

Initial Prior Authorization with Quantity Limit Contrave Weight Loss Management

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Contrave	naltrexone HCl and bupropion HCl extended-release

Indications

FDA-approved Indications

Contrave is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m² or greater (obese) or
- 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)

Limitations of Use

- The effect of Contrave on cardiovascular morbidity and mortality has not been established.
- The safety and effectiveness of Contrave in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

Coverage Criteria

Chronic Weight Management

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity for chronic weight management in an adult when ALL of the following criteria are met:

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced-calorie diet, AND increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy
- The patient meets ONE of the following:
 - The patient has a baseline body mass index (BMI) greater than or equal to 30 kg/m² [ACTION REQUIRED: Documentation is required for approval.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.]
 - The patient has a baseline BMI greater than or equal to 27 kg/m² [ACTION REQUIRED: Documentation is required for approval.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.] In addition, the following criteria is met:
 - The patient has at least ONE weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia) [ACTION REQUIRED: Documentation is required for approval.] [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their weight-related comorbid condition(s) at the start of any drug therapy.]

Continuation of Therapy

Chronic Weight Management

Authorization may be granted when the requested drug will be used with a reduced-calorie diet And increased physical activity for chronic weight management in an adult when All of the following criteria are met:

- The patient has completed at least 4 months of therapy with the requested drug
- The patient has lost at least 5 percent of baseline body weight OR the patient has continued to maintain their initial 5 percent weight loss [Action Required: Documentation is required for approval.]

Reference number(s)
1190-C

Quantity Limits Apply

120 tablets per 25 days or 360 tablets per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 1190-A: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months

References

1. Contrave Extended-Release [package insert]. Brentwood, TN: Currax Pharmaceuticals LLC; May 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed June 28, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 06/28/2024).
4. Jensen MD, Ryan DH, Apovian DM, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society. Circulation. 2014;129(suppl 2):S102-S138.
5. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(2):342–362.