

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	WEIGHT LOSS MANAGEMENT
BRAND NAME (generic)	XENICAL (orlistat)
Status: CVS Caremark® Criteria Type: Initial Prior Authorization with Quantity Limit	

POLICY

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/m² or greater than or equal to 27 kg/m² in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).

COVERAGE CRITERIA

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

- The requested drug will be used with a reduced calorie diet and increased physical activity for obesity management
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 kg/m². [ACTION REQUIRED: Documentation is required for approval.]
 - OR**
 - The patient has a body mass index (BMI) greater than or equal to 27 kg/m². [ACTION REQUIRED: Documentation is required for approval.]
AND
 - 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.]
- OR**
 - The patient has completed at least 6 months of therapy with the requested drug
AND
 - The patient has lost at least 5 percent of baseline bodyweight 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.*

Xenical PA with Limit Policy 250-C UDR 08-2023.docx

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Duration of Approval (DOA):

- 250-C: Initial therapy DOA: 12 months; Continuation of therapy DOA: 12 months

REFERENCES

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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.