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Section: Prescription Drugs Effective Date: October 1, 2025

Subsection: Cardiovascular Agent Original Policy Date: May 27, 2022

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Last Review Date: September 19, 2025

Camzyos

Description

Camzyos (mavacamten)

Background

Camzyos (mavacamten) is an allosteric and reversible inhibitor selective for cardiac myosin. Camzyos 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 hypertrophic cardiomyopathy (HCM). Camzyos shifts the overall myosin population towards and energy-sparing, recruitable, super-relaxed state. In HCM patients, myosin inhibition with Camzyos reduces dynamic left ventricular outflow tract (LVOT) obstruction and improves cardiac filing pressures (1).

Regulatory Status

FDA-approved indication: Camzyos is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms (1).

Camzyos has a boxed warning regarding risk of heart failure. Camzyos reduces left ventricular ejection fraction (LVEF) and can cause heart failure due to systolic dysfunction. Echocardiogram assessments of LVEF are required prior to and during treatment with Camzyos. Initiation of Camzyos in patients with LVEF <55% is not recommended. Concomitant use of Camzyos with certain cytochrome P450 inhibitors or discontinuation of certain cytochrome P450 inducers may increase the risk of heart failure due to systolic dysfunction; therefore, the use of Camzyos is contraindicated with the following:

Strong CYP2C19 inhibitors

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• Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers Because of the risk of heart failure due to systolic dysfunction, Camzyos is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called Camzyos REMS Program (1).

Regular LVEF and Valsalva left ventricular outflow tract (LVOT) gradient assessment is required for careful titration to achieve an appropriate target Valsalva LVOT gradient, while maintaining LVEF ≥50% and avoiding heart failure symptoms (1).

Camzyos also contains a warning for embryo-fetal toxicity. Camzyos may cause fetal toxicity when administered to a pregnant female. Confirm absence of pregnancy in females of reproductive potential prior to treatment and advise patients to use effective contraception during treatment with Camzyos and for 4 months after the last dose. Camzyos may reduce the effectiveness of some combined hormonal contraceptives (CHCs). Advise patients using those CHCs to use an alternative method that is not affected by CYP450 enzyme induction or to add nonhormonal contraception (1).

The safety and effectiveness of Camzyos in pediatric patients less than 18 year of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Camzyos may be considered **medically necessary** if the conditions indicated below are met.

Camzyos may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

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Obstructive hypertrophic cardiomyopathy (HCM)

AND ALL of the following:

- 1. NYHA activity class II III
- 2. Inadequate treatment response, intolerance, or contraindication to a beta blocker or a calcium channel blocker
- 3. Prescribed by or recommended by a cardiologist
- 4. Left ventricular ejection fraction (LVEF) ≥ 55%
- 5. Prescriber agrees to monitor echocardiogram, EKG, LVEF, and Valsalva left ventricular outflow tract (LVOT) gradient during treatment with Camzyos
- Prescriber agrees to monitor for and counsel patient regarding CYP450 drug interactions with Camzyos
- 7. Patient and prescriber are enrolled in the Camzyos REMS Program
- 8. Females of reproductive potential **only**: absence of pregnancy has been confirmed and patient will be advised to use effective contraception during treatment with Camzyos and for 4 months after the last dose

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Obstructive hypertrophic cardiomyopathy (HCM)

AND ALL of the following:

- 1. Symptoms have improved or stabilized
- 2. Prescriber agrees to monitor echocardiogram, EKG, LVEF, and Valsalva left ventricular outflow tract (LVOT) gradient during treatment with Camzyos
- 3. Prescriber agrees to interrupt treatment with Camzyos if LVEF <50%
- 4. Prescriber agrees to monitor for and counsel patient regarding CYP450 drug interactions with Camzyos
- 5. Patient and prescriber are enrolled in the Camzyos REMS Program
- Females of reproductive potential only: patient will be advised to use effective contraception during treatment with Camzyos and for 4 months after the last dose

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Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 90 capsules per 90 days

Duration 12 months

Prior - Approval Renewal Limits

Same as above

Rationale

Summary

Camzyos (mavacamten) is an allosteric and reversible inhibitor selective for cardiac myosin and is indicated for the treatment of adults with symptomatic NYHA class II-III obstructive hypertrophic cardiomyopathy (HCM). Camzyos contains a boxed warning regarding the risk of heart failure. Camzyos is only available through the Camzyos REMS Program. The safety and effectiveness of Camzyos in pediatric patients less than 18 year of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Camzyos while maintaining optimal therapeutic outcomes.

References

1. Camzyos [package insert]. Brisbane, CA: Bristol Myers Squibb; April 2025.

Policy History

Date	Action
May 2022	Addition to PA

June 2022 Annual review and reference update

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August 2022 Per FEP: addition of requirement of "inadequate treatment response,

intolerance, or contraindication to beta blockers or calcium channel

blockers"

September 2022 Annual review. Per SME, addition of requirements to monitor EKG and

mavacamten concentration

March 2023 Annual review and reference update
March 2024 Annual review and reference update
March 2025 Annual review and reference update

August 2025 Per PI update, modified boxed warning statement in regulatory status. Per

reconsideration review, removed requirement to monitor Camzyos

concentration

September 2025 Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.