Clinical Policy: Phentermine (Adipex-P, Lomaira)

Reference Number: CP.PCH.13
Effective Date: 05.01.17
Last Review Date: 05.23
Line of Business: Commercial, HIM* Revision Log

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

Description

Phentermine (Adipex-P ®, Lomaira™) is a sympathomimetic amine with pharmacologic activity similar to the amphetamines.

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***For Health Insurance Marketplace (HIM),** Adipex-P/phentermine tablets and Lomaira are plan exclusions and are not covered.*

FDA Approved Indication(s)

Adipex-P and Lomaira are indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity for patients with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obese), or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia.

The limited usefulness of agents of this class, including Adipex-P and Lomaira, should be measured against possible risk factors inherent in their use.

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 Adipex-P and Lomaira 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, 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 17 years: BMI ≥ 95th percentile standardized for age and sex (*see Appendix D*);
2. Age ≥ 17 years;

3. Member must use generic phentermine, unless contraindicated or clinically significant adverse effects are experienced;
4. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy;
5. Dose does not exceed one of the following (a or b):
   a. Adipex-P: 37.5 mg per day (1 capsule per day);
   b. Lomaira: 24 mg per day (3 tablets 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 and HIM.PA.33 for health insurance marketplace; 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 and HIM.PA.103 for health insurance marketplace; 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 and HIM.PA.154 for health insurance marketplace.

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 weight loss from baseline;
3. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy;
4. Total treatment duration does not exceed 12 weeks;
5. If request is for a dose increase, new dose does not exceed:
   a. Adipex-P: 37.5 mg per day (1 capsule per day);
   b. Lomaira: 24 mg per day (3 tablets per day).

Approval duration: Up to 12 weeks total

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 and HIM.PA.33 for health insurance marketplace; 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 and HIM.PA.103 for health insurance marketplace; 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 and HIM.PA.154 for health insurance marketplace.

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 policies – CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace 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, nursing, glaucoma, hyperthyroidism, concomitant use or within 14 days use of monoamine oxidase inhibitors, known hypersensitivity to sympathomimetic amines, history of drug abuse, agitated states, and history of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension)
- 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.
- If tolerance develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued.

- BMI cut-offs (95th percentile) for obesity by age and sex for adolescent patients aged ≥ 17 years:

	95th Percentile BMI Value	
Age (in years)	**Male**	**Female**
17	28.2	29.6
17.5	28.6	30.0

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Phentermine (Adipex-P)	15-37.5 mg PO QD	37.5 mg/day
Phentermine (Lomaira)	8 mg PO TID	24 mg/day

VI. Product Availability

Drug Name	Availability
Phentermine	Capsules: 15 mg, 30 mg, 37.5 mg Tablets: 37.5 mg
Phentermine (Adipex-P)	Capsule: 37.5 mg Tablet: 37.5 mg
Phentermine (Lomaira)	Tablet: 8 mg

VII. References

1. Phentermine Drug Monograph. Clinical Pharmacology. Accessed January 11, 2023. Available at: http://www.clinicalpharmacology-ip.com.
2. Adipex-P Prescribing Information. Horsham, P: Teva Select Brands; September 2020. Available at: http://www.adipex.com. Accessed January 11, 2023.
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4. 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.
5. 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.
6. Garvey WT, Mechanick JI, Bret EM et al. Reviewers of the AACE/ACE Obesity Clinical Practice Guidelines. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. Endocr Pract. 2016 Jul;22 Suppl 3:1-203.12.
7. Grunvald E, Shah R, Hernaez R et al. AGA clinical practice guidelines on pharmacological interventions for adults with obesity. Gastroenterology 2022;163:1198-1225.
8. 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.
9. 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 January 19, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy. 2Q 2019 annual review: policy adapted from CP.PMN.135; no significant changes from previously approved corporate policy; added contraindications and new generic tablet dosing form; removed criteria for pregnancy test within 30 days; references reviewed and updated.	02.05.19	05.19
2Q 2020 annual review: no significant changes; updated contraindications; references reviewed and updated.	02.05.20	05.20
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.	05.26.20	08.20
2Q 2021 annual review: no significant changes; added redirection to generic phentermine; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	02.12.21	05.21
2Q 2022 annual review: no significant changes; references reviewed and updated.	01.21.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.29.22	
2Q 2023 annual review: changed age requirement to ≥ 17 years instead of > 16 years; for age 17 years, added obesity defined as BMI ≥ 95th percentile standardized for age and sex; removed continued therapy criterion of BMI ≥ 25 kg/m^2; references reviewed and updated.	01.11.23	05.23

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.