Pharmacy Medical Necessity Guidelines: Anti-Obesity Medications

Effective: November 12, 2024

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Anti-obesity medications are used in combination with diet and exercise in the treatment of obesity. In addition to diet and exercise, some patients with severe obesity and/or other significant medical concerns, may gain additional benefit by using anti-obesity drugs as part of a comprehensive approach to weight loss.

The policy applies to the medications listed in the table below:

Generic Agents		
Drug Name	**Dosage Forms**	**Coverage Status**
Benzphetamine	25 mg, 50 mg tablets	PA
Diethylpropion	25 mg tablet	PA
Diethylpropion SR	75 mg tablet	PA
Phendimetrazine	35 mg tablet, 105 mg capsule	PA
Phentermine	15 mg, 30 mg, 37.5 mg capsules	PA
Phentermine	37.5 mg tablets	PA
Brand Agents		
Drug Name	**Dosage forms**	**Coverage Status**
Alli (orlistat)	60 mg capsule	PA
Contrave (naltrexone/bupropion)	8-90 mg tablet	PA
Qsymia (phentermine/topiramate ER)	3.75-23 mg, 7.5-69 mg, 15-92 mg capsules	PA
Saxenda (liraglutide)	3 mg pen	PA
Xenical (orlistat)	120 mg capsule	PA

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Contrave (naltrexone/bupropion), phendimetrazine, phentermine, Qsymia (phentermine/topiramate ER), and Saxenda (liraglutide) are indicated as adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obese), or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes)

Qsymia is also approved in pediatric patients 12 years of age and older with a BMI in the 95th percentile or greater standardized for age or sex.

Saxenda is also approved in pediatric patients 12 years of age and older with a body weight above 60 kilograms and an initial BMI corresponding to 30 kg/m^2 or greater for adults (obese) by international cut-offs (Cole Criteria). Saxenda contains the same active ingredient as the antidiabetic agent Victoza. However, Saxenda is not approved for the treatment of type 2 diabetes. It should not be used with insulin and it has not been studied in patients with a history of pancreatitis. The effects of Saxenda on cardiovascular morbidity and mortality have not been established, nor has the safety and efficacy of co-administration with other products for weight loss.

Benzphetamine, diethylpropion, and diethylpropion ER are approved for the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction in patients with an initial BMI of 30 kg/m^2 or higher who have not responded to appropriate weight reducing regimens (diet and/or exercise) alone. Phentermine and phendimetrazine are indicated

as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction in the management of exogenous obesity for patients with an initial BMI of at least 30 kg/m^2 OR greater than or equal to 27 kg/m^2 in the presence of other risk factors like controlled hypertension, diabetes, and hyperlipidemia.

Xenical (orlistat) is indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet. It is also indicated to reduce the risk of weight regain after prior weight loss. It is indicated for obese patients with an initial BMI of at least 30 kg/m^2 OR at least 27 kg/m^2 in the presence of other risk factors like hypertension, diabetes, and hyperlipidemia.
Alli is the over-the-counter formulation of orlistat and is approved for weight loss in overweight adults when used along with a reduced-calorie and low-fat diet.

COVERAGE GUIDELINES

The plan may authorize coverage of an anti-obesity medication for Members when the following criteria are met:

Initial Authorization

Alli (orlistat), Benzphetamine, Diethylpropion, Diethylpropion SR, Phendimetrazine, Phentermine

Documentation of the following:

1. The member has a body mass index (BMI) ≥ 30 kg/m^2

   OR

   The member has a BMI ≥ 27 kg/m^2 and has at least one of the following high risk factors:
   - Coronary heart disease
   - Atherosclerotic disease
   - Type 2 diabetes
   - Sleep apnea
   - Hypertension
   - Hyperlipidemia

   AND

2. Member was not able to meet weight loss target despite lifestyle modifications, including dietary changes and participating in a structured exercise program for at least 2 months

Contrave (naltrexone/bupropion), Qsymia (phentermine/topiramate extended-release), Saxenda (liraglutide), Xenical (orlistat)

Documentation of the following:

1. The Member is 12 through 17 years of age with a BMI in the 95th percentile or greater standardized for age and sex and the request is for Qsymia

   OR

2. The Member is 12 through 17 years of age with a body weight above 60 kilograms and an initial BMI corresponding to 30 kg/m^2 or greater for adults by international cut-offs (i.e., Cole Criteria)

   OR

3. The Member meets all of the following:
   a. The member has a body mass index (BMI) ≥ 30 kg/m^2

      OR

      The member has a BMI ≥ 27 kg/m^2 and has at least one of the following high risk factors:
      - Coronary heart disease
      - Atherosclerotic disease
      - Type 2 diabetes
      - Sleep apnea
      - Hypertension
      - Hyperlipidemia

      AND

   b. Member was not able to meet weight loss target despite lifestyle modifications, including dietary changes and participating in a structured exercise program for at least 2 months

      AND

   c. Member has had a trial and failure of therapy with or contraindication to over-the-counter Alli

Reauthorization for Alli, Contrave, Qsymia, Saxenda, Xenical

Documentation of the following:

1. Member continues to practice lifestyle modifications, including dietary changes and regular exercise

AND

2. **If first renewal request:** documentation member has had the expected reduction in body weight during the initial trial

   If subsequent renewal request: documentation that member has maintained weight loss on therapy.

LIMITATIONS

1. Approval for benzphetamine, diethylpropion, diethylpropion SR, phendimetrazine, and phentermine will be limited to 12 weeks every 365 days.
2. Approval for Contrave and Qsymia will be limited to 12 weeks initially; initial approvals for Saxenda will be limited to 16 weeks. Requests for reauthorization will be limited to 1 year.
3. Approval for Xenical and Alli will be limited to 1 year.
4. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

CODES

None

REFERENCES

1. Adipex-P (phentermine) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA; September 2020.
2. Benzphetamine [prescribing information]. Laurelton, NY: Epic Pharmacy, LLC; January 2021.
3. Contrave (naltrexone/bupropion) [prescribing information]. Brentwood, TN: Currax Pharmaceuticals, LLC; November 2021.
4. Diethylpropion ER [prescribing information]. Congers, NY: Chartwell RX, LLC; March 2023.
5. Phendimetrazine [prescribing information]. Langhorne, PA: Acertis Pharmaceuticals, LLC.; September 2019.
6. Qsymia (phentermine and topiramate extended-release) [prescribing information]. Campbell, CA: Vivus, Inc; October 2024.
7. Saxenda (liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk; April 2023.
8. Xenical (orlistat) [prescribing information]. Montgomery, AL: H2-Pharma, LLC; July 2024.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 14, 2023: Updated Pharmacy Utilization Management fax number. No criteria changes.
2. November 12, 2024: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services