# Clinical Policy: Diethylpropion (Tenuate, Tenuate Dospan)

Reference Number: ERX.NPA.95
Effective Date: 12.01.18
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

Revision Log

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

## Description

Diethylpropion (Tenuate®, Tenuate Dospan®) is a sympathomimetic amine with pharmacologic activity similar to the amphetamines.

## FDA Approved Indication(s)

Tenuate and Tenuate Dospan 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 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 Tenuate and Tenuate Dospan 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. 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 (Tenuate: 3 tablets per day; Tenuate Dospan: 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 (Tenuate: 3 tablets per day; Tenuate Dospan: 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): pulmonary hypertension, advanced arteriosclerosis, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma, severe hypertension, agitated states, patients with a history of drug abuse, use in combination with other anorectic agents, during or within 14 days following the administration of monoamine oxidase inhibitors
- 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.
- Tenuate and Tenuate Dospan are 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

| Drug Name | Dosing regimen | Maximum Dose |
|---|---|---|
| Diethylpropion (Tenuate) | 25 mg PO TID | 75 mg/day |
| Diethylpropion (Tenuate Dospan) | 75 mg PO QD | 75 mg/day |

## VI. Product Availability

| Drug Name | Availability |
|---|---|
| Diethylpropion (Tenuate) | Immediate-release tablet: 25 mg |
| Diethylpropion (Tenuate Dospan) | 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-ad44a956332bAccessed February 1, 2021.
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 |

**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.