
5.99.027

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| Section: | Prescription Drugs | Effective Date: | April 1, 2024 |
| Subsection: | Miscellaneous Products | Original Policy Date: | September 9, 2022 |
| Subject: | Weight Loss Medications | Page: | 1 of 9 |

Last Review Date: March 8, 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

Imcivree

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** patient has at least one weight related comorbid condition (e.g., type 2 diabetes mellitus, dyslipidemia, hypertension, coronary heart disease, sleep apnea)

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- b. Age 12-17 only: Body mass index (BMI) $\geq 95^{\text{th}}$ 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:

1. Patient has had a clinically significant improvement in weight and/or patient has maintained their weight loss while on this medication

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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 |

| Medication | Quantity Limit |
|------------|----------------|
|------------|----------------|

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

Duration 12 months

Rationale

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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

| Date | Action |
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| January 2023 | Addition to PA |

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| 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 |

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 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 |