Clinical Policy: Phendimetrazine

Reference Number: CP.PCH.47
Effective Date: 06.01.22
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

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 non-formulary for California and Florida HIM, a benefit exclusion for other HIMs, and should not be approved using these criteria. For California and Florida, refer to the formulary exception policy, HIM.PA.103.*

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/m^2 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 ≥ 27 kg/m^2 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, 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., controlled hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
   c. If age ≥ 17 years but < 18 years: BMI ≥ 95th percentile standardized for age and sex (*see Appendix D*);
2. Age is one of the following (a or b):
   a. If request is for phendimetrazine ER: ≥ 17 years;
   b. If request is for phendimetrazine IR: ≥ 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: both of the following (i and ii):
      i. 210 mg per day;
      ii. 6 tablets per day;
   b. Phendimetrazine ER: both of the following (i and ii):
      i. 105 mg per day;
      ii. 1 capsule 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 or b):
   a. Phendimetrazine IR: both of the following (i and ii):
      i. 210 mg per day;
      ii. 6 tablets per day;

b. Phendimetrazine ER: both of the following (i and ii):
   i. 105 mg per day;
   ii. 1 capsule 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.

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 x [weight (lbs)/height (inches)^2]
- 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

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.; December 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=4a64fde2-1db7-5878-e054-00144ff8d46c&type=display. Accessed February 3, 2023.
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 February 3, 2023.
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: Elsevier, Inc.; 2023. Available at: http://www.clinicalkeys.com/pharmacology. Accessed February 3, 2023.

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.	04.19.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.29.22	
2Q 2023 annual review: clarified phendimetrazine ER is non-formulary for California and Florida LOB; added obesity definition for age < 18 years to initial criteria; removed continued therapy criterion of BMI ≥ 25 kg/m^2; references reviewed and updated.	02.10.23	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.