Pharmacy Medical Necessity Guidelines: Anti-Obesity Medications

Effective: March 19, 2018

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

This Pharmacy Medical Necessity Guideline applies to the following:
**Tufts Health Plan Commercial Plans**
☐ Tufts Health Plan Commercial Plans – large group plans
☐ Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
☐ Tufts Health Direct – Health Connector
☐ Tufts Health Together – A MassHealth Plan
☐ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
☐ Tufts Health Freedom Plan – large group plans
☐ Tufts Health Freedom Plan – small group plans

Fax Numbers: RXUM: 617.673.0988

**Note:** For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**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 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®, benzphetamine, Bontril PDM, Belviq®, Belviq XR®, Contrave®, diethylpropion, Lomaira™, Qsymia®, phendimetrazine ER, Regimex™, 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 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 Member’s overall health status

AND

4. Documentation that blood pressure (BP) and heart rate (HR) have been monitored during treatment with an anti-obesity medication and records reflect current BP of 150/90 or less, and HR 100 or less. (If this criterion is not met, refer to a Tufts Health Plan Medical Director for review).

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 over the previous year

LIMITATIONS

1. The plan will not authorize coverage of an anti-obesity medication when used in combination with another anti-obesity medication.

2. Duration of coverage authorization is subject to the specific criteria stated within the Pharmacy Coverage Guidelines.

CODES
None

REFERENCES


APPROVAL HISTORY
May 2002: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- April 12, 2005: No changes.
- April 11, 2006: Added "Angina" to section g. of criteria #2.
- March 13, 2007: No changes.
- 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.
- 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.
- July 14, 2009: No changes.
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
- July 13, 2010: No changes.
- November 9, 2010: Removed Meridia from Anti-Obesity Medications Medical Necessity Guideline. The drug has been discontinued.
- November 15, 2011: No changes.
- July 9, 2012: Administrative Change: Removed the words “discount program” from Weight Watchers.
- 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.
- July 9, 2013: Added Belviq to Medical Necessity Guideline.
- July 8, 2014: No changes.
- November 4, 2014: Added Contrave to the Medical Necessity Guideline.
- June 9, 2015: Added Saxenda to the Medical Necessity Guideline.
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- June 14, 2016: Added benzphetamine to the Medical Necessity Guideline.
- November 15, 2016: Added Belviq XR to the Medical Necessity Guideline.
- January 10, 2017: Added Lumaria to the Medical Necessity Guideline.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- 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.
- March 13, 2018: Removed phentermine and phendimetrazine from the Medical Necessity Guideline.

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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.