PRIOR AUTHORIZATION POLICY

POLICY: Vecamyl Prior Authorization Policy
- Vecamyl™ (mecamylamine hydrochloride tablets – Vyera)

REVIEW DATE: 07/03/2024

OVERVIEW

Vecamyl, a nicotinic parasympathetic ganglionic blocker, is indicated for the following uses:[1]
- **Moderately severe to severe essential hypertension**.
- **Uncomplicated malignant hypertension**.

Guidelines

The clinical practice guidelines from the American College of Cardiology (ACC)/American Heart Association (AHA) 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 ≥ 160 mm Hg or average diastolic blood pressure ≥ 100 mm Hg. 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 ACC/AHA guidelines advise 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.[2]

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 BOTH of the following (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)** For each of these agents, patient meets ONE of the following (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 BOTH of the following (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) For each of these agents, patient meets ONE of the following (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.[4]

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; November 2022.
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. Silver A, Shytle RD, Sheehan K, et al. Multicenter, double-blind, placebo-controlled study of mecamylamine monotherapy for Tourette's Disorder. *J Am Acad Child Adolesc Psychiatry. 2001:40:9: 1103-1110.*