

Clinical Policy: Phendimetrazine

Reference Number: CP.PCH.47

Effective Date: 06.01.22

Last Review Date: 05.22

Line of Business: Commercial, HIM*

[Revision Log](#)

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

Description

Phendimetrazine is a sympathomimetic amine with pharmacologic activity similar to the amphetamines.

**For Health Insurance Marketplace (HIM), if request is through pharmacy benefit, phendimetrazine ER is a benefit exclusion and should not be approved using these criteria.*

FDA Approved Indication(s)

Phendimetrazine IR/ER is indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of 30 kg/m² or higher who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone.

Phendimetrazine ER is also indicated in patients with a BMI \geq 27 kg/m² in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia) who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone.

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 phendimetrazine 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 or b):
 - a. BMI \geq 30 kg/m²;
 - b. BMI \geq 27 kg/m² with at least one indicator of increased cardiovascular risk (e.g., controlled hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
2. Age is one of the following (a or b):
 - a. If request is for phendimetrazine ER: \geq 17 years;
 - b. If request is for phendimetrazine IR: \geq 18 years;
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. Dose does not exceed (a or b):
 - a. Phendimetrazine IR: 210 mg (6 tablets) per day;
 - b. Phendimetrazine ER: 105 mg (1 capsule) per day.

Approval duration: 12 weeks

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace.

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 weight loss from baseline;
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. Total treatment duration does not exceed 12 weeks;
6. If request is for a dose increase, new dose does not exceed (a or b):
 - a. Phendimetrazine IR: 210 mg (6 tablets) per day;
 - b. Phendimetrazine ER: 105 mg (1 capsule) per day.

Approval duration: Up to 12 weeks total

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 12 weeks (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): 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.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BMI: body mass index
ER: extended release

FDA: Food and Drug Administration
IR: immediate release

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Phendimetrazine IR: known hypersensitivity or idiosyncrasy to sympathomimetics, advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, glaucoma, highly nervous or agitated patients, patients with a history of drug abuse, patients taking other CNS stimulants including monoamine oxidase inhibitors
 - Phendimetrazine ER: history of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension, pulmonary hypertension), during or within 14 days following administration of monoamine oxidase inhibitors, hyperthyroidism, glaucoma, agitated states, history of drug abuse, pregnancy, nursing, use in combination with other anorectic agents or CNS stimulants, known hypersensitivity or idiosyncratic reactions to sympathomimetics
- Boxed warnings(s): none reported

Appendix D: General Information

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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Weight management	IR: 35 mg PO BID-TID ER: 105 mg PO QD	IR: 210 mg/day ER: 105 mg/day

VI. Product Availability

- Immediate-release tablet: 35 mg
- Extended-release capsule: 105 mg

VII. References

1. Phendimetrazine Prescribing Information. Northvale, NJ: Elite Laboratories, Inc.; January 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6e5cd1e8-b00c-484b-9a98-8f68aa19e729>. Accessed February 15, 2022.
2. Phendimetrazine Tartrate ER and Phendimetrazine Tartrate Prescribing Information. Langhorne, PA: Virtus Pharmaceuticals, Inc.; March 2021. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=669fafd4-ac03-4bbc-ba86-28d1efbaf8c6&type=display/>. Accessed April 19, 2022.
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.

5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2022. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed February 15, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy HIM.PA.114 (to be retired); no significant change from previously approved policy; added Commercial line of business and phendimetrazine ER formulation to policy; removal of coronary artery/heart disease and clarified “controlled” hypertension in indicators of increased cardiovascular risk in initial approval section; updated contraindications for phendimetrazine ER; references reviewed and updated.	004.19.22	05.22

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.

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