Prior Authorization Criteria For Weight Loss Medications
(only covered for specified self-funded groups which have elected to include a weight loss medication rider in their contract)

Drugs Addressed in this Policy
Belviq® (lorcaserin)
Qsymia® (phentermine and topiramate extended-release)
Contrave® (bupropion and naltrexone)
Saxenda (liraglutide)

FDA-Approved Indications
Chronic weight management, as an adjunct to a reduced-calorie diet and increased physical activity in adults who are obese (BMI ≥30 kg/m²) or overweight (BMI ≥27 kg/m²) in the presence of at least one weight-related comorbidity (e.g., hypertension, dyslipidemia, type 2 diabetes)

Background
Phentermine is a sympathomimetic amine with pharmacologic activity similar to the prototype drugs of this class used in obesity, amphetamine. The effect of phentermine on chronic weight management is likely mediated by release of catecholamines in the hypothalamus, resulting in reduced appetite and decreased food consumption, but other metabolic effects may also be involved. However, the exact mechanism is unknown.

The exact mechanism of action of topiramate on chronic weight management is unknown. Topiramate may have an effect on chronic weight management due to its effects on both appetite suppression and satiety enhancement, induced by a combination of pharmacologic effects including augmentation of the activity of the neurotransmitter GABA, modulation of voltage-gated ion channels, inhibition of the AMPA/kainite excitatory glutamate receptors, or inhibition of carbonic anhydrase.
Lorcaserin is a Serotonin 2C (5-HT\(_{2C}\)) receptor agonist and is believed to decrease food consumption and promote satiety by selectively activating 5-HT\(_{2C}\) receptors on anorexigenic pro-opiomelanocortin neurons located in the hypothalamus. However, the exact mechanism is unknown.

Bupropion/naltrexone works by addressing behavioral and physiological aspects of obesity. It regulates energy balance and decreases appetite by working in the hypothalamus (appetite regulatory center) and the mesolimbic dopamine circuit (the reward system).

Saxenda (liraglutide) is an acylated human glucagon-like peptide-1 (GLP-1) receptor agonist which binds to the GLP-1 receptor ultimately leading to a decrease in caloric intake resulting in lower body weight. Saxenda (liraglutide) does not increase 24-hour energy expenditure.

Initiation refers to members who are new to therapy. Continuation refers to the period after the initiation phase (7 months for Qsymia, 4 months for all others). Maintenance refers to a member who has been using the chronic weight loss agent for more than 12 months.

Members who have a gap in therapy should be evaluated using the initiation criteria.

Limitations of Coverage (lorcaserin, phentermine/topiramate extended-release, bupropion/naltrexone):

- Phentermine/topiramate extended-release should only be dispensed from a certified mail-order pharmacy as mandated by the Qsymia™ REMS program for risk of birth defects with topiramate-containing products.
- Bupropion/naltrexone should not be used in patients currently using other bupropion-containing bupropion-containing products or on chronic opioid or opiate agonist (e.g. methadone) or partial agonists (e.g. buprenorphine).
- Saxenda (liraglutide) is not indicated for the treatment of type 2 diabetes.
- The effects of Saxenda (liraglutide) on cardiovascular morbidity and mortality have not been established.
- Saxenda (liraglutide) should not be used in combination with another GLP-1 receptor agonist.
- Saxenda (liraglutide) should not be used with insulin.

Approval Criteria

Approval Criteria:

I. Belviq, Contrave or Qsymia

A. Initiation

- 0 to < 4 months previous therapy for Belviq and Contrave
- 0 to < 7 months previous therapy for Qsymia

When a benefit, initiation of Belviq, Contrave or Qsymia will be approved if all of the following criteria are met (1. and 2.):

1. The member is 18 years of age or older.
2. The prescriber submits documentation (i.e. chart notes) substantiating all of the following (a. through c.):
   a. Documentation of baseline height, weight and BMI.
   b. The member meets one of the following (i. or ii.):
      i. The member has a BMI ≥ 30 kg/m\(^2\)
      ii. The member meets both of the following (A and B):
         A) The member has a BMI ≥ 27 kg/m\(^2\)
         B) The member has one of the following weight-related comorbidities (1 through 7):
1) hypertension  
2) dyslipidemia  
3) type 2 diabetes mellitus  
4) obstructive sleep apnea  
5) symptomatic arthritis of the lower extremities  
6) gastroesophageal reflux disease  
7) coronary artery disease

c. The member will be using the product in adjunct to all of the following healthy lifestyle modifications (i. and ii.):  
i. Reduced calorie diet  
ii. Exercise regimen

B. Continuation  
- 4 to < 12 months previous therapy for Belviq and Contrave  
- 7 to < 12 months previous therapy for Qsymia

When a benefit, a continuation of therapy for Belviq, Contrave or Qsymia will be approved if all of the following criteria are met (1. through 3.):  
1. The member is 18 years of age or older.  
2. The prescriber submits documentation (i.e. chart notes) substantiating all of the following (a. through c.):  
a. Documentation of baseline and current height, weight and BMI.  
b. The member meets one of the following (i. or ii.):  
   i. The member’s baseline BMI was ≥ 30 kg/m$^2$  
   ii. The member meets both of the following (A and B):  
      A) The member’s baseline BMI was ≥ 27 kg/m$^2$  
      B) The member had one of the following weight-related comorbidities at baseline (1 through 7):  
         1) hypertension  
         2) dyslipidemia  
         3) type 2 diabetes mellitus  
         4) obstructive sleep apnea  
         5) symptomatic arthritis of the lower extremities  
         6) gastroesophageal reflux disease  
         7) coronary artery disease  
   
   c. The member will be using the product in adjunct to all of the following healthy lifestyle modifications (i. and ii.):  
      i. Reduced calorie diet  
      ii. Exercise regimen  
3. The member has experienced ≥ 5% weight loss from baseline.

C. Maintenance  
- ≥ 12 months previous therapy

When a benefit, maintenance therapy for Belviq, Contrave or Qsymia will be approved if all of the following criteria are met (1. through 3.):  
1. The member is 18 years of age or older.  
2. The prescriber submits documentation (i.e. chart notes) substantiating all of the following (a. through d.):  
a. Documentation of baseline and current height, weight and BMI.  
b. Documentation of height, weight and BMI from 12 months previously  
c. The member meets one of the following (i. or ii.):  
   i. The member’s baseline BMI was ≥ 30 kg/m$^2$  
   ii. The member meets both of the following (A and B):  
      A) The member’s baseline BMI was ≥ 27 kg/m$^2$  
      B) The member had one of the following weight-related comorbidities at baseline (1 through 7):  
         1) hypertension  
         2) dyslipidemia  
         3) type 2 diabetes mellitus
4) obstructive sleep apnea
5) symptomatic arthritis of the lower extremities
6) gastroesophageal reflux disease
7) coronary artery disease
d. The member will be using the product in adjunct to all of the following healthy lifestyle modifications (i. and ii.):
   i. Reduced calorie diet
   ii. Exercise regimen

3. The member has experienced continued weight loss in the past 12 months.

II. Saxenda
A. Initiation
   • 0 to < 4 months previous therapy
   When a benefit, initiation of Saxenda will be approved if all of the following criteria are met (1. through 4.):
   1. The member is 18 years of age or older.
   2. The prescriber submits documentation (i.e. chart notes) substantiating all of the following (a. through c.):
      a. Documentation of baseline height, weight and BMI.
      b. The member meets one of the following (i. or ii.):
         i. The member has a BMI ≥ 30 kg/m²
         ii. The member meets both of the following (A and B):
            A) The member has a BMI ≥ 27 kg/m²
            B) The member has one of the following weight-related comorbidities (1 through 7):
               1) hypertension
               2) dyslipidemia
               3) type 2 diabetes mellitus
               4) obstructive sleep apnea
               5) symptomatic arthritis of the lower extremities
               6) gastroesophageal reflux disease
               7) coronary artery disease
      c. The member will be using the product in adjunct to all of the following healthy lifestyle modifications (i. and ii.):
         i. Reduced calorie diet
         ii. Exercise regimen
   3. The member has tried and failed two of the following medications or all are contraindicated (a. through d.):
      a. Belviq
      b. Contrave
      c. Qsymia
      d. Xenical
   4. The member will not be using Saxenda with any of the following products (a. through f.):
      a. Insulin
      b. Bydureon
      c. Byetta
      d. Tanzeum
      e. Trulicity
      f. Victoza

B. Continuation
   • 4 to < 12 months previous therapy
   When a benefit, a continuation of therapy for Saxenda will be approved if all of the following criteria are met (1. through 5.):
   1. The member is 18 years of age or older.
   2. The prescriber submits documentation (i.e. chart notes) substantiating all of the following (a. through c.):
      a. Documentation of baseline and current height, weight and BMI.
      b. The member meets one of the following (i. or ii.):
i. The member’s baseline BMI was ≥ 30 kg/m\(^2\)

ii. The member meets both of the following (A and B):
   A) The member’s baseline BMI was ≥ 27 kg/m\(^2\)
   B) The member had one of the following weight-related comorbidities at baseline (1 through 7):
      1) hypertension
      2) dyslipidemia
      3) type 2 diabetes mellitus
      4) obstructive sleep apnea
      5) symptomatic arthritis of the lower extremities
      6) gastroesophageal reflux disease
      7) coronary artery disease

c. The member will be using the product in adjunct to all of the following healthy lifestyle modifications (i. and ii.):
   i. Reduced calorie diet
   ii. Exercise regimen

3. The member has experienced ≥ 4% weight loss from baseline.

4. The member has tried and failed two of the following medications or all are contraindicated (a. through d.):
   a. Belviq
   b. Contrave
   c. Qsymia
   d. Xenical

5. The member will not be using Saxenda with any of the following products (a. through f.):
   a. Insulin
   b. Bydureon
   c. Byetta
   d. Tanzeum
   e. Trulicity
   f. Victoza

C. Maintenance

   • ≥ 12 months previous therapy

When a benefit, maintenance therapy for Saxenda will be approved if all of the following criteria are met (1. through 5.):

1. The member is 18 years of age or older.

2. The prescriber submits documentation (i.e. chart notes) substantiating all of the following (a. through d.):
   a. Documentation of baseline and current height, weight and BMI.
   b. Documentation of height, weight and BMI from 12 months previously
   c. The member meets one of the following (i. or ii.):
      i. The member’s baseline BMI was ≥ 30 kg/m\(^2\)
      ii. The member meets both of the following (A and B):
          A) The member’s baseline BMI was ≥ 27 kg/m\(^2\)
          B) The member had one of the following weight-related comorbidities at baseline (1 through 7):
             1) hypertension
             2) dyslipidemia
             3) type 2 diabetes mellitus
             4) obstructive sleep apnea
             5) symptomatic arthritis of the lower extremities
             6) gastroesophageal reflux disease
             7) coronary artery disease
      d. The member will be using the product in adjunct to all of the following healthy lifestyle modifications (i. and ii.):
         i. Reduced calorie diet
         ii. Exercise regimen

3. The member has experienced continued weight loss in the past 12 months.
4. The member has tried and failed two of the following medications or all are contraindicated (a. through d.):
   a. Belviq
   b. Contrave
   c. Qsymia
   d. Xenical

5. The member will not be using Saxenda with any of the following products (a. through f.):
   a. Insulin
   b. Bydureon
   c. Byetta
   d. Tanzeum
   e. Trulicity
   f. Victoza

- Use of anti-obesity agents for disease states outside of its FDA-approved indications should be denied based on the lack of clinical data to support its effectiveness and safety in other conditions.
- For members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Duration of authorization:
If approved, a duration of authorization will be granted as follows:
I. Initiation
   A. Belviq, Contrave, Saxenda – 4 months
   B. Qsymia – 7 months
II. Continuation – 12 months
III. Maintenance – 12 months
IV. Discontinuation
   A. 1 week of additional coverage of Belviq or Contrave will be granted for discontinuation of the product.

References:

Adapted from Highmark J-184

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