Clinical Policy: Diethylpropion (Tenuate, Tenuate Dospan)

Reference Number: CP.CPA.328
Effective Date: 06.01.18
Last Review Date: 05.20
Line of Business: Commercial

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.

It is the policy of health plans affiliated with Centene Corporation® 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. 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 CP.CPA.09 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. Total treatment duration does not exceed 12 weeks;
5. 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 Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 weeks (whichever is less); or
2. Refer to CP.CPA.09 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 – CP.CPA.09 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, glaucoma, 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.
- 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. Tenuate, Tenuate Dospan Prescribing Information. Bridgewater, NJ: Merrell Pharmaceuticals Inc.; November 2003. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/11722s029,12546s032lbl.pdf. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: split from CP.CPA.197 Weight Loss; removed requirement for documentation of baseline weight; for re-auth: added requirement that member is responding positively to therapy as evidenced by weight loss from baseline and that BMI must be ≥ 25 kg/m^2; references reviewed and updated.	02.12.18	05.18
Q2 2019 annual review: no significant changes; added contraindications and boxed warnings; references reviewed and updated.	02.05.19	5.19
2Q 2020 annual review: no significant changes; references reviewed and updated.	02.05.20	05.20

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.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions. Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.