

# Initial Prior Authorization with Quantity Limit Xenical 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
Xenical	orlistat

## Indications

### FDA-approved Indications

Xenical is indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet. Xenical is also indicated to reduce the risk for weight regain after prior weight loss. Xenical is indicated for obese patients with an initial body mass index (BMI) greater than or equal to 30 kg/m<sup>2</sup> or greater than or equal to 27 kg/m<sup>2</sup> in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).

## Coverage Criteria

### Obesity Management

Reference number(s)
250-C

Authorization may be granted when the requested drug will be used with a reduced-calorie diet AND increased physical activity for obesity management 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/m<sup>2</sup> [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/m<sup>2</sup> [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

### Obesity Management

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

- The patient has completed at least 6 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.]

## Quantity Limits Apply

90 capsules per 25 days or 270 capsules 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.

Reference number(s)
250-C

## Duration of Approval (DOA)

- 250-C: DOA: 12 months

## References

1. Xenical [package insert]. Montgomery, AL: H2-Pharma, LLC; December 2023.
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.
6. Torgerson JS, Hauptman J, Boldrin MN, et al. Xenical in the Prevention of Diabetes in Obese Subjects (XENDOS) Study: A randomized study of orlistat as an adjunct to lifestyle changes for the prevention of type 2 diabetes in obese patients. *Diabetes Care*. 2004;27:155-161.