Pharmacy Medical Necessity Guidelines: Anti-Obesity Medications

Effective: April 14, 2020

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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 – small group plans
- CareLinkSM – 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 Member’s 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


**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
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.
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.
15. July 8, 2014: No changes.
18. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
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.
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.