

Clinical Policy: Benzphetamine

Reference Number: ERX.NPA.92

Effective Date: 12.01.18

Last Review Date: 05.22

Line of Business: Commercial, Medicaid

[Revision Log](#)

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

Description

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

FDA Approved Indication(s)

Benzphetamine is indicated in the management of exogenous obesity as a short term (a few weeks) adjunct 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.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that benzphetamine 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/m²;
 - b. BMI ≥ 27 kg/m² 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 ≥ 17 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 150 mg 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/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 150 mg 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): pregnancy, advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to sympathomimetic amines, glaucoma, patients who are in an agitated state or who have a history of drug abuse, use with or within 14 days following monoamine oxidase inhibitors
- Boxed warning(s): none reported

Appendix D: General Information

- $BMI = 703 \times [\text{weight (lbs)}/\text{height (inches)}^2]$
- 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.
- The American College of Cardiology/American Heart Association/The Obesity Society Guideline for the Management of Overweight and Obesity in Adults reviewed randomized clinical trials on weight loss interventions and determined that the best weight loss outcomes occur with frequent face-to-face visits (16 visits per year on average).
 - A diet that is individually planned and takes into account the patient's overweight status in order to help create a deficit of 500 to 1,000 kcal/day should be an integral part of any weight loss program. A patient may choose a diet of 1,000 to 1,200 kcal/day for women and 1,200 to 1,500 kcal/day for men.
 - There is no standardized set of rules to optimize weight reduction with a given type of patient. A theoretical and qualitative analysis of cultural appropriateness in obesity treatment programs has been conducted, and it provides some guidance for incorporating patient characteristics and perspectives when designing and delivering weight loss programs.
 - Some examples follow: Adapt the setting and staffing to the patient population. The setting should: be physically accessible to the patient; have features likely to be familiar to the patient; be free of negative psychosocial connotations; be devoid of aspects that create a large social distance among patients or between patient and practitioner; and promote active patient participation and high patient self-esteem and self-efficacy.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Weight management	25-50 mg PO QD-TID	150 mg/day

VI. Product Availability

Tablet: 50 mg

VII. References

1. Benzphetamine Prescribing Information. Laurelton, NY: Epic Pharma, LLC. January 2021. Available at: <http://labeling.pfizer.com/ShowLabeling.aspx?id=565>. Accessed January 20, 2022.
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. NHLBI Obesity Education Initiative. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report. Bethesda (MD): National Heart, Lung, and Blood Institute; 1998 Sep. Available from: https://www.nhlbi.nih.gov/files/docs/guidelines/ob_gdlns.pdf

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy ERX.NPA.14; added coronary artery/heart disease as an example of cardiovascular risk indicator; 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
2Q 2019 annual review: no significant changes; references reviewed and updated.	03.06.19	05.19
2Q 2020 annual review: no significant changes; revised age restriction from 12 to 17 years of age as per label update; references reviewed and updated.	04.21.20	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; updated Appendix D; references reviewed and updated.	07.27.20	08.20
2Q 2021 annual review: no significant changes; removed references to Regimex due to discontinuation of product; references reviewed and updated.	02.01.21	05.21
2Q 2022 annual review: no significant changes; removed references to Didrex due to discontinuation of product; references reviewed and updated.	01.20.22	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.

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.

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