UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1114-18
Program	Prior Authorization/Notification - Plans with Weight Loss/Appetite Suppression Medication Coverage
Medication	**Includes both brand and generic versions and all formulations of the listed products unless otherwise noted:** Weight Loss/Appetite Suppresion – 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), Vykat XR™ (diazoxide choline), 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, 7/2024, 3/2025, 5/2025, 6/2025
Effective Date	9/1/2025

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, North Dakota Essential Health Benefits (EHB) 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**

Section Overview
Section 2: General coverage criteria
Section 3: Coverage criteria for North Dakota Fully Insured EHB (Small Group and Individual) Plans

2. Coverage Criteria[a]:

A. <u>Initial Authorization</u>

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 (i.e. prior myocardial infarction, ischemic or hemorrhagic stroke, or peripheral arterial disease)[b]
(3) Zepbound is being requested for moderate to severe obstructive sleep apnea[c]

-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/m^2 or for pediatric patients a BMI ≥ 95th percentile

-OR-

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

(a) BMI ≥ 27 kg/m^2

-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 or Saxenda: Authorization will be issued for 4 months.

Wegovy: Authorization will be issued for 5 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/m^2

      -OR-

      (2) Pediatric patient with weight >95th 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.

3. **Vykat XR** will be approved based on **all** of the following criteria:

   a. Diagnosis of hyperphagia associated with Prader-Willi Syndrome

   -AND-

   b. Prader-Willi Syndrome is confirmed by genetic testing

   -AND-

   c. Patient is at least 4 years of age and older

   Authorization will be issued for 12 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 ≥ 3% of baseline body weight for Qsymia
(2) Weight loss of ≥ 4% of baseline body weight for Saxenda
(3) Weight loss of ≥ 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 ≥5% of baseline weight

-OR-

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

Authorization will be issued for 12 months.

3. Vykat XR will be approved based on the following criterion:

a. Documentation of positive clinical response to Vykat XR therapy

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.
[c] Refer to Nonformulary Zepbound criteria for plans that do not cover weight loss medications.

3. Coverage Criteria for North Dakota Fully Insured EHB (Small Group and Individual) Plans[a]:

A. Initial Authorization

1. **Wegovy or Zepbound** 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 (i.e. prior myocardial infarction, ischemic or hemorrhagic stroke, or peripheral arterial disease)[b]
(3) Zepbound is being requested for moderate to severe obstructive sleep apnea[c]

-AND-

b. **One** of the following:

(1) Patient is ≥ 12 years of age for Wegovy
(2) Patient is > 16 years of age for Zepbound

-AND-

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

-AND-

d. Body Mass Index (BMI) ≥ 40 kg/m^2 or for pediatric patients a BMI ≥ 120% of 95th percentile

Wegovy: Authorization will be issued for 5 months.

Zepbound: Authorization will be issued for 6 months.

B. Reauthorization

1. **Wegovy or Zepbound** will be approved based on **both** of the following criteria:

a. Weight loss of ≥ 5% of baseline body weight

-AND-

b. Continuation of lifestyle modification

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.
[c] Refer to Nonformulary Zepbound criteria for plans that do not cover weight loss medications.

4. Additional Clinical Rules:

- Supply limits may be in place.

5. 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. Benzphetamine [package insert]. Laurelton, NY: Epic Pharma, LLC; June 2023.
3. Diethylpropion ER [package insert]. Congers, NY: Chartwell RX, LLC; March 2023.
4. Phendimetrazine Slow-Release Capsules [package insert]. Langhorne, PA: Acertis Pharmaceuticals, LLC; September 2019.
5. Adipex-P® [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc; March 2024.
6. Xenical [package insert]. Montgomery, AL: H2-Pharma, LLC; July 2024.
7. Qsymia [package insert]. Moutain View, CA. Vivus, Inc ; September 2024.
8. Contrave [package insert]. Brentwood, TN: Nalpropion Pharmaceuticals, LLC; May 2024.
9. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk ; November 2024.
10. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism 2015 100:2, 342-362
11. 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
12. 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
13. Lomaira [package insert]. Newtown, PA: KVK-Tech, Inc. December 2023.
14. Imcivree [package insert]. Boston, MA: Rhythm Pharmaceuticals, Inc; November 2023.
15. Wegovy [package insert]. Plainsboro, NJ: Novo Nordisk; November 2024.
16. Jastreboff, AM, et al. Tirzepatide Once Weekly for the Treatment of Obesity. N Engl J Med 2022 ; 387 : 205-216.
17. Zepbound [package insert]. Indianapolis, IN: Lilly USA, LLC ; December 2024.
18. Grunvald E, Shah R, Hernaez R, etc al. AGA Clinical Practice Guideline on Pharmacological Interventions for Adults with Obesity. Gastroenterology 2022;163:1198-1225.
19. Vykat XR [package insert]. Redwood City, CA : Soleno Therapeutics, Inc.; March 2025.

Program	Weight Loss/Appetite Suppression
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.
7/2024	Added coverage requirements for North Dakota EHB.
3/2025	Added coverage for obstructive sleep apnea for Zepbound.
5/2025	Updated Wegovy initial authorization duration to 5 months.
6/2025	Added Vykat XR as in scope. Added Vykat XR criteria and updated program name to include appetite suppressants. Updated references. Formatting changes.