

Document ID#: 1035139  
Subject: Anti-Obesity Medications  
Effective Date: May 8, 2012

Clinical Documentation and Prior Authorization Required	√	Type of Review — Case Management	
Not Covered		Type of Review — Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Administrative Process (Internal Use Only)	LPN

**Note:** This pharmacy medical necessity guideline applies to commercial products. For Tufts Health Plan Medicare Preferred members, please refer to the Tufts 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. Tufts Health 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.

### Pharmacy Coverage Guidelines

Tufts Health 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:
    - Heart surgery (bypass surgery or CABG)
    - History of a heart attack (myocardial infarction MI)
    - History of stroke
    - Angina

**AND**

3. Documentation that the Member is actively involved in a dietary / behavior modification program for weight loss including, but not limited to:

- Weight Watchers® Discount Program
- Tufts Health Plan nutritional Counseling Benefit
- Curves® Weight Loss Program
- 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

Tufts Health 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. Tufts Health 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
2. Documentation by the prescribing physician that the Member continues active involvement in BOTH a **Dietary / Behavioral AND Exercise / Fitness regimen.**
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.
4. Documentation that BP and HR have been monitored during treatment with Adipex-P®, Bontril® PDM, Bontril® Slow Release, diethylpropion, Fastin®, Ionamin®, phendimetrazine, phentermine or Suprenza™ ODT 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)

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

Tufts Health 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.

**Note:** To submit an Anti-obesity Medication prior authorization exception request, please refer to the **Pharmacy Medical Review Request Form: Anti-obesity Medications**, at the end of this document. (Requests submitted via the Universal Pharmacy Medical Review Request Form are also accepted.)

**Limitations**

1. Tufts Health Plan will not authorize coverage of Adipex-P®, Bontril® PDM, Bontril® Slow Release, diethylpropion, Fastin®, Ionamin®, phendimetrazine, phentermine, Suprenza™ ODT, or Xenical® 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**

1. Walsh, P. ed. *2001 Physicians' Desk Reference*. New Jersey:Medical Economics Company

2. McEvoy, G. ed. *2001 AHFS Drug Information*. Maryland: American Society of Health-System Pharmacists.
3. IOF Symposium on Recent Advances in Osteoarthritis Michael C. Nevitt, PhD

## Approval History

Reviewed by the Pharmacy and Therapeutics Committee in May 2002.

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<sup>®</sup>" from the Pharmacy Medical Necessity Guideline. The drug has been discontinued.
  - Incorporated the following drugs into the Pharmacy Medical Necessity Guideline: Adipex-P<sup>®</sup>, Bontril<sup>®</sup> PDM, Bontril<sup>®</sup> Slow Release, diethylpropion, Fastin<sup>®</sup>, Ionamin<sup>®</sup>, and 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 Medicare Preferred language (separate criteria have been created specifically for Tufts 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 Guidelines.

## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health 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). Tufts Health 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 Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan offerings unless otherwise noted in this policy or the Member's benefit document. Check the applicable formulary in the

Pharmacy section of our Web site at <http://www.tuftshealthplan.com/providers> to determine if the drug requires you to get prior authorization. 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 CareLink<sup>SM</sup> 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 Medicare Preferred, please refer to Tufts 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.

Pharmacy Medical Review Request Form:  
Anti-obesity Medications

<p><b>PATIENT INFORMATION</b></p> <p>Date: _____</p> <p>Name: _____</p> <p>DOB: _____</p> <p>THP ID: _____</p> <p>Diagnosis: _____</p> <p>_____</p> <p>Relevant Comorbid Diagnosis: _____</p> <p>_____</p> <p><b>PRESCRIBER INFORMATION</b></p> <p>Name: _____</p> <p>Provider ID: _____</p> <p>Specialty: _____</p> <p>Phone: _____</p> <p>Fax: _____</p> <p>Office Contact: _____</p> <p><b>REQUESTED DRUG INFORMATION</b></p> <p>Drug Name/Strength: _____</p> <p>_____</p>	<p><b>General Anti-obesity Medication Prior Authorization Guidelines:</b> Tufts Health Plan may authorize <b>initial coverage</b> of an anti-obesity drug for a period of up to 8 weeks, provided that the member is actively involved in a dietary / behavior modification program for weight loss AND is actively following a fitness / exercise regimen. <b>Continuing coverage</b> may be authorized for Members who demonstrate significant weight loss in the initial 8 weeks of therapy with one of these agents. In addition, Members must also: continue involvement in a dietary / behavior modification program for weight loss, follow a fitness exercise regimen, exhibit good tolerance of the antiobesity medication, and have their heart rate and blood pressure monitored.</p> <p><b>Please complete the following questions for if requesting <b>initial coverage</b> authorization of Anti-obesity Medications:</b></p> <ol style="list-style-type: none"> <li>1. What is the Member's body mass index (BMI)? _____ (if &gt; 30, proceed to question #3)</li> <li>2. If the Member's BMI is 27-29, does the member have one of the following comorbid conditions: (Please check applicable box)             <ul style="list-style-type: none"> <li><input type="checkbox"/> Diabetes mellitus    <input type="checkbox"/> Hypertension    <input type="checkbox"/> Sleep Apnea    <input type="checkbox"/> Hyperlipidemia    <input type="checkbox"/> GERD</li> <li><input type="checkbox"/> Symptomatic osteoarthritis of the lower extremities (knee or hip)</li> <li><input type="checkbox"/> Coronary heart disease, shown by a history of any of the following: Heart surgery (bypass surgery or CABG), history of a heart attack (myocardial infarction MI), history of stroke, angina</li> </ul> </li> <li>3. Is the Member actively involved in a dietary/behavior modification program? (Please check) Yes <input type="checkbox"/> No <input type="checkbox"/></li> <li>4. Is the Member actively following a fitness / exercise regimen? (Please check) Yes <input type="checkbox"/> No <input type="checkbox"/></li> </ol> <p><b>Please complete the following questions for if requesting <b>continuing coverage</b> authorization of Anti-obesity Medications:</b></p> <ol style="list-style-type: none"> <li>1. Did the Member experience a weight loss of at least 6lbs. during the first 6-8 weeks of treatment with the anti-obesity agent? (Please check) Yes <input type="checkbox"/> No <input type="checkbox"/></li> <li>2. Does the Member continue active involvement in BOTH a Dietary / Behavioral AND Exercise / Fitness regimen? (Please check) Yes <input type="checkbox"/> No <input type="checkbox"/></li> <li>3. Does the Member exhibit good tolerance of the anti-obesity agent and has not experienced significant side effects that may be detrimental to the Members overall health status? (Please check) Yes <input type="checkbox"/> No <input type="checkbox"/></li> <li>4. Confirm that Member's BP and HR have been monitored during treatment with the anti-obesity agent 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). (Please check) Yes <input type="checkbox"/> No <input type="checkbox"/></li> <li>5. If request of therapy is for continued treatment beyond one year, confirm that the Member has maintained a 5% weight reduction over the past year(Please check) Yes <input type="checkbox"/> No <input type="checkbox"/></li> </ol> <p><b>Additional comments:</b></p> <p>_____</p> <p>_____</p>
<p><b>Prescriber Signature (required):</b> _____</p>	<p style="text-align: right;"><b>Date:</b> _____</p>