Pharmacy Medical Necessity Guidelines: Anti-Obesity Medications

Effective: January 1, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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. The Plan does not consider anti-obesity drugs to be medical necessary in the treatment of all patients with obesity, as diet and exercise constitute the mainstay of therapy in most cases. Some patients, however, 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
Belviq (lorcaserin)	10 mg tablet	PA
Belviq XR (lorcaserin ER)	20 mg tablet	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

Belviq (lorcaserin), Belviq XR, 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)

Benzphetamine is 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.

Diethylpropion is approved for short-term (few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification, and caloric restriction in the management of exogenous obesity.

Phentermine is contraindicated in patients with a history of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension), during or 14 days following the administration of MAO inhibitors, hyperthyroidism, glaucoma, agitated states, history of drug abuse, pregnancy, nursing, or known hypersensitivity or idiosyncrasy to the sympathomimetic amines.

Xenical 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 gain after prior weight loss. 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.

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.

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, Diethlypropion, 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

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

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

AND

3. Member has had a trial and failure of therapy with or contraindication to one of the generic weight loss agents AND over-the-counter Alli

Reauthorization for Alli, Belviq, Belviq XR, 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:
   - **Alli, Belviq, Belviq XR, Contrave, or Xenical:** Member had a 5% reduction in body weight in 12 weeks of treatment
   - **Qsymia:** Member had a 3% reduction in 12 weeks of treatment
   - **Saxenda:** Member had a 4% reduction in body weight in 16 weeks of treatment.

3. 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 Alli, Belviq, Belviq XR, Contrave, Qsymia, and Xenical 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. 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]. Sellersville, PA: Teva Pharmaceuticals USA; January 2012
2. Belviq (lorcaserin) [prescribing information]. Woodcliff Lake, NJ: Eisai, Inc; April 2018.
3. Belviq XR (lorcaserin extended-release) [prescribing information]. Woodcliff Lake, NJ: Eisai, Inc; April 2018.
4. Contrave (naltrexone/bupropion) [prescribing information]. San Diego, CA: Nalpropion Pharmaceuticals, Inc; April 2019.
5. Qsymia (phentermine and topiramate extended-release) [prescribing information]. Campbell, CA: Vivus, Inc; March 2018.
6. Saxenda (liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk; October 2018.
7. Xenical (orlistat) [prescribing information]. Montgomery, AL: H2-Pharma, LLC; August 2017.

APPROVAL HISTORY

May 9, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. December 11, 2018: Removed Suprenza from criteria due to product discontinuation. Effective 4/1/19, clarified that reauthorization criteria apply only to Alli, Belviq, Belviq XR, Contrave, Qsymia, Saxena, and Xenical. Administrative changes made to template.

2. October 15, 2019: Added hypertension and hyperlipidemia to the approvable diagnoses for members with a BMI ≥27 kg/m^2. Updated first renewal request for Alli and Xenical, decreasing the percent of weight loss from 10% to 5%. Updated renewal criteria for all agents to include subsequent renewal criteria. Added to limitations section of the MNG that requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

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.