

Clinical Policy: Anti-Obesity Medications

Reference Number: NH.PMN.50

Effective Date: 07.21 Last Review Date: 07.21 Line of Business: Medicaid

Coding Implications
Revision Log

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

Description

The following are anti-obesity medications requiring prior authorization:

- Adipex-P[®] (phentermine)
- Contrave[®] (naltrexone/bupropion)
- Phentermine
- Lomaira® (phentermine)
- Qsymia[®] (phentermine/topiramate)
- Saxenda[®] (liraglutide)
- Xenical[®] (orlistat)

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 anti-obesity medications are **medically necessary** for members meeting the following criteria:

Initial Criteria:

- 1. Patient must be \geq 12 years old (Xenical[®] only), \geq 16 years old (Adipex[®], phentermine, Lomaira[®]) or \geq 18 years old (Contrave[®], Qsymia[®], Saxenda[®]); AND
- 2. Documented failure of at least a three-month trial on a low-calorie diet; AND
- 3. A regimen of increased physical activity unless medically contraindicated by comorbidity; AND
- 4. Baseline body mass index (BMI) must be:
 - a. $> 30 \text{ kg/m}^2 \text{ with no risk factors; OR}$
 - b. $> 27 \text{ kg/m}^2$ with at least one very high factor; OR
- 5. At least two other risk factors (see Table 1); OR
 - a. Waist circumference must be >102 cm for men and > 88 cm for women with at least one very high risk factor; OR
- 6. At least two other risk factors (see Table 1); AND
- 7. No contraindication (disease state or current therapy) should exist unless the prescriber documents that benefits outweigh risks (see Table 2).

Approval Duration: 3 Months

Continuation Criteria:

- 1. Ongoing prescriber documentation of adherence to a low calorie diet (1,200 kcal/day for women, 1,600 kcal/day for men); AND
- 2. A regimen of increased physical activity (unless medically contraindicated by comorbidity) during anti-obesity therapy; AND
- 3. No contraindications (disease state or current therapy) should exist, unless prescriber documents that benefits outweigh risks (see Table 2); AND
- 4. After three months of therapy, for 3 months of continued approval, patient must have lost at least 4 pounds in the first month and one pound per month for second and third month;
- 5. After six months of therapy, a six month approval may be granted if a 5% weight reduction has been achieved;
- 6. After one year of therapy, an additional 6 month approval may be granted if a 10% reduction has been achieved AND the patient continues to maintain weight loss;
- 7. If lapses of therapy occur, additional trials may be approved if criteria requirements are met;
- 8. If request is for phentermine approval may not be granted beyond nine months of treatment;
- 9. If request is for Xenical® approval may not be given beyond four years.

Approval Duration – As noted in criteria above

Table 1: Risk Factors				
Very high risk	 → Type 2 diabetes → Established coronary heart disease → Other atherosclerotic disease → Sleep apnea 			
Other risk factors	 + Hypertension + Dyslipidemia + Impaired fasting glucose concentration + Cigarette smoking + Family history of premature heart disease + Age (men > 45 years, women > 55 years or postmenopausal) + Gynecologic abnormalities + Osteoarthritis + Gallstones + Stress incontinence 			

Table 2: Contraindications, Precautions, and Drug Interactions						
Drug	Contraindications	Precautions	Drug Interactions			
orlistat	Chronic malabsorption syndromeCholestasis	 Hx of hyperoxaluria or Caoxalate nephrolithiasis Patients with deficiency of any fat-soluble vitamins 				
phentermine	 + Hx of glaucoma + Hx of hypertension (moderate to severe) + Hx of hyperthyroidism + Hx of cardiovascular disease 	 + Hx of drug abuse + Hx of anxiety disorders + Hx of diabetes mellitus + Hx of hypertension (mild) 	→ Monoamine oxidase inhibitors (MAOI): contraindicated			
phentermine/ topiramate	 + Pregnancy + Glaucoma + Hyperthyroidism + During or within 14 days of taking MAOI 	 Increase in heart rate Suicidal behavior and ideation Acute myopia and secondary angle closure glaucoma 	 → Oral → contraceptive Non-potassium → sparing diuretic CNS depressants including alcohol 			
naltrexone/bupropion	 Uncontrolled hypertension Seizure disorders Anorexia nervosa or bulimia Undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, or antiepileptic drugs Concurrent use of other bupropion-containing products if the total daily dose of all 	→ Suicidal thoughts and ideation	→ MAOI→ Opioid analgesics			
	bupropion-containing products is above the FDA maximum recommended dose + Chronic opioid use + During or within 14 days of taking MAOI					

liraglutide	 → Pregnancy Personal or family Hx of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2 → Coadministration of insulin → Coadministration of GLP-1 receptor agonist 	 Suicidal behavior and ideation Acute pancreatitis Acute gallbladder disease Renal impairment 	
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Reviews, Revisions, and Approvals		Approval Date
Policy developed.	07.21	07.21

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.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed <u>prior to</u> applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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