



## PHARMACY POLICY STATEMENT North Carolina 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
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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.

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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 with3.6 (en )0.6 (f3297-(av)4 (ac)-17(f3297 ()1.7 (t)9.fd0329f)3.5 (er)4.6 (en)6.1 (c)-1.9 (e)6.1 (s)-2 (:))1.7 (av) Tw 0.