Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2024**
Policy Number: PA.CP.PMN.136	**Effective Date: 04/2019** **Revision Date: 04/2024**
Policy Name: Mecamylamine (Vecamyl)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2024 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Mecamylamine (Vecamyl)

Reference Number: PA.CP.PMN.136
Effective Date: 04/2019
Last Review Date: 04/2024

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 PA Health & Wellness® 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, unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy.

Approval duration: 12 months

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 – PA.CP.PMN.53 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 18, 2024.
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

Reviews, Revisions, and Approvals	Date
Policy created.	04/2019
2Q 2020 annual review: references reviewed and updated.	04/2020
2Q 2021 annual review: references reviewed and updated.	04/2021
2Q 2022 annual review: references reviewed and updated.	04/2022

Reviews, Revisions, and Approvals	Date
2Q 2023 annual review: no significant changes; references reviewed and updated.	04/2023
2Q 2023 annual review: no significant changes; references reviewed and updated.	04/2024