BlueCross BlueShield Federal Employee Program

CAMZYOS
(mavacamten)

RATIONALE FOR INCLUSION IN PA PROGRAM

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:

- Moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors
- 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).

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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 combine hormonal contraceptives (CHCs). Advise patients using 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).

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 2024.