RXADVANCE
2 Park Central Drive
Southborough, MA 01772

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| **Clinical Policy Title:** | mecamylamine |
| **Policy Number:** | RxA.540 |
| **Drug(s) Applied:** | Vecamyl® |
| **Original Policy Date:** | 03/06/2020 |
| **Last Review Date:** | 12/07/2020 |
| **Line of Business Policy Applies to:** | All lines of business |

## Background

Mecamylamine (Vecamyl®) is an oral anti-hypertension agent and ganglion blocker. It is indicated for the management of moderately severe to severe essential hypertension and in uncomplicated cases of malignant hypertension.

## Dosing Information

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| mecamylamine (Vecamyl®) | 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 |

## Dosage Forms

- Tablet: 2.5 mg

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

**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*) from different classes, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced.

**Approval Duration**

**Commercial:** 6 months

**Medicaid:** 6 months

## II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy.

**Approval Duration**
**Commercial:** 12 months
**Medicaid:** 12 months

## III. Appendices

**APPENDIX A: Abbreviation/Acronym Key**
FDA: Food and Drug Administration

**APPENDIX B: Therapeutic Alternatives**

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

| 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) | 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.

**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 CCB or a b-blocker were receiving ≥ 3 antihypertensive medications at the end of the 2-year follow-up period.20
  - 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 CV disease were receiving at least 1 other antihypertensive agent in addition to initial therapy with either benazepril /amlodipine or benazepril /HCTZ.

**References**

1. Vecamyl Prescribing Information. New York, NY: Vyera Pharmaceuticals, LLC; July 2018. Available at: www.vecamyl.com . Accessed September 12, 2020.
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 Feb 5;311(5):507-20. doi: 10.1001/jama.2013.284427. Accessed September 12, 2020.
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 Dec;42(6):1206-52. Epub 2003 Dec 1. Accessed September 12, 2020.
4. 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. Accessed September 12, 2020.

| Review/Revision History | Review/Revision Date | P&T Approval Date |
|---|---|---|
| Policy established. | 01/2020 | 03/06/2020 |
| Policy was reviewed:<br>1. Clinical policy title was updated.<br>2. Lines of business policy applies to was updated to all lines of business.<br>3. Continued therapy approval criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance…".<br>4. References were reviewed and updated. | 09/12/2020 | 12/07/2020 |