Clinical Policy: Mecamylamine (Vecamyl)

Reference Number: ERX.NPA.112
Effective Date: 06.01.19
Last Review Date: 05.20
Line of Business: Commercial, 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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)* from different classes at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated.

Approval duration:
Medicaid – 6 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to ERX.PA.01 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 – ERX.PA.01 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 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 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.

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. Colorado Springs, Co: Nexgen Pharma; July 2018. Available at: www.vecamyl.com. Accessed February 13, 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.
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.
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	P&T Approval Date
Policy created	02.08.19	05.19
2Q 2020 annual review: no significant changes; references reviewed and updated.	02.13.19	05.20
2Q 2020 annual review: no significant changes; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	02.14.20	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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.