# Pharmacy Medical Necessity Guidelines: Anti-Obesity Medications

*Effective: April 14, 2020*

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| 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

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

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 medically 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.
This policy applies to the following anti-obesity medications: Adipex-P®, Contrave®, Lomaira™, Qsymia®, phendimetrazine ER, Saxenda®, and Xenical®.

## COVERAGE GUIDELINES

The plan may authorize **initial coverage** of an anti-obesity drug for a period of up to 8 weeks for Members meeting one of the following clinical criteria:

1. The Member has a BMI of 30 or greater

**OR**

2. The Member has a BMI of 27-29 AND one or more of the following co-morbid conditions:
    a. Diabetes mellitus
    b. Hypertension
    c. Sleep Apnea
    d. Hyperlipidemia (high cholesterol)
    e. Symptomatic osteoarthritis of the lower extremities (knee or hip)
    f. GERD (gastroesophageal reflux disease or acid reflux)
    g. Coronary heart disease, shown by a history of any of the following:
        i. Heart surgery (bypass surgery or CABG)
        ii. History of a heart attack (myocardial infarction MI)
        iii. History of stroke
        iv. Angina

**1 OR 2 AND**

3. Documentation that the Member is actively involved in a dietary/behavior modification program for weight loss including, but not limited to:
    a. Weight Watchers®
    b. Tufts Health plan nutritional Counseling Benefit
    c. Curves® Weight Loss Program
    d. Other (specify)

**AND**

4. Documentation by the prescribing physician that the Member is actively following a fitness exercise regimen.

**Requests for continuation of treatment (8 weeks to 1 year) of therapy**

The plan may authorize continued treatment with anti-obesity agents for Members who demonstrate significant weight loss in the initial 8 weeks of therapy with one of these agents. Therefore, if a provider is requesting ongoing therapy with an anti-obesity agent beyond the initial 8 weeks, he/she must submit follow-up information at 8 weeks into therapy describing the Member's response treatment. The plan may authorize up to 12 additional months of continued treatment with anti-obesity agents for Members meeting the following clinical criteria:

1. Documented weight loss of at least 6 lbs. during the first 6-8 weeks of treatment with the anti-obesity agent

**AND**

2. Documentation by the prescribing physician that the Member continues active involvement in **BOTH** a dietary/behavioral regimen **AND** an exercise/fitness regimen

**AND**

3. Documentation that the Member has exhibited good tolerance of the anti-obesity agent and has not experienced significant side effects that may be detrimental to the Members overall health status

**Requests for Continuation of Treatment Past 1 Year**

The plan may authorize continued treatment with anti-obesity agents for Members who meet the following clinical criteria:

1. The Member must maintain a 5% reduction in weight, from baseline, over the previous year

## LIMITATIONS

- The plan will not authorize coverage of an anti-obesity medication when used in combination with another anti-obesity medication.
- Duration of coverage authorization is subject to the specific criteria stated within the Pharmacy Coverage Guidelines.

## CODES

None

## REFERENCES


1. Contrave (naltrexone/bupropion) [package insert]. Deerfield, IL: Takeda Pharmaceuticals America Inc.; September 2014.
2. Expert Panel on the Identification, Evaluation, and Treatment of Overweight Adults. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: executive summary. Expert Panel on the Identification, Evaluation, and Treatment of Overweight in Adults. *Am J Clin Nutr*. 1998;68(4):899-917.
3. Flegal KM, Carroll MD, Kit BK, et al. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999-2010. *JAMA*. 2012;307(5):491-7.
4. Gallagher D, Heymsfield SB, Heo M, et al. Healthy percentage body fat ranges: an approach for developing guidelines based on body mass index. *Am J Clin Nutr*. 2000;72(3):694-701.
5. Goodpaster BH, Delany JP, Otto AD, et al. Effects of diet and physical activity interventions on weight loss and cardiometabolic risk factors in severely obese adults: a randomized trial. *JAMA*. 2010;304(16):1795-802.
6. Hainer V. Comparative efficiency and safety of pharmacological approaches to the management of obesity. *Diabetes Care.* 2011;34:S349-S54.
7. Lomaira (phentermine) [package insert]. Newtown, PA: KVK-Tech, Inc.; December 2018.
8. Losina E, Walensky RP, Reichmann WM, et al. Impact of obesity and knee osteoarthritis on morbidity and mortality in older Americans. *Ann Intern Med*. 2011;154(4):217-26.
9. Mozaffarian D, Hao T, Rimm EB, et al. Changes in diet and lifestyle and long-term weight gain in women and men. *N Engl J Med*. 2011;364(25):2392-404.
10. Oreopoulos A, Padwal R, McAlister FA, et al. Association between obesity and health-related quality of life in patients with coronary artery disease. *Int J Obes (Lond)*. 2010;34(9):1434-41.
11. Qsymia (phentermine hydrochloride and topiramate extended-release) [package insert]. Mountain View, CA: VIVUS, Inc.; November 2018.
12. Saxenda (liraglutide) [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S. October 2018.
13. Xenical (orlistat) [package insert]. South San Francisco, CA: Genentech USA, Inc.; December 2018.

14. Yaemsiri S, Slining MM, Agarwal SK. Perceived weight status, overweight diagnosis, and weight control among US adults: the NHANES 2003-2008 Study. *Int J Obes (Lond)*. 2011;35(8):1063-70.

## APPROVAL HISTORY

May 2002: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. April 12, 2005: No changes.
2. April 11, 2006: Added "Angina" to section g. of criteria #2
3. March 13, 2007: No changes.
4. March 4, 2008: Removed the drug "Tenuate®" from the Pharmacy Medical Necessity Guideline. The drug has been discontinued. Incorporated the following drugs into the Pharmacy Medical Necessity Guideline: Adipex-P®, Bontril® PDM, Bontril® Slow Release, diethylpropion, Fastin®, Ionamin®, phendimetrazine.
5. July 8, 2008: Added pharmacy coverage guidelines #3 and #4 requiring Members to be involved in both a dietary / behavior modification program and an exercise / fitness program at the initiation of treatment. Changed criteria #2 under continuation of treatment to state that Members must continue involvement in both a dietary / behavior modification program and an exercise / fitness program. Added Antiobesity authorization form.
6. July 14, 2009: No changes.
7. January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
8. July 13, 2010: No changes
9. November 9, 2010: Removed Meridia from Ant-Obesity Medications Medical Necessity Guideline. The drug has been discontinued.
10. November 15, 2011: No changes.
11. May 8, 2012: Added Suprenza ODT to the Medical Necessity Guideline.
12. July 9, 2012: Administrative Change: Removed the words "discount program" from Weight Watchers.
13. November 6, 2012: Added Regimex and Qsymia to Medical Necessity Guidelines. Removed Bontril® Slow Release, Fastin®, and Ionamin® from Anti-Obesity Medications Medical Necessity Guidelines. These drugs have been discontinued.
14. July 9, 2013: Added Belviq to Medical Necessity Guideline.
15. July 8, 2014: No changes.
16. November 4, 2014: Added Contrave to the Medical Necessity Guideline.
17. June 9, 2015: Added Saxenda to the Medical Necessity Guideline.
18. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
19. June 14, 2016: Added benzphetamine to the Medical Necessity Guideline.
20. November 15, 2016: Added Belviq XR to the Medical Necessity Guideline.
21. January 10, 2017: Added Lomaria to the Medical Necessity Guideline.
22. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
23. January 9, 2018: Administrative update, removed Suprenza ODT from the overview section and re-ordered the list of medications alphabetically. Also removed the note section that described how to submit a prior authorization exception request.
24. March 13, 2018: Removed phentermine and phendimetrazine from the Medical Necessity Guideline.
25. January 8, 2019: Administrative changes to the template. Removed the requirement for documentation of blood pressure and heart rate monitoring. Removed Bontril® PDM from the Medical Necessity Guideline. This drug has been discontinued.
26. September 10, 2019: Removed benzphetamine, diethylpropion and Regimex from the overview section of the MNG. PA is no longer required for benzphetamine and diethylpropion, and Regimex is no longer on the market. Updated the criteria for continuation of treatment past 1 year to clarify maintaining 5% weight reduction over the previous year is from baseline weight.
27. April 14, 2020: Administrative update: removed Belviq and Belviq XR from MNG, as the medication is no longer on the market.

## 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.