

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Camzyos (mavacamten)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home/Outpatient
STATUS	Prior Authorization Required

Camzyos is a cardiac myosin inhibitor initially approved by the FDA in 2022. It is indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms. Hypertrophic cardiomyopathy is the most common inherited cardiovascular disorder, affecting approximately 1 in 500 individuals worldwide. About two-thirds of patients with HCM are diagnosed with oHCM. Camzyos is the first FDA-approved cardiac myosin inhibitor that targets the underlying pathophysiology of oHCM.

Camzyos' approval is supported by results from the Phase 3 EXPLORER-HCM trial, which enrolled 251 adult participants with symptomatic oHCM. In the trial, significantly more patients who received mavacamten met the primary endpoint, defined by gains in peak oxygen consumption (pV02) and improvement or stabilization of NYHA functional class, compared with those treated with placebo.

Camzyos (mavacamten) will be considered for coverage when the following criteria are met:

Hypertrophic Cardiomyopathy (HCM)

For **initial** authorization:

1. Member is at least 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a cardiologist; AND
3. Member has a diagnosis of obstructive hypertrophic cardiomyopathy, confirmed by echocardiography (EKG) or cardiac magnetic resonance imaging (MRI); AND
4. Member has documentation of New York Heart Association (NYHA) class II-III symptoms; AND
5. Member has a left ventricular ejection fraction (LVEF) \geq 55%; AND
6. Member has a left ventricular outflow tract gradient \geq 50 mmHg; AND
7. Member has a trial and failure of beta-blockers (i.e. metoprolol, carvedilol) or non-dihydropyridine calcium channel blockers (i.e. verapamil, diltiazem); AND
8. Member is not currently taking disopyramide, ranolazine, verapamil with a beta blocker, or diltiazem with a beta blocker.
9. **Dosage allowed/Quantity limit:** Initiate 5 mg once daily. Maintenance dosage must be individualized based on clinical status and echocardiographic assessment of patient response. See package insert for dosing information. Quantity Limit: 30 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease (i.e. reduction of symptoms, improvement in mixed pVO₂ or NYHA classification improvement).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Camzyos (mavacamten) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/17/2022	New policy for Camzyos created.

References:

1. Camzyos [Prescribing Information]. Brisbane, CA: MyoKardia, Inc.; April 2022.
2. Olivotto I, Oreziak A, Barriaes-Villa R, et al. Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2020;396(10253):759-769.
3. Ho CY, Olivotto I, Jacoby D, et al. Study design and rationale of EXPLORER-HCM: evaluation of mavacamten in adults with symptomatic obstructive hypertrophic cardiomyopathy. Circ: Heart Failure. 2020;13(6).
4. Rader F, Choudhury L, Saberi S, et al. Long-term safety of Mavacamten in patients with obstructive hypertrophic cardiomyopathy: interim results of the MAVA-long term extension (LTE) study. J Am Coll Cardiol. 2021;77(18):532.
5. Ommen SR, Mital S, Burke MA, et al. 2020 AHA/ACC guideline for the diagnosis and treatment of patients with hypertrophic cardiomyopathy: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2020;76:e159–240.

Effective date: 01/01/2023

Revised date: 06/17/2022