UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1172-3
Program	Prior Authorization - California 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) Belviq, Belviq XR (lorcaserin), Contrave (naltrexone and bupropion), Qsymia (phentermine and topiramate extended-release), and Saxenda (liraglutide)
P&T Approval Date	11/2015, 9/2016, 9/2018
Effective Date	12/1/2018; Oxford only: 12/1/2018

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/m²)**	
	Principal cut-off points	**Additional cut-off points**
Underweight	**< 18.50**	**< 18.50**
Severe thinness	< 16.00	< 16.00
Moderate thinness	16.00 - 16.99	16.00 - 16.99
Mild thinness	17.00 - 18.49	17.00 - 18.49
Normal range	**18.50 - 24.99**	**18.50 - 22.99**
		23.00 - 24.99
Overweight	**≥ 25.00**	**≥ 25.00**
Pre-obese	25.00 - 29.99	25.00 - 27.49
		27.50 - 29.99
Obese	**≥ 30.00**	**≥ 30.00**
Obese class I	30.00 - 34.99	30.00 - 32.49
		32.50 - 34.99
Obese class II	35.00 - 39.99	35.00 - 37.49

		37.50 - 39.99
Obese class III	≥ 40.00	≥ 40.00

WHO Global Database on Body Mass Index

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

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 one of the following weight-related

comorbidities:

- Dyslipidemia defined as HDL < 40mg/dL, LDL cholesterol ≥ 160 mg/dL or triglycerides ≥ 500 mg/dL.
- Hypertension (systolic blood pressure higher than 140 mm Hg or diastolic blood pressure higher than 90 mm Hg)
- 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, Belviq, Belviq XR, 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 Belviq, Belviq XR, Contrave, 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 one of the following weight-related comorbidities:
- Dyslipidemia defined as HDL < 40mg/dL, LDL cholesterol ≥ 160 mg/dL or triglycerides ≥ 500 mg/dL.
- Hypertension (systolic blood pressure higher than 140 mm Hg or diastolic blood pressure higher than 90 mm Hg
- Type 2 diabetes
- Sleep apnea

Belviq, Belviq XR: Authorization will be issued for 3 months.
Contrave: Authorization will be issued for 4 months.
Qsymia, Xenical: Authorization will be issued for 6 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.

C. **Saxenda**

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 ≥ 18 years of age

(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. Belviq or Belviq XR
iv. 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 one of the following weight-related comorbidities:
- Dyslipidemia defined as HDL < 40 mg/dL, LDL cholesterol ≥ 160 mg/dL or triglycerides ≥ 500 mg/dL.
- Hypertension (systolic blood pressure higher than 140 mm Hg or diastolic blood pressure higher than 90 mm Hg
- Type 2 diabetes
- Sleep apnea

Authorization will be issued for 4 months.

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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.

3. Additional Clinical Rules:

- Supply limits may be in place.

4. References:

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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 Obestiy: Summary Report. Pediatrics 2007.
6. Product Information : Benzphentermine Tablets (Didrex® – Pharmacia Pharmaceuticals) August, 2010.
7. Product Information : Diethylpropion Dospan (Tenuate®- Merrell Pharmaceuticals). November, 2003.
8. Product Information : Phendimetrazine Slow-Release Capsules (Bontril® - Carnick Laboratories) April, 2010.
9. Adipex-P® Product Information,Gate Pharmaceuticals. March 2017.
10. Xenical®Product Information. Roche Pharmaceuticals South San Francisco, CA. December 2017.
11. Belviq Prescribing information. Eisai Inc, Woodcliff Lake, NJ. June 2018.
12. Qsymia Prescribing Information. Vivus, Inc. Mountain View, CA March 2018.
13. Contrave Prescribing Information. Takeda Pharmacuticals America, Inc. Deerfield, IL. September, 2014.
14. Saxenda Prescribing Information. Novo Nordisk. Plainsboro, NJ. April 2017.
15. Bray, GA. Obesity in Adults. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on September 14, 2015.)
16. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive summary of the third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA. 2001;285:2486-2497.

17. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism 2015 100:2, 342-362
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19. World Health Organization. (2006). *Global Database on Body Mass Index.* Retrieved from http://apps.who.int/bmi/index.jsp?introPage=intro_3.html
20. Belviq XR Prescribing Information. Eisai Inc, Woodcliff Lake, NJ. J.
21. Lomaira Prescribing Information. KVK-Tech, Inc. Newtown, PA. September 2016.

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.