Pharmacy Policy Bulletin

Title:	Mavacamten (Camzyos™)
Policy #:	Rx.01.265

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for Mavacamten (Camzyos™) as provided under the member's prescription drug benefit.

Description:

Hypertrophic cardiomyopathy (HCM) is a common inherited cardiovascular disease characterized by hypertrophy of a nondilated left ventricle in the absence of any other cardiac or systemic disease (such as hypertension) that could account for observed hypertrophy, microvascular dysfunction and myocardial fibrosis. Histopathological features include myofiber disarray and myocardial fibrosis resulting from microvascular ischemia and cell death. HCM is caused largely by mutations in genes encoding thick and thin contractile myofilament proteins of the cardiac sarcomere. Phenotypically, HCM can be obstructive (70% of patients), with presence of left ventricular outflow tract obstruction, or nonobstructive (30% of patients). Complications include syncope, heart failure, and sudden death.

Mavacamten is an allosteric and reversible inhibitor selective for cardiac myosin. Mavacamten modulates the number of myosin heads that can enter “on actin” (power-generating) states, thus reducing the probability of force-producing (systolic) and residual (diastolic) cross-bridge formation. Excess myosin actin cross-bridge formation and dysregulation of the super-relaxed state are mechanistic hallmarks of HCM. Mavacamten shifts the overall myosin population towards an energy-sparing, recruitable, super-relaxed state. In HCM patients, myosin inhibition with mavacamten reduces dynamic left ventricular outflow tract (LVOT) obstruction and improves cardiac filling pressures.

Mavacamten is indicated for treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

Policy:

INITIAL CRITERIA Mavacamten (Camzyos™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM); and
2. Members is 18 years of age or older; and
3. Member’s baseline left ventricular ejection fraction (LVEF) is greater than or equal to 55%; and
4. Member has Valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation; and
5. Inadequate response or inability to tolerate BOTH of the following at a maximally tolerated dose:
    a. Non-vasodilating beta blocker (e.g., bisoprolol, propranolol); and
    b. Calcium channel blocker (e.g., verapamil, diltiazem); and
6. Prescribed by or in consultation with a cardiologist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Mavacamten (Camzyos™) is re-approved when ALL of the following are met:

1. Documentation of improvement in functional capacity and symptoms; and
2. Member's left ventricular ejection fraction (LVEF) is greater than or equal to 50%; and
3. Member does not have worsening heart failure symptoms; and
4. Prescribed by or in consultation with a cardiologist.

Reauthorization duration: 12 months

Black Box Warning as shown in the drug Prescribing Information:

Risk of Heart Failure

- CAMZYOS can cause heart failure due to systolic dysfunction.
- Echocardiogram assessments of left ventricular ejection fraction (LVEF) required before and during CAMZYOS use.
- Initiation in patients with LVEF <55% not recommended. Interrupt if LVEF <50% or if worsening clinical status.
- Certain CYP450 inhibitors and inducers are contraindicated in patients taking CAMZYOS because of an increased risk of heart failure.

CAMZYOS is available only through a restricted program called the CAMZYOS REMS Program.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

DynaMed. Hypertrophic Cardiomyopathy. EBSCO Information Services. Accessed October 19, 2022. https://www.dynamed.com/condition/hypertrophic-cardiomyopathy.

Camzyos™ (mavacamten) [prescribing information]. Brisbane, CA: MyoKardia, Inc.; May 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214998s000lbl.pdf. Accessed October 19, 2022.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Camzyos™	Mavacamten

Cross References:

Rx.01.33 Off Label Use

Rx.01.76 Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit

Policy Version Number:	2.00
P&T Approval Date:	September 15, 2022
Policy Effective Date:	January 01, 2023

Next Required Review Date: June 09, 2023