# PRIOR AUTHORIZATION POLICY

**POLICY:** Cardiology – Camzyos Prior Authorization with Step Therapy Policy
- Camzyos® (mavacamten capsules – MyoKardia/Bristol Myers Squibb)

**REVIEW DATE:** 04/01/2026

***INSTRUCTIONS FOR USE***

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## CIGNA NATIONAL FORMULARY COVERAGE:

## OVERVIEW

Camzyos, a cardiac myosin inhibitor, is indicated for the **treatment of symptomatic New York Heart Association Class (NYHA) II to III obstructive hypertrophic cardiomyopathy (HCM)** in adults to improve functional capacity and symptoms.[1]

### Disease Overview

HCM is a complex, heterogeneous myocardial disorder characterized by thickening (hypertrophy) of the left ventricular wall without dilation and in the absence of another identifiable cardiac, systemic, or metabolic cause.[2-5] The condition is typically inherited in an autosomal dominant pattern and affects approximately 1 in 200 to 500 adults across all ethnic backgrounds, equally in men and women. Patients of any age can be impacted, though many remain undiagnosed or asymptomatic. Diagnosis is usually established by echocardiography or cardiac magnetic resonance imaging, which reveals a hypertrophied, nondilated left ventricle. The hypertrophied

ventricle becomes stiff, impairing diastolic filling and reducing stroke volume. In addition, the heart muscle may contract with excessive force, further compromising cardiac efficiency. Approximately 70% of patients have obstructive HCM, in which left ventricular outflow tract obstruction occurs due to systolic contact between the mitral valve and the ventricular septum. This obstruction forces the heart to generate higher pressures to maintain cardiac output. Cardiac hypercontractility, driven by excessive actin-myosin crossbridge formation within the sarcomere, further promotes obstruction and increases myocardial workload. Patients may experience exertional dyspnea, fatigue, chest pain, palpitations, lightheadedness, syncope, or exercise intolerance.[2] Many develop atrial fibrillation, ventricular arrhythmias, or heart failure, and sudden cardiac death can occur.

## Clinical Efficacy

EXPLORER-HCM was a randomized, double-blind, placebo-controlled, parallel-group trial evaluating Camzyos in over 250 patients with symptomatic NYHA Class II or III obstructive HCM.[1,2] Eligible patients had a left ventricular ejection fraction (LVEF) ≥ 55% and a left ventricular outflow tract (LVOT) peak gradient ≥ 50 mmHg at rest or with provocation, along with unexplained left ventricular hypertrophy (maximal wall thickness ≥ 15 mm, or ≥ 13 mm in those with familial HCM). Approximately 75% of patients were receiving beta-blockers and 17% were receiving calcium channel blockers (CCBs). The primary composite endpoint at 30 weeks assessed functional improvement based on peak oxygen consumption ($pVO_2$) and NYHA class; a significantly greater proportion of patients receiving Camzyos met this endpoint compared with placebo (37% vs 17%; P = 0.0005). Camzyos also demonstrated greater improvements in secondary endpoints, including LVOT obstruction, functional capacity, health status, and biomarkers, as measured by post-exercise LVOT gradient, $pVO_2$, NYHA class, Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-23) Clinical Summary Score, Hypertrophic Cardiomyopathy Symptoms Questionnaire (HCMSQ) Shortness of Breath domain score, and reductions in N-terminal pro B-type natriuretic peptide and high-sensitivity cardiac troponin I.[1,2] Other data are also available.[6]

## Guidelines

The American Heart Association and American College of Cardiology, alongside other organizations, published updated guidelines for the diagnosis and treatment of patients with HCM in 2024.[7] For symptomatic patients with obstructive HCM attributable to LVOT obstruction, non-vasodilating beta-blockers are recommended to be titrated to effectiveness or maximally tolerated doses. In patients for whom beta-blockers are not effective or not tolerated, substitution with nondihydropyridine CCBs (e.g., verapamil, diltiazem) is recommended. If patients continue to have severe symptoms despite treatment with beta-blockers and/or nondihydropyridine CCBs, adding a myosin inhibitor (i.e., Camzyos) or disopyramide (in combination with an atrioventricular nodal blocking agent), or septal reduction performed at experienced centers is recommended. The guidelines note that Camzyos is only for use in adults. Camzyos is also contraindicated in pregnant patients due to potential teratogenic effects.

## Safety

Camzyos has a Boxed Warning regarding the risk of heart failure.[1] The agent may cause heart failure due to systolic dysfunction. Echocardiogram assessment of LVEF is required before and during Camzyos use. Initiation in patients with a LVEF < 55% is not recommended. Therapy should be interrupted if LVEF is < 50% or if worsening clinical status occurs. Certain cytochrome P450 inhibitors and inducers are contraindicated in patients receiving Camzyos due to an increased risk of heart failure. Camzyos is available only through a restricted program called the Camzyos Risk Evaluation and Mitigation Strategy (REMS) program. Notable requirements include the following:

- Prescribers must be certified by enrolling in the Camzyos REMS program.
- Patients must enroll in the Camzyos REMS program and comply with ongoing monitoring requirements.
- Pharmacies must be certified by enrolling in the Camzyos REMS program and must only dispense to patients who are authorized to receive Camzyos.
- Wholesalers and distributors must only distribute the medication to certified pharmacies.

## POLICY STATEMENT

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

- **Camzyos® (mavacamten capsules - MyoKardia/Bristol Myers Squibb) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

### FDA-Approved Indication

1. **Obstructive Hypertrophic Cardiomyopathy.** Approve for the duration noted below if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets BOTH of the following (a and b):
       - **a)** Patient has at least one symptom associated with obstructive hypertrophic cardiomyopathy; AND
         Note: Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise.
       - **b)** Patient has New York Heart Association Class II or III symptoms of heart failure; AND
     - **iii.** Patient with left ventricular hypertrophy meets ONE of the following (a or b):
       - **a)** Patient has maximal left ventricular wall thickness ≥ 15 mm; OR

**b)** Patient has familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness ≥ 13 mm; AND

**iv.** Patient has a peak left ventricular outflow tract gradient ≥ 30 mmHg at rest or ≥ 50 mmHg after provocation (Valsalva maneuver or post exercise); AND

**v.** Patient has a left ventricular ejection fraction of ≥ 55%; AND

**vi.** Patient meets ONE of the following (a or b):

**a)** Patient has tried or is currently receiving at least one beta-blocker or nondihydropyridine calcium channel blocker for at least 3 months; OR
Note: Examples of beta-blockers include metoprolol, atenolol, and bisoprolol. Examples of nondihydropyridine calcium channel blockers include verapamil and diltiazem.

**b)** According to the prescriber, the patient has a contraindication or intolerance to a beta-blocker or nondihydropyridine calcium channel blocker; AND
Note: Examples of contraindications to beta-blockers include bradycardia, severe hypotension, severe reactive airway disease or active bronchospasms. Examples of intolerances to beta-blockers include symptomatic fatigue or exercise intolerance, symptomatic bradycardia, and hypotension. Examples of contraindications to calcium channel blockers include bradycardia and hypotension. Examples of intolerances to calcium channel blockers include peripheral edema and dizziness or orthostasis.

**vii.** The medication is prescribed by a cardiologist; OR

**B)** Patient Currently Receiving Camzyos. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, and v):

**i.** Patient has been established on therapy for at least 1 year; AND
Note: A patient who has received < 1 year of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).

**ii.** Patient is ≥ 18 years of age; AND

**iii.** Patient meets BOTH of the following (a and b):

**a)** Currently or prior to starting therapy, patient has or has experienced at least one symptom associated with obstructive hypertrophic cardiomyopathy; AND
Note: Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise.

**b)** Currently or prior to starting therapy, patient is in or was in New York Heart Association Class II or III heart failure; AND

**iv.** Patient meets ONE of the following (a or b):

**a)** Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
Note: Examples include improved peak oxygen consumption/mixed venous oxygen tension; decreases in left ventricular outflow tract gradient; reductions in N-terminal pro-B-type natriuretic peptide levels; decreased high-sensitivity cardiac troponin I levels; reduced ventricular mass index; and/or a reduction in maximum left atrial volume index.

**b)** Patient experienced stabilization or improvement in at least one symptom related to obstructive hypertrophic cardiomyopathy; AND
Note: Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, ability to perform physical exercise, and/or favorable changes in the Kansas City Cardiomyopathy Questionnaire-23 (KCCQ-23) Clinical Summary Score (CSS) or Hypertrophic Cardiomyopathy Symptom Questionnaire (HCMSQ) Shortness of Breath domain scores.

**v.** The medication is prescribed by a cardiologist.

## CONDITIONS NOT COVERED

- **Camzyos® (mavacamten capsules - MyoKardia/Bristol Myers Squibb) is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.**

## REFERENCES


1. Camzyos® capsules [prescribing information]. Princeton, NJ: MyoKardia/Bristol Myers Squibb; April 2025.
2. Olivotto I, Oreziak A, Barriales-Villa R, et al, for the EXPLORER-HCM study investigators. Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomized, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2020;396(10253):759-769.
3. Maron BJ. Clinical course and management of hypertrophic cardiomyopathy. *N Engl J Med*. 2018;379(7):655-668.
4. Ommen SR, Semsarian C. Hypertrophic cardiomyopathy: a practical approach to guideline directed management. *Lancet*. 2021;398(10316):2102-2108.
5. Burstein Waldman CY, Owens A. A plain language summary of the EXPLORER-HCM study: mavacamten for obstructive hypertrophic cardiomyopathy. *Future Cardiol*. 2021;17(7):1269-1275.
6. Keam SJ. Mavacamten: first approval. *Drugs*. 2022;82:1127-1135.
7. Ommen SR, Ho CY, Asif IM, et al. 2024 AHA/ACC/AMSSM/HRS/PACES/SCMR guideline for the management of hypertrophic cardiomyopathy: a report of the American Heart Association/American College of Cardiology joint committee on clinical practice guidelines. *Circulation*. 2024;149(23): e1239-1311.
8. Mital S, Burke MA, et al. 2020 AHA/ACC guideline for the diagnosis and treatment of patients with hypertrophic cardiomyopathy. *J Am Coll Cardiol*. 2020;76(25):e159-240.


## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | No criteria changes. | 06/05/2024 |
| Annual Revision | No criteria changes. | 06/11/2025 |
| Update | Updated guidelines in the Overview section. | 07/15/2025 |
| Selected Revision | **Obstructive Hypertrophic Cardiomyopathy**. The specialist requirement was clarified to state the medication could be prescribed in consultation with a cardiologist. | 12/30/2025 |
| Selected Revision | **Obstructive Hypertrophic Cardiomyopathy**. The approval duration for initial therapy was changed to 1 year. Previously, it was 8 months. The Note defining Class II and Class III heart failure was removed. The requirement for a peak left ventricular outflow | 01/14/2026 |

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| | tract gradient was changed to ≥ 30 mmHg at rest and ≥ 50 mmHg after provocation (Valsalva maneuver or post exercise). For patients currently receiving Camzyos, the requirement regarding patients being established on therapy for at least 8 months was changed to at least 1 year. The specialist requirement was updated to only allow a cardiologist to prescribe the medication; previously, consultation with a cardiologist was allowed. | |
| Selected Revision | **Obstructive Hypertrophic Cardiomyopathy.** The requirement for ejection fraction to be ≥ 50% for patients currently receiving Camzyos was removed. The Note defining Class II and Class III heart failure symptoms was also removed. | 03/11/2026 |

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Early Annual Revision | The policy name was changed to as listed. Previously, it was Cardiology – Camzyos Prior Authorization Policy.<br>**Obstructive Hypertrophic Cardiomyopathy**. For initial treatment, a requirement was added that a patient has tried or is currently receiving at least one beta-blocker or nondihydropyridine calcium channel blocker for at least 3 months, or, according to the prescriber, the patient has a contraindication or intolerance to a beta-blocker or nondihydropyridine calcium channel blocker. A Note of Examples of beta-blockers and nondihydropyridine calcium channel blockers was added. Another Note of Examples of contraindications and intolerances was added. | 04/01/2026 |