Clinical Policy: Orlistat (Xenical)

Reference Number: CP.CPA.335
Effective Date: 06.01.18
Last Review Date: 05.24
Line of Business: Commercial

Revision Log

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

Description

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

FDA Approved Indication(s)

Xenical is indicated:

- For obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet
- 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 orlistat or Xenical is **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, b, or c):
   a. BMI ≥ 30 kg/m^2;
   b. BMI ≥ 27 kg/m^2 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);
   c. If age is between 12 and 17 years: BMI ≥ 95th percentile standardized for age and sex (*see Appendix D*);
2. Age ≥ 12 years;
3. Documentation supports member's participation in a weight loss program that involves a reduced calorie diet, increased physical activity, and behavioral modification that meets both of the following (a and b):
   a. Been actively enrolled in a weight loss program for at least 6 months;
   b. Will continue to be actively enrolled in a weight loss program adjunct to therapy;
4. For brand Xenical requests, member must use generic orlistat, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 360 mg (3 capsules) per day.

Approval duration: 12 weeks

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

A. Weight Management (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. 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 (adults) or baseline BMI (pediatrics);
   b. If this is a second or subsequent renewal request, member has lost weight and/or maintained weight loss on therapy;
3. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet. increased physical activity, and behavioral modification adjunct to therapy;
4. For brand Xenical requests, member must use generic orlistat, unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for a dose increase, new dose does not exceed 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

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 Xenical or any component of this product
- 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.
- An effective response to a weight loss medication is defined by the Endocrine Society (2015) as weight loss ≥ 5% of body weight at 3 months of therapy. If there is weight loss < 5% of body weight, the Endocrine Society recommends discontinuation of the medication.
- BMI cut-offs (95th percentile) for obesity by age and sex for pediatric patients aged ≥ 12 years:

	95th Percentile BMI Value	
Age (in years)	**Male**	**Female**
12	24.2	25.2
12.5	24.7	25.7
13	25.1	26.3
13.5	25.6	26.8

	95th Percentile BMI Value	
Age (in years)	Male	Female
14	26.0	27.2
14.5	26.4	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.5	28.9
16.5	27.9	29.3
17	28.2	29.6
17.5	28.6	30.0

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Weight management	120 mg PO TID with each main meal containing fat	360 mg/day

VI. Product Availability

Capsule: 120 mg

VII. References

1. Xenical Prescribing Information. Montgomery, AL: H2-Pharma, LLC; November 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020766s038lbl.pdf. Accessed January 16, 2024.
2. 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.
3. 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.
4. Grunvald E, Shah R, Hernaez R et al. AGA clinical practice guidelines on pharmacological interventions for adults with obesity. Gastroenterology 2022;163:1198-1225.
5. Hampl SE, Hassink SG, Skinner AC, et al. Clinical practice guideline for the evaluation and treatment of children and adolescents with obesity [published online ahead of print, 2023 Jan 9]. Pediatrics. 2023;e2022060640.
6. Data Table of BMI-for-Age Charts. CDC National Center for Health Statistics. Available at: https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm. Accessed February 16, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Criteria added requiring documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy as per FDA label; removed Alli from policy; references reviewed and updated.	07.27.20	08.20
2Q 2021 annual review: no significant changes; references reviewed and updated.	02.02.21	05.21
2Q 2022 annual review: no significant changes; WCG.CP.CPA.335 for off-label use of orlistat retired per health plan; references reviewed and updated.	01.24.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.28.22	
2Q 2023 annual review: FDA indications updated per PI; added redirection to generic orlistat for brand Xenical requests per formulary status; for age between 12 and 17 years added obesity defined as BMI $\geq 95^{th}$ percentile standardized for age and sex; removed continued therapy criterion of BMI ≥ 25 kg/m^2; specified continuation of therapy positive response criterion of $\geq 5\%$ loss of baseline body weight for adults and BMI for pediatrics; references reviewed and updated.	01.11.23	05.23
2Q 2024 annual review: for documentation of weight loss program, added members has been actively enrolled for at least 6 months to initial criteria and added a weight loss program that also involves behavioral modification as supported by ACC/AHA guidelines; references reviewed and updated.	01.16.24	05.24

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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