

## PRIOR AUTHORIZATION POLICY

**POLICY:** Vecamyl Prior Authorization Policy

- Vecamyl™ (mecamylamine hydrochloride tablets – Vyera)

**REVIEW DATE:** 05/25/2022

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### OVERVIEW

Vecamyl, a nicotinic parasympathetic ganglionic blocker, is indicated for the following uses:<sup>1</sup>

- **Moderately severe to severe essential hypertension.**
- **Uncomplicated malignant hypertension.**

### Guidelines

The clinical practice guidelines from the American College of Cardiology/American Heart Association Task Force (2017) state the prevalence of severe hypertension has been declining, but approximately 12.3% of US adults with hypertension have an average systolic blood pressure  $\geq 160$  mm Hg or average diastolic blood pressure  $\geq 100$  mm Hg.<sup>2</sup> Numerous classes of antihypertensive agents are available to treat high blood pressure. Vecamyl is not suggested as a primary or secondary agent in the treatment of hypertension. The Evidence-Based Guideline for the Management of High Blood Pressure in Adults from the panel members of the eighth joint national committee (2014 [JNC 8]) advises selection among four specific medication classes (thiazide-type diuretics, calcium channel blockers, angiotensin-converting enzyme inhibitors, or angiotensin receptor blockers) as initial and secondary choices in treatment.<sup>3</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vecamyl. All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vecamyl is recommended in those who meet one of the following criteria:

#### FDA-Approved Indications

- 1. Essential Hypertension, Moderately Severe to Severe.** Approve for 1 year if the patient meets the following criteria (A and B):
  - A)** Patient has tried four antihypertensive therapies, each from different pharmacologic classes (e.g., diuretics, calcium channel blockers, angiotensin-converting enzyme inhibitors, and angiotensin receptor blockers [as single-entity or as combination products]); **AND**
  - B)** Patient had at least one of the following from each of these agents (i or ii):
    - i.** Patient has had inadequate efficacy; **OR**
    - ii.** Patient has experienced adverse event(s) severe enough to warrant discontinuation of this agent, according to the prescriber.
- 2. Uncomplicated Malignant Hypertension.** Approve for 1 year if the patient meets the following criteria (A and B):

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- A) Patient has tried four antihypertensive therapies, each from different pharmacologic classes (e.g., diuretics, calcium channel blockers, angiotensin-converting enzyme inhibitors, and angiotensin receptor blockers [as single-entity or as combination products]); AND
- B) Patient had at least one of the following from each of these agents (i or ii):
  - i. Patient has had inadequate efficacy; OR
  - ii. Patient has experienced adverse event(s) severe enough to warrant discontinuation of this agent, according to the prescriber.

#### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Vecamyl is not recommended in the following situations:

1. **Tourette Syndrome.** Limited data are available to validate the use of mecamylamine in Tourette Syndrome. A clinical trial has shown mecamylamine to not be an effective treatment for tics or for the total spectrum of symptoms associated with Tourette Syndrome.<sup>4</sup>
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

#### **REFERENCES**

1. Vecamyl™ tablets [prescribing information]. New York, NY: Vyera; January 2021.
2. Whelton P, Carey R, Aronow W, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Hypertension*. 2018;71:e13-e115.
3. James P, Oparil S, Carter B, et al. 2014 evidence-based guideline for the management of high blood pressure in adults: report by the panel appointed to the Eighth Joint National Committee (JNC 8). *JAMA*. 2014;311:17:507-520.
4. Silver A, Shytle RD, Sheehan K, et al. Multicenter, double-blind, placebo-controlled study of mecamylamine monotherapy for Tourette's Disorder. *Journal of the American Academy of Child and Adolescent Psychiatry*. 2001;40:9: 1103-1110.