

Federal Employee Program.

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5.99.027

Section: **Prescription Drugs Effective Date:** January 1, 2025

Subsection: Miscellaneous Products **Original Policy Date:** September 9, 2022

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Last Review Date: December 13, 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)

Xenical (orlistat)

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)

Adipex-P, Contrave, Lomaira, phentermine, Qsymia, and Xenical 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:

^{*}Prior authorization for the brand formulation applies only to formulary exceptions due to being a noncovered medication.

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o 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, and Plenity in pediatric patients less than 17 years of age have not been established. The safety and effectiveness of benzphetamine, phendimetrazine tablets, Qsymia and Xenical in pediatric patients less than 12 years of age have not been established (4-17).

Related policies

Imcivree, Saxenda Wegovy, Zepbound

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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

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

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) \geq 27 kg/m² **AND ONE** of the following:
 - Patient has established cardiovascular disease (e.g., congenital heart disease, cerebrovascular disease, peripheral artery disease, coronary heart disease, acute coronary syndrome (ACS), myocardial infarction (MI), unstable angina, coronary or other arterial revascularization, or prior percutaneous coronary intervention/coronary bypass surgery)

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 Patient has at least one weight related comorbid condition (e.g., type 2 diabetes mellitus, dyslipidemia, or hypertension)

- b. Age 12-17 **ONLY**: Body mass index (BMI) ≥95th percentile for their age
- 2. Patient has participated in a comprehensive weight management program (e.g., Teledoc or another weight loss program)
- 3. **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

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

Diagnosis

Patient must be using for the following:

Chronic weight management

AND ALL of the following:

- Age 18+ ONLY: The patient has lost at least 5 percent of baseline body weight OR the patient continued to maintain their initial 5 percent weight loss
- 2. Age 12-17 **ONLY**: Patient has maintained clinically significant weight loss
- 3. Patient has participated in a comprehensive weight management program (e.g., Teledoc or another weight loss program)
- 4. **NO** dual therapy with another Prior Authorization (PA) medication for weight loss (see Appendix 1)

Policy Guidelines

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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
Xenical	270 capsules per 90 days OR

Medication	Quantity Limit
with approved formulary exception	
<u>only</u>	
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

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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
Xenical	270 capsules per 90 days OR

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

Duration 12 months

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.

References

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- 14. Xenical [package insert]. Montgomery, AL: H2-Pharma, LLC.: January 2018.

Policy History	
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
December 2024	Annual review. Per FEP, placed Saxenda/Wegovy and Zepbound on their own policies, added behavior modification requirement for initiation and continuation, changed requirement for adults to have a 5% BMI reduction and pediatrics to have clinically significant weight loss for continuation
Keywords	

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.

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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