



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2024 P 1114-14 |
| Program | Prior Authorization/Notification - Plans with Weight Loss Medication Coverage |
| Medication | Includes both brand and generic versions and all formulations of the listed products unless otherwise noted: Weight Loss – phentermine (all brand products including Adipex-P® and Lomaira™), benzphetamine, Contrave® (naltrexone HCl and bupropion HCl, diethylpropion, Imcivree® (setmelanotide), phendimetrazine, orlistat (Xenical®), Qsymia® (phentermine and topiramate extended-release), Saxenda® (liraglutide) Wegovy® (semaglutide) and Zepbound™ (tirzepatide) |
| P&T Approval Date | 1/08, 1/2010, 1/2011, 1/2012, 11/2012, 11/2013, 11/2014, 7/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 4/2021, 9/2021, 9/2022, 2/2023, 12/2023, 5/2024 |
| Effective Date | 8/1/2024 |

1. **Background:**

This is an optional program that is put in place for clients or businesses that have elected to cover weight loss products with Prior Authorization/Notification. It is also designed to meet regulatory requirements for coverage of weight loss medications in California, New Mexico and New York.

| Classification | BMI(kg/m ²) |
|-----------------|-------------------------|
| Underweight | < 18.50 |
| Normal range | 18.50 - 24.99 |
| Overweight | ≥ 25.00 |
| Obese | ≥ 30.00 |
| Obese class I | 30.00 - 34.99 |
| Obese class II | 35.00 - 39.99 |
| Obese class III | ≥ 40.00 |

2. **Coverage Criteria^a:**

A. Initial Authorization

1. **benzphetamine, Contrave, diethylpropion, phentermine, phendimetrazine, Qsymia, Saxenda, Wegovy, Xenical or Zepbound (Includes both brand and generic versions and all formulations of the listed products unless otherwise noted)** will be approved based on all of the following criteria:

- a. **One** of the following:

- (1) Treatment is being requested for appetite suppression or weight loss
- (2) Wegovy is being requested for risk reduction of major adverse cardiovascular events with established cardiovascular disease^b

-AND-

b. **One** of the following:

- (1) Patient is ≥ 12 years of age (for Qsymia, Saxenda, Wegovy and Xenical)
- (2) Patient is > 16 years of age (for other appetite suppressants)

-AND-

c. Used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

-AND-

d. **One** of the following:

- (1) Body Mass Index (BMI) ≥ 30 kg/m² or for pediatric patients a BMI $\geq 95^{\text{th}}$ percentile

-OR-

(2) **Both** of the following:

- (a) BMI ≥ 27 kg/m²

-AND-

- (b) Patient has a weight-related comorbidity (e.g., dyslipidemia, hypertension, type 2 diabetes, sleep apnea)

benzphetamine, diethylpropion, phendimetrazine, phentermine: Authorization will be issued for 3 months.

Contrave, Qsymia, Saxenda or Wegovy: Authorization will be issued for 4 months.

Xenical or Zepbound: Authorization will be issued for 6 months.

2. **Imcivree** will be approved based on **all** of the following criteria:

a. **One** of the following:

- (1) Diagnosis of obesity is due to POMC, PCSK1, or LEPR gene deficiency confirmed with genetic testing interpreted as pathogenic, likely pathogenic, or of uncertain significance

-OR-

- (2) Diagnosis of Bardet-Biedl syndrome

-AND-

b. **One** of the following:

(1) Adult patient with BMI ≥ 30 kg/m²

-OR-

(2) Pediatric patient with weight $>95^{\text{th}}$ percentile for age on growth chart assessment

-AND-

c. Patient is currently enrolled in or has history of a weight loss management program

Authorization will be issued for 6 months.

B. Reauthorization

1. **benzphetamine Contrave, diethylpropion, phentermine, phendimetrazine, Qsymia, Saxenda, Wegovy, Xenical or Zepbound (Includes both brand and generic versions and all formulations of the listed products unless otherwise noted)** will be approved based on **both** of the following criteria:

a. One of the following:

(1) Weight loss of $\geq 3\%$ of baseline body weight for Qsymia

(2) Weight loss of $\geq 4\%$ of baseline body weight for Saxenda

(3) Weight loss of $\geq 5\%$ of baseline body weight for all other appetite suppressants

-AND-

b. Continuation of lifestyle modification

Authorization for Contrave, Qsymia, Saxenda, Wegovy Xenical or Zepbound will be issued for 12 months.

Authorization for benzphetamine, diethylpropion, phentermine or phendimetrazine or will be issued for 6 months.

2. **Imcivree** will be approved based on **one** of the following criteria:

a. If on therapy for less than 12 months, documentation of a positive clinical response to Imcivree therapy defined as weight loss $\geq 5\%$ of baseline weight

-OR-

- b. If on therapy for ≥ 12 months, documentation of a positive clinical response to Imcivree therapy defined as $\geq 10\%$ weight loss from baseline

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

^b Refer to Nonformulary Wegovy criteria for plans that do not cover weight loss medications.

3. **Additional Clinical Rules:**

- Supply limits may be in place.

4. **References:**

1. American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. *Endocr Pract.* 2016;22(Suppl 3).
2. National Institutes of Health, National Heart, Lung, and Blood Institute, and North American Association for the Study of Obesity. The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. 2000.
3. American Gastroenterological Association medical position statement on obesity. *Gastroenterology* 2002 Sep;123(3):879-81.
4. Bray, GA, Ryan, DH. Medical Therapy for the Patient with Obesity. *Circulation.* 2012;125:1695-1703.
5. Barlow, SE. Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report. *Pediatrics* 2007.
6. Benzphetamine [package insert]. Laurelton, NY: Epic Pharma, LLC; January 2021.
7. Diethylpropion ER [package insert]. Congers, NY: Chartwell RX, LLC; March 2023.
8. Phendimetrazine Slow-Release Capsules [package insert]. Princeton, NJ: Sandoz Inc.; November 2018.
9. Adipex-P® [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc; ;March 2020.
10. Xenical [package insert]. Montgomery, AL: H2-Pharma, LLC; November 2022.
11. Qsymia [package insert]. Mountain View, CA. Vivus, Inc ; June 2023.
12. Contrave [package insert]. Brentwood, TN: Currax Pharmaceuticals, LLC; December 2022.
13. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk ; April 2023.
14. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism* 2015 100:2, 342-362
15. AHA/ACC/TOS Prevention Guideline: 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults: A Report to the American College of Cardiology/American Health Association Task Force on Practice Guidelines and The Obesity Society. *Circulation.* 2014; 129:S102-138
16. World Health Organization. (2006). *Global Database on Body Mass Index*. Retrieved from <https://www.who.int/data/gho/data/themes/topics/topic-details/GHO/body-mass-index>
17. Lomaira [package insert]. Newtown, PA: KVK-Tech, Inc. December 2018.
18. Imcivree [package insert]. Boston, MA: Rhythm Pharmaceuticals, Inc; June 2022.
19. Wegovy [package insert]. Plainsboro, NJ: Novo Nordisk; July 2023.

20. Jastreboff, AM, et al. Tirzepatide Once Weekly for the Treatment of Obesity. N Engl J Med 2022 ; 387 : 205-216.
21. Zepbound [package insert]. Indianapolis, IN: Lilly USA, LLC ; November 2023.

| Program | Weight Loss |
|-----------------------|---|
| Change Control | |
| Date | Change |
| 11/2013 | Reformatted to standard and updated references. Clarified risk factors required in addition to BMI of 27-29. Removed criteria that coverage would not be provided if used in combination with other weight loss agents. Shortened initial authorization for sympathomimetics to 3 months based on PI recommendations for short-term use. Added reauthorization criteria for 6 months, changed initial authorization period of Xenical from 4 months to 3 months, and shortened reauthorization of Belviq and Xenical to 12 months for alignment with OptumRx. |
| 11/2014 | Added Contrave to guideline. |
| 7/2015 | Added Saxenda to guideline. |
| 9/2016 | Annual Review. Added Belviq XR to guideline. Revised authorization period for Xenical. Removed ASO from title- program will remain as ASO option. |
| 9/2017 | Annual Review. Added Lomaira. Updated references. Revised weightloss percentage for Saxenda per PI. |
| 9/2018 | Annual Review. Updated references. |
| 9/2019 | Annual Review. Revised background section. Revised list of modifications of weight related comorbidity. |
| 9/2020 | Annual review. Updated references. Removed Belviq/Belviq XR. |
| 4/2021 | Added Imcivree as in scope. Added Imcivree criteria. Updated references. Formatting changes. |
| 9/2021 | Added Wegovy to criteria. Updated Saxenda criteria to allow for coverage for 12 years and older. Updated Qsymia weight loss goal to greater than 3 percent per label and changed initial authorization to 4 months. Updated references. |
| 9/2022 | Added background note that this program is intended to meet regulatory requirements for coverage of weight loss medications in California, Maryland, New Mexico and New York. This program is replacing policy P 1172-8. Changed Qsymia age requirement to 12 or older due to new pediatric labeling. Updated Imcivree to include new FDA approved indication for Bardet-Biedl syndrome. Updated references. |
| 2/2023 | Updated Wegovy criteria to include pediatric patients based on new labeling. Added state mandate language. |
| 12/2023 | Added Zepbound to criteria. Removed Maryland from background. |
| 5/2024 | Removed notation that Zepbound may be excluded at launch. Added coverage for secondary cardiovascular risk reduction for Wegovy. |