Harvard Pilgrim Health Care | TUFTS Health Plan

# Pharmacy Medical Necessity Guidelines: **Weight Loss Medications**

*Effective: July 1, 2025*

| | |
|---|---|
| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

**Food and Drug Administration – Approved Indications**

This policy applies to the following anti-obesity medications: **Contrave (naltrexone/bupropion) and Zepbound (tirzepatide)**.

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.

In addition, **Zepbound (tirzepatide)** is FDA-approved to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

## Clinical Guideline Coverage Criteria

**Initial Criteria**

The plan may authorize initial coverage of an anti-obesity drug for a period of up to 6 months for patients meeting the following clinical criteria:

**Contrave and Zepbound:**

1. Patient is 18 years of age or older

**AND**

2. One of the following:
   a. The patient has a BMI of 30 or greater

   **OR**

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

3. History of stroke
4. Angina

**AND**

3. Used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community based program)

**Reauthorization for continuation of treatment:**
The plan may authorize continued treatment with anti-obesity agents for one year patients who meet the following clinical criteria for reauthorization:

**Contrave and Zepbound for Weight Management:**

1. One of the following:
    a. Documented weight loss or maintenance of weight loss of 5% of baseline bodyweight during the first 6 months of treatment with the anti-obesity agent (submission of baseline and follow-up weights from visit required)

    **OR**

    b. The patient is new to the plan and stable on the medication (submission of baseline and follow-up weights from visit required)

    **AND**

2. Documentation by the prescribing physician that the patient is adherent to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community based program)

## Limitations

1. Duration of approval for initial authorization is limited to 6 months. Additional reauthorizations will be limited to 1 year.
2. The plan will not authorize coverage of an anti-obesity medication when used in combination with another anti-obesity medication.
3. The plan will not authorize coverage of a GLP-1 agonist or GLP-1 compounded product that is not FDA-approved for weight loss.
4. Members new to the plan stable on the requested medication will be reviewed against Reauthorization Criteria.
5. Members who have already initiated the requested medication using samples, free goods, or similar offerings do not qualify for an established clinical response and should be reviewed against initial approval criteria.
6. Members who have already initiated a GLP-1 agonist or compound that is not FDA-approved for weight loss do not qualify for an established clinical response and should be reviewed against initial approval criteria.
7. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
8. Weight loss medications are only covered if your plan includes weight loss medication coverage. Additional restrictions may apply. Refer to benefit documents.

## Codes

None

## References


1. Contrave (naltrexone/bupropion) [package insert]. Deerfield, IL: Takeda Pharmaceuticals America Inc.; May 2024.
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. 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.
8. 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.
9. 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.

10. Saxenda (liraglutide) [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S. November 2024.
11. Wegovy (semaglutide) [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S. November 2024.
12. Zepbound (tirzepatide) [package insert]. Indianapolis, IN: Lilly USA, LLC. December 2024.
13. 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.
14. Apovian CM, Aronne LJ, Bessesen DH, McDonnell ME, Murad MH, Pagotto U, Ryan DH, Still CD; Endocrine Society. Pharmacological management of obesity: an endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015 Feb;100(2):342-62. doi: 10.1210/jc.2014-3415. Epub 2015 Jan 15. Erratum in: J Clin Endocrinol Metab. 2015 May;100(5):2135-6. doi: 10.1210/jc.2015-1782. PMID: 25590212.
15. Garvey WT, Mechanick JI, Brett EM, Garber AJ, Hurley DL, Jastreboff AM, Nadolsky K, Pessah-Pollack R, Plodkowski R; Reviewers of the AACE/ACE Obesity Clinical Practice Guidelines. American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. Endocr Pract. 2016 Jul;22 Suppl 3:1-203. doi: 10.4158/EP161365.GL. Epub 2016 May 24. PMID: 27219496.

## Approval And Revision History

September 12, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

1. December 12, 2023: Effective March 1, 2024, for Wegovy in patients between age 12 and 17 years, updated the initial BMI at the 95$^{th}$ percentile or greater for age and sex (obesity) to align with the labeling. Limitations updated to include: The plan will not authorize coverage of GLP-1 agonists indicated for weight loss when used in combination with another GLP-1 receptor agonist. Members new to the plan stable on the requested medication will be reviewed against Reauthorization Criteria. Members who have already initiated the requested medication using samples, free goods, or similar offerings do not qualify for an established clinical response and should be reviewed against initial approval criteria. Members who have already initiated a GLP-1 agonist or compound that is not FDA-approved for weight loss do not qualify for an established clinical response and should be reviewed against initial approval criteria. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions.
2. October 8, 2024: Effective November 1, 2024, added Zepbound to the Medical Necessity Guideline. Added coverage criteria for Wegovy's supplemental indication for secondary cardiovascular prevention in overweight/obesity. Updated verbiage in reauthorization criteria. Removed limitation statement that the plan will not authorize coverage of GLP-1 agonists indicated for weight loss when used in combination with another GLP-1 receptor agonist. Added limitation statement that weight loss medications are only covered if your plan includes weight loss medication coverage. Additional restrictions may apply. Refer to benefit documents.
3. March 11, 2025: Effective April 1, 2025, updated established cardiovascular disease within criteria for Wegovy for secondary cardiovascular prevention in overweight/obesity. Administrative update to overview with Zepbound's supplemental indication for moderate to severe obstructive sleep apnea in obesity.

   Effective July 1, 2025, removed Wegovy and Saxenda from the MNG. Added age of 18 years or older to initial criteria for Zepbound and Contrave. Added requirement in reauthorization criteria for submission of baseline and follow-up weights from visit. Added limitation statement that the plan will not authorize coverage of a GLP-1 agonist or GLP-1 compounded product that is not FDA-approved for weight loss.

## 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.