# Clinical Policy: Mecamylamine (Vecamyl)

Reference Number: CP.PMN.136
Effective Date: 06.01.17
Last Review Date: 05.25
Line of Business: Commercial, HIM, Medicaid

Revision Log

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

## Description

Mecamylamine (Vecamyl®) is an oral anti-hypertension agent and ganglion blocker.

## FDA Approved Indication(s)

Vecamyl is indicated for the management of moderately severe to severe essential hypertension and in uncomplicated cases of malignant hypertension.

## 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 Vecamyl is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Hypertension** (must meet all)**:**

1. Diagnosis of hypertension;
2. Age ≥ 18 years;
3. Failure of a combination of 3 formulary antihypertensive agents (*see Appendix D for rationale*), each from different classes at up to maximally indicated doses (*see Appendix B)*, unless clinically significant adverse effects are experienced or all are contraindicated.*

   ** For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*

**Approval duration: 6 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

**A. Hypertension** (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## 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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Angiotensin-converting enzyme (ACE) inhibitors (e.g., lisinopril, enalapril, benazepril) | Refer to the prescribing information | Refer to the prescribing information |
| Angiotensin II receptor blockers (ARBs; e.g., losartan, valsartan, candesartan) | Refer to the prescribing information | Refer to the prescribing information |
| Thiazide diuretics (e.g., hydrochlorothiazide) | Refer to the prescribing information | Refer to the prescribing information |
| Calcium channel blockers (e.g., amlodipine, diltiazem, verapamil) | Refer to the prescribing information | Refer to the prescribing information |
| Beta blockers (e.g., carvediolol. metroprolol, nebivolol) | Refer to the prescribing information | Refer to the prescribing information |
| Alpha blockers (e.g., prazosin, terazosin, doxazosin) | Refer to the prescribing information | Refer to the prescribing information |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): concomitant antibiotics or sulfonamides, coronary insufficiency, glaucoma, mild or moderate hypertension, organic pyloric stenosis, recent myocardial infarction, renal insufficiency, uremia, and hypersensitivity to mecamylamine
- Boxed warning(s): none reported

*Appendix D: General Information*

- Rationale for combination of 3 formulary antihypertensive agents: The recognition that triple-combination therapy is frequently a necessity is based on large-scale studies.
  - In the Study on Cognition and Prognosis in the Elderly (SCOPE) of 4,964 elderly patients with stage 2 hypertension (BP: 160–179⁄90–99 mm Hg), 49% of patients were receiving ≥ 3 antihypertensive agents by the end of the study.
  - Similarly, in the International Verapamil SR and Trandolapril Study (INVEST) involving patients with hypertension (mean BP: 150⁄86 mm Hg) and coronary artery disease, about half of the patients assigned to receive a calcium channel blocker or a beta blocker were receiving ≥ 3 antihypertensive medications at the end of the 2-year follow-up period.
  - In ALLHAT, ≥ 3 antihypertensive agents were necessary for 24% of black patients and 24% of nonblack patients initially assigned to receive chlorthalidone, for 41% and 31%, respectively, initially assigned to receive lisinopril, and for 28% and 25%, respectively, of those initially assigned to receive amlodipine.
  - At study end point in ACCOMPLISH, 32% of the 11,506 patients with hypertension at high risk for cardiovascular disease were receiving at least 1 other antihypertensive

agent in addition to initial therapy with either benazepril/amlodipine or benazepril /hydrochlorothiazide.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Hypertension | Initiate therapy with 2.5 mg PO BID. Titrate in increments of 2.5 mg at intervals of not less than 2 days until desire blood pressure response occurs. | Based on individual response |

## VI. Product Availability

Tablet: 2.5 mg

## VII. References

1. Vecamyl Prescribing Information. New York, NY: Vyera Pharmaceuticals; July 2018. Available at: https://www.vecamyl.com/. Accessed January 14, 2025.
2. James PA, Oparil S, Carter BL, et al. 2014 evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). *JAMA*. 2014; 5;311(5):507-20. doi: 10.1001/jama.2013.284427.
3. Chobanian AV, Bakris GL, Black HR, et al. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Hypertension*. 2003;42(6):1206-52. Epub 2003 Dec 1.
4. Carey RM, Whelton PK, 2017 ACC/AHA Hypertension guideline writing committee. Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Synopsis of the 2017 American College of Cardiology/American Heart Association Hypertension Guideline. *Ann Intern Med*. 2018; 168(5):351-358
5. Gradman, AH. Rationale for triple-combination therapy for management of high blood pressure. *J Clin Hypertens.* 2010; 12:869-878. doi: 10.1111/j.1751-7176.2010.00360.x
6. Carey RM, Calhoun DA, Bakris GL, et al. Resistant hypertension: Detection, evaluation, and management: A scientific statement from the American Heart Association. 2018;72:e53-e90.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 2Q 2021 annual review: no significant changes; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated. | 02.15.21 | 05.21 |
| 2Q 2022 annual review: no significant changes; references reviewed and updated. | 01.27.22 | 05.22 |
| Template changes applied to other diagnoses/indications and continued therapy section. | 10.03.22 | |
| 2Q 2023 annual review: no significant changes; references reviewed and updated. | 02.03.23 | 05.23 |
| 2Q 2024 annual review: for Commercial line of business, updated approval duration from length of benefit to 6/12 months for initial and continued therapy respectively; references reviewed and updated. | 01.18.24 | 05.24 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 2Q 2025 annual review: no significant changes; references reviewed and updated.<br>Added step therapy bypass for IL HIM per IL HB 5395. | 04.08.25 | 05.25 |

**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.

**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.