UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

<table>
<thead>
<tr>
<th>Program Number</th>
<th>2019 P 1172-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td>Prior Authorization – California, Maryland and New York Regulatory Program - Weight Loss</td>
</tr>
<tr>
<td>Medication</td>
<td>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)</td>
</tr>
<tr>
<td>Effective Date</td>
<td>1/1/2020; Oxford only: 2/1/2020</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI(kg/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt; 18.50</td>
</tr>
<tr>
<td>Normal range</td>
<td>18.50 - 24.99</td>
</tr>
<tr>
<td>Overweight</td>
<td>≥ 25.00</td>
</tr>
<tr>
<td>Obese</td>
<td>≥ 30.00</td>
</tr>
<tr>
<td>Obese class I</td>
<td>30.00 - 34.99</td>
</tr>
<tr>
<td>Obese class II</td>
<td>35.00 - 39.99</td>
</tr>
<tr>
<td>Obese class III</td>
<td>≥ 40.00</td>
</tr>
</tbody>
</table>

   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 Maryland and New York and morbid obesity in California.

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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/m² (Obesity Class III). Documentation of current height and weight required.

      -OR-

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

         i. BMI ≥ 30 kg/m² (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, 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/m² (Obesity Class III) Documentation of current height and weight required.

         -OR-

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

            i. BMI ≥ 30 kg/m² (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)

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

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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/m² (Obesity Class III). Documentation of current height and weight required.

    -OR-

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

   i. BMI ≥ 30 kg/m² (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 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.**

3. **Additional Clinical Rules:**
   
   • Supply limits may be in place.

4. **References:**

   1. AACE position statement on obesity and obesity medicine. September/October 2012.

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6. Product Information: Benzphetamine Tablets (Didrex – Pharmacia Pharmaceuticals)  
   August, 2010.
7. Product Information: Diethylpropion Dospan (Tenuate- Merrell Pharmaceuticals). March  
   2014.
8. Product Information: Phendimetrazine Slow-Release Capsules (Bontril - Carnick  
10. Xenical Product Information. Roche Pharmaceuticals  South San Francisco, CA. December  
    2016.
13. Contrave Prescribing Information. Takeda Pharmaceuticals America, Inc. Deerfield, IL.  
    September, 2014.
15. Bray, GA. Obesity in Adults. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA.  
    (Accessed on September 14, 2015.)
    Executive summary of the third report of the National Cholesterol Education Program  
    (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol  
17. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice  
    Guideline. The Journal of Clinical Endocrinology & Metabolism 2015 100:2, 342-362
18. 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  

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization - California and New York Regulatory Program - Weight Loss</th>
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<tbody>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>11/2015</td>
<td>New program.</td>
</tr>
<tr>
<td>9/2016</td>
<td>Annual review. Added Belviq XR.</td>
</tr>
<tr>
<td>9/2018</td>
<td>Added Lomaira as in scope. Updated references. Formatting changes.</td>
</tr>
<tr>
<td>11/2019</td>
<td>Added Maryland as in scope per rider requirements.</td>
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