

Pharmacy Policy

Anti-Obesity Medications

Policy Number: 9.322

Version Number: 2.1

Version Effective Date: 1/1/2022

<p>Product Applicability <input type="checkbox"/> All Plan+ Products</p>	
<p>Well Sense Health Plan</p> <p><input type="checkbox"/> New Hampshire Medicaid</p>	<p>Boston Medical Center HealthNet Plan</p> <p><input type="checkbox"/> MassHealth - MCO</p> <p><input type="checkbox"/> MassHealth - ACO</p> <p><input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p>

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Xenical (orlistat)
- Contrave (naltrexone/bupropion)
- Qsymia (phentermine/topiramate)
- Saxenda (liraglutide)
- Wegovy (semaglutide)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Concurrent use of another anti-obesity agent
Required Medical Information	<p>Xenical</p> <p>Adult members ≥ 18 years of Age</p> <p>1. Body Mass index (BMI) ≥ 30 kg/m²; OR</p> <p>Body Mass Index ≥ 27kg/m² and at least one of the following high risk factors:</p>

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- Obstructive Sleep Apnea
- Coronary Heart Disease
- Hypertension
- Dyslipidemia
- Type 2 Diabetes
- Impaired glucose tolerance; **AND**

2. Member has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss; **AND**
3. Member is currently engaged in behavioral modification and on a reduced calorie diet

Pediatric members ≥ 12 to < 18 Years:

1. Body Mass Index (BMI) ≥ 95th percentile for age and sex; **OR**
 Body Mass Index ≥ 85th percentile but < 95th percentile for age and sex and has at least one of the following:
 - Type 2 diabetes
 - cardiovascular disease (CVD)
 - Strong family history of type 2 diabetes or premature CVD; **AND**
2. Member has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss; **AND**
3. Member is currently engaged in behavioral modification and on a reduced calorie diet.

Contrave, Qsymia

1. Body Mass index (BMI) ≥ 30 kg/m²; **OR**
 Body Mass Index ≥ 27kg/m² and at least one of the following high risk factors:
 - Obstructive Sleep Apnea
 - Coronary Heart Disease
 - Hypertension
 - Dyslipidemia
 - Type 2 Diabetes
 - Impaired glucose tolerance; **AND**
2. Member has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss; **AND**
3. Member is currently engaged in behavioral modification and on a reduced calorie diet.

Saxenda

Adult members ≥ 18 years of Age :

1. Body Mass index (BMI) ≥ 30 kg/m²; **OR**
 Body Mass Index ≥ 27kg/m² and at least one of the following high risk factors:

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- Obstructive Sleep Apnea
- Coronary Heart Disease
- Hypertension
- Dyslipidemia
- Type 2 Diabetes
- Impaired glucose tolerance; **AND**

2. Member has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss; **AND**
3. Member is currently engaged in behavioral modification and on a reduced calorie diet **AND**
4. Member will not use Saxenda in combination with another weight loss drug or any other GLP-1 receptor agonist

Pediatric members ≥ 12 to < 18 Years:

1. Body Mass Index (BMI) ≥ 95th percentile for age and sex; **OR**

Body Mass Index ≥ 85th percentile but < 95th percentile for age and sex and has at least one of the following:

- Type 2 diabetes
- cardiovascular disease (CVD)
- Strong family history of type 2 diabetes or premature CVD; **AND**

2. Member has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss; **AND**
3. Member is currently engaged in behavioral modification and on a reduced calorie diet; **AND**
4. Member will not use Saxenda in combination with another weight loss drug or any other GLP-1 receptor agonist

Wegovy

1. A diagnosis of weight loss **AND**

i. The member has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; **AND**

2. The member meets ONE of the following:

i. Patient currently has a body mass index (BMI) ≥ 30 kg/m²; **OR**

ii. Patient currently has a BMI ≥ 27 kg/m² and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, or cardiovascular disease; **AND**

3. Wegovy will be used concomitantly with behavioral modification and a reduced-calorie diet. **AND**
4. Member will not use Wegovy in combination with another weight loss drug or any other GLP-1 receptor agonist

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Age Restriction	Xenical: 12 years or older Qsymia, Contrave, Wegovy: 18 years or older Saxenda: 12 years or older
Coverage Duration	Initial: 3 months Reauthorization: 12 months
Other criteria	Reauthorization: Contrave, Qsymia <ol style="list-style-type: none"> 1. Member had an initial Body Mass index (BMI) $\geq 30 \text{ kg/m}^2$; OR Member had an initial Body Mass Index $\geq 27\text{kg/m}^2$ and at least one of the following high risk factors: <ul style="list-style-type: none"> • Obstructive Sleep Apnea • Coronary Heart Disease • Hypertension • Dyslipidemia • Type 2 Diabetes • Impaired glucose tolerance; AND 2. Member is currently engaged in behavioral modification and on a reduced calorie diet; AND 3. Member has lost $\geq 5\%$ of baseline body weight Saxenda Adult members ≥ 18 years of Age <ol style="list-style-type: none"> 1. Body Mass index (BMI) $\geq 30 \text{ kg/m}^2$; OR Body Mass Index $\geq 27\text{kg/m}^2$ and at least one of the following high risk factors: <ul style="list-style-type: none"> • Obstructive Sleep Apnea • Coronary Heart Disease • Hypertension • dyslipidemia • Type 2 Diabetes • Impaired glucose tolerance 2. Member is currently engaged in behavioral modification and on a reduced calorie diet; AND 3. Member has lost $\geq 5\%$ of baseline body weight.

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Pediatric members ≥ 12 to < 18 Years:

1. Body Mass Index (BMI) ≥ 95th percentile for age and sex; **OR**
Body Mass Index ≥ 85th percentile but < 95th percentile for age and sex and has at least one of the following:
 - Type 2 diabetes
 - cardiovascular disease [CVD]
 - Strong family history of type 2 diabetes or premature CVD; **AND**
2. Member is currently engaged in behavioral modification and on a reduced calorie diet; **AND**
3. Member has had a reduction in BMI of ≥ 1% from baseline; **AND**
4. Member currently has a BMI > 85th percentile

Wegovy:

1. Patient meets one of the following (a or b):
 - a) At baseline (prior to the initiation of Wegovy), patient had a BMI ≥ 30 kg/m²; **OR**
 - b) At baseline (prior to the initiation of Wegovy), patient had a BMI ≥ 27 kg/m² and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, or cardiovascular disease; **AND**
2. Response to therapy, as evidenced by:
 - a) At least a 5% reduction in baseline body weight for initial renewal **OR**
 - b) Maintenance of at least a 5% reduction in body weight over the renewal period for subsequent renewals; **AND**
3. Wegovy will be used concomitantly with behavioral modification and a reduced-calorie diet

Xenical

Adult members ≥ 18 years of Age:

1. Body Mass index (BMI) > 30 kg/m²; **OR**
Body Mass Index > 27kg/m² and at least one of the following high risk factors:
 - Obstructive Sleep Apnea
 - Coronary Heart Disease
 - Hypertension
 - Dyslipidemia
 - Type 2 Diabetes
 - Impaired glucose tolerance
2. Member is currently engaged in behavioral modification and on a reduced calorie diet; **AND**
3. Member has lost ≥ 5% of baseline body weight

Pediatric members ≥ 12 to < 18 Years:

1. Body Mass Index (BMI) ≥ 95th percentile for age and sex; **OR**
Body Mass Index ≥ 85th percentile but < 95th percentile for age and sex and has at least one of the following:
 - Type 2 diabetes

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	<ul style="list-style-type: none"> • Cardiovascular disease (CVD) • Strong family history of type 2 diabetes or premature CVD; AND <ol style="list-style-type: none"> 2. Member is currently engaged in behavioral modification and on a reduced calorie diet; AND 3. Member's current BMI percentile has decreased for age and from when Xenical was started; AND 4. Member currently has a BMI > 85th percentile
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Clinical Background Information and References

1. Alli (orlistat) [prescribing information]. Moon Township, PA: GlaxoSmithKline; September 2014.
2. Apovian CM, Aronne LJ, Bessesen DH, McDonnell ME, Murad MH, Pagotto U, Ryan DH, Still CD; Endocrine Society. Pharmacological management of obesity: an endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015 Feb;100(2):342-62.
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4. Bray GA. Obesity in adults: Drug therapy. UpToDate® available at <https://www.uptodate.com>, accessed August 2016
5. Garvey WT, Mechanick JI, Brett EM, Garber AJ, Hurley DL, Jastreboff AM, Nadolsky K, Pessah-Pollack R, Plodkowski R; Reviewers of the AACE/ACE Obesity Clinical Practice Guidelines. American Association of Clinical Endocrinologists and American College of Cardiology comprehensive clinical practice guidelines for medical care of patients with obesity. Endocr Pract. 2016 Jul;22 Suppl 3:1-203.
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7. National Institutes of Health (NIH); National Heart, Lung, and Blood Institute and National Institute of Diabetes and Digestive and Kidney Diseases. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: The evidence report. Bethesda, MD: NIH; 1998. http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf. Accessed July 2012.
8. Prescribing Information. Contrave (naltrexone/bupropion). Takeda Pharmaceuticals, Deerfield, IL. September 2014.
9. Prescribing Information. Saxenda (liraglutide). Novo Nordisk, Plainsboro, New Jersey. January 2015
10. Saxenda® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; December 2020.
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12. Wegovy™ subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; June 2021.
13. Weight and Obesity. Treatment and Prevention Guidelines. <http://fnic.nal.usda.gov/weight-and-obesity/treatment-and-prevention-guidelines>. Accessed July 2012.

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Original Approval Date	Original Effective Date	Policy Owner	Approved by
9/10/2020	1/1/2021	Pharmacy Services	P&T Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
9/10/2020	9.301 Anti-Obesity Policy retired, new policy created. Belviq removed from market and taken off policy, updated Xenical t/f requirement to require Contrave and Qsymia, removed documentation requirements, changed reauth weight reduction requirement to 5%	1/1/2021	P&T Committee
5/24/2021	P&T annual review: aligned with ESI standard policy	8/1/2021	P&T Committee
8/12/2021	P&T New Drug Review: Addition of Wegovy and associated criteria to the policy; addition of criteria to prohibit the concurrent use of Saxenda and Wegovy with another GLP-1 Agonist.	1/1/2022	P&T Committee

Next Review Date

8/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

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Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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