Clinical Policy: Phendimetrazine (Bontril SR, Bontril PDM)

Reference Number: ERX.NPA.93
Effective Date: 12.01.18
Last Review Date: 11.18 Revision Log

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

Description
Phendimetrazine (Bontril® SR, Bontril® PDM) is a sympathomimetic amine with pharmacologic activity similar to the amphetamines.

FDA Approved Indication(s)
Bontril SR and Bontril PDM are 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.

Bontril SR is also indicated in patients with an initial BMI of greater than or equal to 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 Envolve Pharmacy Solutions™ that Bontril SR and Bontril PDM 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 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. Dose does not exceed (a or b):
   a. Bontril PDM: 210 mg (6 tablets) per day;
   b. Bontril SR: 105 mg (1 tablet) per day.

Approval duration: 12 weeks

B. Other diagnoses/indications

1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions 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. 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. Bontril PDM: 210 mg (6 tablets) per day;
   b. Bontril SR: 105 mg (1 tablet) per day.

Approval duration: Up to 12 weeks total

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 weeks (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 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):
  - Bontril PDM and Bontril SR: 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
  - Bontril SR only: pregnancy, nursing
- 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.

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Phendimetrazine (Bontril PDM)	35 mg PO BID-TID	210 mg/day
Phendimetrazine (Bontril SR)	105 mg PO QD	105 mg/day

VI. Product Availability

Drug Name	Product Availability
Phendimetrazine (Bontril PDM)	Immediate-release tablet: 35 mg
Phendimetrazine (Bontril SR)	Extended-release capsule: 105 mg

VII. References

1. Phendimetrazine PDM Prescribing Information. Northvale, NJ: Elite Laboratories, Inc.; August 2017. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed August 7, 2018.
2. Phendimetrazine SR Prescribing Information. Princeton, NJ: Sandoz, Inc.; February 2012. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed August 7, 2018.
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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy ERX.NPA.15; added coronary artery/heart disease as an example of cardiovascular risk indicator; modified age restriction to ≥ 16 years as there is supporting evidence for use of the immediate-release product in this population; modified initial approval duration to 12 weeks (re-auth/total treatment duration remains at a total of 12 weeks); references reviewed and updated.	08.07.18	11.18

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.