Clinical Policy: Mecamylamine (Vecamyl)
Reference Number: ERX.NPA.112
Effective Date: 06.01.19
Last Review Date: 05.19

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 contraindicated or clinically significant adverse effects are experienced.

   Approval duration: 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: 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.

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

The 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 β-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 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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>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.</td>
<td>Based on individual response</td>
</tr>
</tbody>
</table>

VI. Product Availability
Tablet: 2.5 mg

VII. References