Clinical Policy: Phendimetrazine IR (Bontril PDM)

Reference Number: HIM.PA.114
Effective Date: 06.01.17
Last Review Date: 08.20 Revision Log
Line of Business: HIM

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

Description

Phendimetrazine immediate-release (IR) (Bontril® PDM) is a sympathomimetic amine with pharmacologic activity similar to the amphetamines.

FDA Approved Indication(s)

Bontril PDM 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.

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 Bontril PDM 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 ≥ 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);
2. Age ≥ 16 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 210 mg per day (6 tablets per day).

Approval duration: 12 weeks

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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/m^2;
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 210 mg per day (6 tablets 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 HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – HIM.PHAR.21 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): 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
- Boxed warnings(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.
- The extended-release formulation of phendimetrazine is also indicated in patients with an initial BMI of greater than or equal to 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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Weight management	35 mg PO BID-TID 1 hour before meals	210 mg

VI. Product Availability

Immediate-release tablet: 35 mg

VII. References

1. Phendimetrazine Prescribing Information. Northvale, NJ: Elite Laboratories, Inc.; October 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6e5cd1c8-b00c-484b-9a98-8f68aa19e729. Accessed February 5, 2020.
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. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 5, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.17	05.17
2Q 2018 annual review: removed "diagnosis of obesity as evidenced by BMI ≥ 30" since coverage is allowed for BMI ≥ 27 in the presence of other comorbidities; ade added; added coronary artery/heart disease as an example of cardiovascular risk indicator; modified initial approval duration from 6 weeks to 12 weeks; references reviewed and updated.	02.12.18	05.18
2Q 2019 annual review: no significant changes; added contraindications; references reviewed and updated.	02.24.19	05.19
2Q 2020 annual review: no significant changes; added dosage, administration, and product availability; 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

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.

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