

Clinical Policy: Orlistat (Alli, Xenical)

Reference Number: CP.CPA.335

Effective Date: 06.01.18

Last Review Date: 05.20

Line of Business: Commercial

[Revision Log](#)

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 (3 capsules) per day;
 - b. Xenical: 360 mg (3 capsules) per day.

Approval duration: 12 weeks

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 $\geq 5\%$ 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 (3 capsules) per day;
 - b. Xenical: 360 mg (3 capsules) per day.

Approval duration:

First reauthorization – 12 weeks

Second or subsequent reauthorizations – 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, cholestasis, known hypersensitivity to any component of the product.
- Boxed warning(s): none reported

Appendix D: General Information

- BMI = $703 \times [\text{weight (lbs)} / \text{height (inches)}^2]$

- Examples of coronary artery/heart disease include: coronary artery bypass graft, angina, history of myocardial infarction or stroke.

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Orlistat (Alli)	60 mg PO TID with each main meal containing fat	180 mg/day
Orlistat (Xenical)	120 mg PO TID with each main meal containing fat	360 mg/day

VI. Product Availability

Drug Name	Availability
Orlistat (Alli)	Capsule: 60 mg
Orlistat (Xenical)	Capsule: 120 mg

VII. References

1. Xenical Prescribing Information. Montgomery, AL: H2-Pharma, LLC; August 2017. Available at: www.xenical.com. Accessed February 5, 2020.
2. Alli Product Information. Moon Township, PA: GlaxoSmithKline; May 2017. Available at: www.myalli.com. Accessed February 5, 2020.
3. Jensen MD, Ryan DH, Apovian CM, 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.
4. 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): 42–362.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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/m ² ; 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.	02.12.18	05.18
2Q 2019 annual review: no significant changes; added contraindications to appendix; references reviewed and updated.	02.04.19	05.19
2Q 2020 annual review: revised initial and continuation approval duration to align with weight management policies; updated contraindications to appendix; references reviewed and updated.	02.05.19	05.20

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.

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