Drug Coverage Policy

Effective Date.....1/1/2025
Coverage Policy Number.....IP0650
Policy Title.....Vecamyl

Vecamyl for Individual and Family Plans

- Vecamyl™ (mecamylamine hydrochloride tablets – Vyera)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

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]

Medical Necessity Criteria

Vecamyl is considered medically necessary when the following is met:

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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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]

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.*

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Essential Hypertension, Moderately Severe to Severe.** **Added** '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])' **Added** '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.' **Uncomplicated Malignant Hypertension.** **Added** '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])' **Added** '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 Covered.** **Added** 'Tourette Syndrome'	1/1/2025

The policy effective date is in force until updated or retired.