PRIOR AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS</th>
<th>WEIGHT LOSS MANAGEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRAND NAME (generic)</td>
<td>XENICAL (orlistat)</td>
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<tr>
<td>Status: CVS Caremark Criteria</td>
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<tr>
<td>Type: Initial Prior Authorization</td>
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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) ≥30 kg/m² or ≥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 patient has taken the requested drug for a minimum of 6 months 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 OR
- The requested drug will be used with a reduced calorie diet and increased physical activity AND
  - The patient has a body mass index (BMI) greater than or equal to 30 kg per square meter OR
  - The patient has a body mass index (BMI) greater than or equal to 27 kg per square meter AND has additional risk factors

REFERENCES