Clinical Policy Title:	mecamylamine
Policy Number:	RxA.540
Drug(s) Applied:	Vecamyl®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2021
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 orally twice a day. 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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		
lisinopril, enalapril, benazepril	Refer to the prescribing information	Refer to the prescribing information
Angiotensin II receptor blockers (ARBs)		
losartan, valsartan, candesartan	Refer to the prescribing information	Refer to the prescribing information
Thiazide diuretics		
hydrochlorothiazide	Refer to the prescribing information	Refer to the prescribing information
Calcium channel blockers		
amlodipine, diltiazem, verapamil	Refer to the prescribing information	Refer to the prescribing information
Beta blockers		
carvedilol, metoprolol	Refer to the prescribing information	Refer to the prescribing information
Alpha blockers		
prazosin, terazosin, doxazosin	Refer to the prescribing information	Refer to the prescribing information

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):

- Concomitant antibiotics or sulfonamides, coronary insufficiency, glaucoma, mild, moderate, labile 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 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 25, 2021.
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. Available at: https://jamanetwork.com/journals/jama/fullarticle/1791497 . Accessed September 25, 2021.
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. Available at: https://www.ahajournals.org/doi/10.1161/01.HYP.0000107251.49515.c2 . Accessed September 25, 2021.
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. Available at: https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1751-7176.2010.00360.x . Accessed September 25, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title was updated. 2. Lines of business policy applies to was updated to all lines of	09/12/2020	12/07/2020

business. 3. Continued therapy approval criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 4. References were reviewed and updated.		
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 3. Appendix C was updated to include Contraindications “labile” hypertension. 4. References were reviewed and updated.	09/25/2021	12/07/2021