



Drug Coverage Policy

Effective Date9/15/2025

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 where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

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

Coverage Policy

POLICY STATEMENT

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

Vecamyl is considered medically necessary when ONE of 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

Vecamyl for any other use is considered not medically necessary, 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 mecamlamine in Tourette Syndrome. A clinical trial has shown mecamlamine 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 mecamlamine 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 <u>or</u> 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 <u>or</u> 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.'	1/1/2025

	Conditions Not Covered. Added 'Tourette Syndrome'	
Annual Revision	No criteria changes	9/15/2025

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

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