PRIOR AUTHORIZATION POLICY

POLICY: Vecamyl™ (mecamylamine hydrochloride tablets – Vyera Pharmaceuticals)

DATE REVIEWED: 05/27/2020

OVERVIEW

Vecamyl is a nicotinic parasympathetic ganglionic blocker indicated for the management of moderately severe to severe essential hypertension and in uncomplicated cases of malignant hypertension.[1, 2] Vecamyl prevents stimulation of postsynaptic receptors by acetylcholine released from presynaptic nerve endings. The hypotensive effect of Vecamyl is attributed to reduction in sympathetic tone, vasodilation, and reduced cardiac output. Vecamyl is considered a nonselective antagonist that easily passes through the blood-brain barrier, and thus, having the potential to affect nicotinic acetylcholine receptors in the central nervous system.

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 ≥ 160 mm Hg or average diastolic blood pressure ≥ 100 mm Hg.[3] 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]) 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.[4]

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Vecamyl. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Vecamyl as well as the monitoring required for adverse events and long-term efficacy, approval requires Vecamyl to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vecamyl is recommended in those who meet 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):
   - **A)** The 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 has had at least one of the following from each of these agents (i or ii)
     - **i.** The patient has had inadequate efficacy; OR

ii. The 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):

A) The 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 has had at least one of the following from each of these agents (i or ii)

i. The patient has had inadequate efficacy; OR

ii. The patient has experienced adverse event(s) severe enough to warrant discontinuation of this agent, according to the prescriber.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Vecamyl has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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.[5]

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™ oral tablets [prescribing information]. New York, NY: Vyera Pharmaceuticals; October 2018.
2. Nickell J, Grinevich V, Siripurapu K, et al. Potential therapeutic uses of mecamylamine and its stereoisomers. *Pharmacology Biochemistry and Behavior*. 2013; 108:28-43.
3. 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.
4. 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.
5. 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*.