

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS

WEIGHT LOSS MANAGEMENT

**BRAND NAME
(generic)**

**CONTRAVE
(naltrexone HCl and bupropion HCl extended release)**

**Status: CVS Caremark Criteria
Type: Initial Prior Authorization**

POLICY

FDA-APPROVED INDICATIONS

Contrave is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients 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, dyslipidemia, type 2 diabetes)

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

The requested drug will be covered with prior authorization when the following criteria are met:

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

OR

- The requested drug will be used with a reduced calorie diet and increased physical activity for chronic weight management in an adult
AND
 - 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
AND
 - The patient has a body mass index (BMI) greater than or equal to 30 kilogram per square meter
OR
 - The patient has a body mass index (BMI) greater than or equal to 27 kilogram per square meter AND has at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia)

REFERENCES

1. Contrave [package insert]. San Diego, CA: Nalpropion Pharmaceuticals, Inc.; March 2021.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, Ohio: UpToDate, Inc.; 2021; Accessed June 28, 2021.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/>. Accessed June 28, 2021.

4. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. National Heart, Lung, and Blood Institute. NIH Publication No. 12-7486. October 2012.
http://www.nhlbi.nih.gov/guidelines/cvd_ped/peds_guidelines_full.pdf. 141-159. Accessed June 28, 2021.
5. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*, Volume 100, Issue 2, 1 February 2015, Pages 342–362.
<https://academic.oup.com/jcem/article/100/2/342/2813109>. Accessed June 28, 2021.
6. Jensen MD, 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*. 2013; 129:S102–S138