per 84 days

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity

Medication	Quantity Limit
Benzphetamine	270 tablets per 90 days OR
Contrave	360 tablets per 90 days OR
Diethylpropion 25mg	270 tablets per 90 days OR
Diethylpropion 75mg	90 tablets per 90 days OR
Lomaira	270 tablets per 90 days OR
Phendimetrazine 35mg	270 tablets per 90 days OR
Phendimetrazine 105mg	90 capsules per 90 days OR
Phentermine	90 units per 90 days OR
Qsymia	90 capsules per 90 days OR
Saxenda	15 pre-filled pens per 90 days OR
Wegovy	12 single-dose pens per 84 days OR
Xenical	270 capsules per 90 days OR
Zepbound	12 single-dose pens per 84 days

Medication <u>with approved formulary exception</u> <u>only</u>	Quantity Limit
Adipex-P	90 units per 90 days OR
Plenity	504 capsules per 84 days

Duration 12 months

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Rationale

Summary

Weight loss is a pathway to health improvement for patients with obesity-associated risk factors and comorbidities. Medications approved for chronic weight management can be useful adjuncts to lifestyle change for patients who have been unsuccessful with diet and exercise alone (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Weight Loss Management Medications while maintaining optimal therapeutic outcomes.

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Policy History

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Date	Action
January 2023	Addition to PA
February 2023	Per PI update: Wegovy age expanded to 12 years of age and older
March 2023	Annual review
December 2023	Annual review. Pediatric reference added. Added initiation requirement to participate in comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity
January 2024	Addition of Zepbound to policy as non-preferred option on MedEx
March 2024	Annual review
April 2024	Revised indication to include established CVD for overweight patients. Per FEP, made the list of co-morbid and established cardiovascular conditions specific
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.

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Appendix 1 - List of PA Weight Loss Medications

Generic Name	Brand Name
benzphetamine	N/A
carboxymethylcellulose-cellulose-citric acid	Plenity
diethylpropion	N/A
liraglutide	Saxenda
naltrexone/bupropion	Contrave
orlistat	Xenical
phendimetrazine	N/A
phentermine	Adipxex-P/Lomaira
phentermine/topiramate ER	Qsymia
semaglutide	Wegovy
setmelanotide	Imcivree
tirzepatide	Zepbound