Clinical Policy: Orlistat (Alli, Xenical)
Reference Number: CP.CPA.335
Effective Date: 06.01.18
Last Review Date: 05.19
Line of Business: Commercial

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Orlistat (Alli®, Xenical®) is a reversible inhibitor of gastrointestinal lipases.

FDA Approved Indication(s)
Alli and Xenical are indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet.
- Alli is an over-the-counter product indicated for overweight adults (18 years or older) with a body mass index (BMI) of 25 or above.
- Xenical is a prescription product indicated for obese patients with an initial BMI ≥ 30 kg/m² or ≥ 27 kg/m² in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia). Xenical is also indicated to reduce the risk for weight regain after prior weight loss.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Alli and Xenical are medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Weight Management (must meet all):
      1. Member meets one of the following (a or b):
         a. BMI ≥ 30 kg/m²;
         b. BMI ≥ 27 kg/m² with at least one indicator of increased cardiovascular risk (e.g., coronary artery/heart disease, hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
      2. Age ≥ 12 years;
      3. Dose does not exceed one of the following (a or b):
         a. Alli: 180 mg/day (3 capsules/day);
         b. Xenical: 360 mg/day (3 capsules/day).
   Approval duration: 6 months

   B. Other diagnoses/indications
      1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).
II. Continued Therapy
   A. Weight Management (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      2. BMI ≥ 25 kg/m²;
      3. Member is responding positively to therapy as evidenced by one of the following (a or b):
         a. If this is the first renewal request, member has lost ≥ 5% of baseline body weight;
         b. If this is a second or subsequent renewal request, member has lost weight and/or maintained weight loss on therapy;
      4. If request is for a dose increase, new dose does not exceed:
         a. Alli: 180 mg/day (3 capsules/day);
         b. Xenical: 360 mg/day (3 capsules/day).
   Approval duration: 6 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
      Approval duration: Duration of request or 6 months (whichever is less); or
      2. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:
    A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.CPA.09 or evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   BMI: body mass index
   FDA: Food and Drug Administration

   Appendix B: Therapeutic Alternatives
   Not applicable

   Appendix C: Contraindications/Boxed Warnings
   • Contraindication(s): Pregnancy, chronic malabsorption syndrome, and cholestasis
   • Boxed warning(s): none reported

   Appendix D: General Information
   • BMI = 703 x [weight (lbs)/height (inches)²]
   • Examples of coronary artery/heart disease include: coronary artery bypass graft, angina, history of myocardial infarction or stroke.
V. Dosage and Administration

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orlistat (Alli)</td>
<td>60 mg PO TID with each main meal containing fat</td>
<td>180 mg/day</td>
</tr>
<tr>
<td>Orlistat (Xenical)</td>
<td>120 mg PO TID with each main meal containing fat</td>
<td>360 mg/day</td>
</tr>
</tbody>
</table>

VI. Product Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orlistat (Alli)</td>
<td>Capsule: 60 mg</td>
</tr>
<tr>
<td>Orlistat (Xenical)</td>
<td>Capsule: 120 mg</td>
</tr>
</tbody>
</table>

VII. References


Reviews, Revisions, and Approvals

- **Policy created:** split from CP.CPA.197 Weight Loss; removed requirement for documentation of baseline weight; modified age restriction to ≥ 12 years for both products since Alli is the same active ingredient as Xenical; for re-auth: removed “continuation in a formalized weight management program” as this is difficult to verify/enforce; added that BMI must be ≥ 25 kg/m²; modified response to therapy requirement for Alli to be the same as Xenical (at least 5% weight loss) since they are the same active ingredient; references reviewed and updated.
- **Date:** 02.12.18 **P&T Approval Date:** 05.18

- **2Q 2019 annual review:** no significant changes; added contraindications to appendix; references reviewed and updated.
- **Date:** 02.04.19 **P&T Approval Date:** 05.19

**Important Reminder**
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical
policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions. Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

©2018 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.