UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1172-8
Program	Prior Authorization – California, Maryland, New Mexico and New York Regulatory Program - Weight Loss
Medication	**Includes both brand and generic versions and all formulations of the listed products unless otherwise noted** Xenical (orlistat), benzphetamine, diethylpropion, phendimetrazine, phentermine (all brand products including Adipex-P and Lomaira) Contrave (naltrexone and bupropion), Imcivree (setmelanotide), Qsymia (phentermine and topiramate extended-release), Saxenda (liraglutide), and Wegovy (semaglutide)
P&T Approval Date	11/2015, 9/2016, 9/2018, 9/2019, 11/2019, 11/2020, 4/2021, 9/2021
Effective Date	12/1/2021; Oxford only: 12/1/2021

1. Background:

Anti-obesity agents are indicated in the management of obesity as an adjunct to lifestyle modifications including diet, exercise and behavioral modification. Medication therapy may provide modest weight reduction in conjunction with lifestyle modifications and therapy selection may be based on a specific medications side effects and warnings.

Body Mass Index (BMI) uses weight and height to create an index of underweight, overweight or obesity in adults. The international classification is as follows:

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**

WHO Global Database on Body Mass Index

This program uses Obese Class III (morbid obesity) and Obese Class I (with weight related comorbidities) as markers for coverage. It is designed to meet regulatory requirements for coverage of weight loss medications in: California and Maryland, which

require coverage for morbid obesity; New Mexico, which requires coverage for obesity and morbid obesity; and New York, which requires coverage for weight loss.

2. Coverage Criteria:

A. benzphetamine, diethylpropion, phendimetrazine, phentermine (Includes both brand and generic versions and all formulations of the listed products unless otherwise noted):

1. **Initial Authorization:**

a. Coverage will be approved based on **all** of the following:

(1) Treatment is being requested for weight loss

(2) Patient is > 16 years of age

(3) Failure to lose ≥ 5% of body weight after at least 6 months of lifestyle modification alone (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program). Document lifestyle modifications employed and total weight loss

(4) **One** of the following:

(a) Failure to lose ≥ 5% of body weight after six months of treatment with OTC orlistat (Alli) (document date of trial of orlistat and total body weight lost)
(b) Contraindication (including age) or intolerance to OTC orlistat (Alli)

(5) Used as an adjunct to lifestyle modification. Document which lifestyle modification will be employed.

(6) **One** of the following:

(a) Body Mass Index (BMI) ≥ 40 kg/m^2 (Obesity Class III). Documentation of current height and weight required.

-OR-

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

i. BMI ≥ 30 kg/m^2 (Obesity Class I). Documentation of current height and weight required.
ii. Documentation of a weight-related comorbidity(examples include dyslipidemia, hypertension, type 2 diabetes, sleep apnea)

Authorization will be issued for 3 months.

2. **Reauthorization:**

a. Coverage will be approved based on **both** of the following:

(1) Documentation of current weight showing a weight loss of ≥ 5% of baseline body weight

(2) Documentation of continuation of lifestyle modification

Authorization for will be issued for 6 months.

B. **Xenical, Contrave or Qsymia (Includes both brand and generic versions and all formulations of the listed products unless otherwise noted):**

1. **Initial Authorization:**

a. Coverage will be approved based on **all** of the following:

(1) Treatment is being requested for weight loss

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

(a) Patient is ≥ 12 years of age for Xenical
(b) Patient is ≥ 18 years of age for Contrave or Qsymia

(3) Failure to lose ≥ 5% of body weight through at least 6 months of lifestyle modification alone (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program). Document lifestyle modifications employed and total weight loss

(4) **One** of the following:

(a) Failure to lose ≥ 5% of body weight after six months of treatment with OTC orlistat (Alli) (document date of trial of orlistat and total body weight lost)
(b) Contraindication (including age) or intolerance to OTC orlistat (Alli)

(5) Used as an adjunct to lifestyle modification. Document which lifestyle modification will be employed.

(6) **One** of the following:

(a) Body Mass Index (BMI) ≥ 40 kg/m^2 (Obesity Class III) Documentation of current height and weight required.

-OR-

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

i. BMI ≥ 30 kg/m^2 (Obesity Class I) Documentation of current height and weight required.
ii. Documentation of a weight-related comorbidity (e.g. dyslipidemia, hypertension, type 2 diabetes, sleep apnea)

Contrave or Qsymia: Authorization will be issued for 4 months.
Xenical: Authorization will be issued for 6 months.

2. Reauthorization

a. Coverage will be approved based on **both** of the following:

(1) **One** of the following:
(a) Documentation of current weight showing a weight loss of ≥ 3% of baseline body weight for Qsymia
(b) Documentation of current weight showing a weight loss of ≥ 5% of baseline body weight for Contrave or Xenical

(2) Documentation of continuation of lifestyle modification

Authorization will be issued for 6 months.

C. Saxenda or Wegovy

1. **Initial Authorization:**

a. Coverage will be approved based on **all** of the following:

(1) Treatment is being requested for weight loss

(2) **One** of the following:
(a) Patient is ≥ 18 years of age for Wegovy
(b) Patient is ≥ 12 years of age for Saxenda

(3) Failure to lose ≥ 5% of body weight through at least 6 months of lifestyle modification alone (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program). Document lifestyle modifications employed and total weight loss

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

(a) **One** of the following:

i. Failure to lose ≥ 5% of body weight after six months of treatment with OTC orlistat (Alli) (document date of trial of orlistat and total body weight lost)

ii. Contraindication (including age) or intolerance to OTC orlistat (Alli)

(b) Contraindication, intolerance or failure to lose and maintain ≥ 5% body weight following 3 month trial EACH, of **two** of the following medications (document date of trial of each medication and total body weight lost):
i. Prescription Xenical
ii. Qsymia
iii. Contrave

(5) Used as an adjunct to lifestyle modification. Document which lifestyle modification will be employed

(6) **One** of the following:

(a) Body Mass Index (BMI) ≥ 40 kg/m^2 (Obesity Class III). Documentation of current height and weight required.

-OR-

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

i. BMI ≥ 30 kg/m^2 (Obesity Class I). Documentation of current height and weight required.
ii. Documentation of a weight-related comorbidity (e.g. dyslipidemia, hypertension, type 2 diabetes, sleep apnea)

Authorization will be issued for 4 months.

2. Reauthorization

a. Coverage will be approved based on **both** of the following:

(1) Documentation of current weight showing a weight loss of ≥ 5% of baseline body weight

(2) Documentation of continuation of lifestyle modification

Authorization will be issued for 6 months.

D. **Imcivree**

1. **Initial Authorization:**

a. Coverage will be approved based on **all** of the following:

(1) Diagnosis of obesity is due to POMC, PCSK1, or LEPR gene deficiency

-AND-

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

(a) Adult patient with BMI ≥ 30 kg/m^2

-OR-

(b) Pediatric patient with weight >95th percentile for age on growth chart assessment

-AND-

(3) Genetic testing confirming variants in POMC, PCSK1, or LEPR genes interpreted as pathogenic, likely pathogenic, or of uncertain significance

-AND-

(4) Patient is currently enrolled in or has history of a weight loss management program

Authorization will be issued for 6 months.

2. Reauthorization

a. Coverage will be approved based on **one** the following criterion:

(1) 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-

(2) 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. Additional Clinical Rules:

- Supply limits may be in place.

4. References:

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8. Phendimetrazine Slow-Release Capsules [package insert]. Princeton, NJ: Sandoz Inc.; November 2018.
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17. Lomaira [package insert]. Newtown, PA: KVK-Tech, Inc. December 2018.
18. Imcivree [package insert]. Boston, MA: Rhythm Pharmaceuticals, Inc; November 2020.
19. Wegovy [package insert]. Plainsboro, NJ: Novo Nordisk; June 2021.

Program	Prior Authorization - California and New York Regulatory Program - Weight Loss
Change Control	
Date	Change
11/2015	New program.
9/2016	Annual review. Added Belviq XR.
9/2018	Added Lomaira as in scope. Updated references. Formatting changes.
9/2019	Annual Review. Revised background section. Revised list of modifications of weight related comorbidity.
11/2019	Added Maryland as in scope per rider requirements.
11/2020	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 New Mexico to list of states program applies to. 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.