

Clinical Pharmacy Program Guidelines for Vecamyl

Program	Prior Authorization
Medication	Vecamyl (mecamylamine)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	12/2013
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Vecamyl (mecamylamine) is indicated for the management of moderately severe to severe essential hypertension and uncomplicated cases of malignant hypertension. Vecamyl was originally approved under the brand name Inversine, which was launched in the 1950s. The product was withdrawn in September 2009, withdrawal was not due to safety concerns. As of March, 2013, the FDA issued an approval for mecamylamine to be re-marketed in the United States.

2. Coverage Criteria:

<p>A. <u>Initial Authorization</u></p> <p>1. Vecamyl will be approved based on <u>one</u> of the following criteria:</p> <p style="margin-left: 40px;">a. Diagnosis of moderately severe to severe essential hypertension</p> <p style="text-align: center; margin-left: 80px;">-OR-</p> <p style="margin-left: 40px;">b. Diagnosis of uncomplicated malignant hypertension</p> <p>Authorization will be issued for 12 months.</p> <p>B. <u>Reauthorization</u></p> <p>1. Vecamyl will be approved based on the following criterion:</p> <p style="margin-left: 40px;">a. Documentation of a positive clinical response to Vecamyl therapy</p> <p>Authorization will be issued for 12 months.</p>

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Vecamyl [package insert]. New York, NY: Vyera Pharmaceuticals, LLC; July 2018.
2. U.S. Food and Drug Administration website.
www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&AppNo=204054. Accessed April 29, 2020.

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Change Control	
12/2013	New Guideline for a non-preferred drug
2/2013	Removed Nicotine Dependence section
3/2013	Updated numbering in criteria. “2” changed to “1.2” to allow for proper decision flow.
12/2015	Annual Review
3/2016	Removed requirement for prior therapy with other antihypertensive agents Created new reauthorization criteria
4/2017	Annual review. Updated references and policy template.
5/2018	Annual review. Updated references.
6/2019	Annual review, updated references.
6/2020	Annual review. Added reference for mecamylamine history.