Clinical Policy: Diethylpropion

Reference Number: ERX.NPA.95
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
Diethylpropion is a sympathomimetic amine with pharmacologic activity similar to the amphetamines.

FDA Approved Indication(s)
Diethylpropion 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 and 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 diethylpropion 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 75 mg per day (IR: 3 tablets per day; ER: 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. 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 75 mg per day (IR: 3 tablets per day; ER: 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
ER: extended release
FDA: Food and Drug Administration
IR: immediate release

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): pulmonary hypertension, advanced arteriosclerosis, hyperthyroidism glaucoma, severe hypertension, agitated states, history of drug abuse, concurrent use of other anorectic agents, concomitant use or use within 14 days of MAO inhibitors, and known hypersensitivity to sympathomimetic amines.
- 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.
- Diethylpropion is not recommended for patients who used any anorectic agents within the prior year.
- If tolerance develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Weight management	IR: 25 mg PO TID ER: 75 mg PO QD	75 mg/day

VI. Product Availability

- Immediate-release tablet: 25 mg
- Extended-release tablet: 75 mg

VII. References

1. Diethylpropion Hydrochloride Extended Release Tablets. Philadelphia, PA. Lannett Company, Inc.; December 2019. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=dab53f4f-68d4-4477-a2b6-ad44a956332b Accessed January 19, 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy ERX.NPA.17; added coronary artery/heart disease as an example of cardiovascular risk indicator; modified age restriction per prescribing information; 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.	03.05.19	05.19
2Q 2020 annual review: no significant changes; 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
2Q 2021 annual review: no significant changes; references reviewed and updated.	02.02.21	05.21
2Q 2022 annual review: no significant changes; removed references to Tenuate and Tenuate Dospan due to discontinuation of product; reviewed and updated.	01.19.22	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.

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.