

Mavacamten (CAMZYOS)

Criteria for Use

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VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to the following is met, then the patient should NOT receive mavacamten.

- Left ventricular ejection fraction (e.g., per echocardiogram) < 55%
- Concomitant moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors
- Concomitant moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers
- Concomitant use with disopyramide or ranolazine

Inclusion Criteria

All of the following criteria must be met.

- Care is provided by a VA / VA Community Care cardiologist or locally designated expert in managing obstructive hypertrophic cardiomyopathy
- Diagnosis of obstructive hypertrophic cardiomyopathy ^1 with New York Heart Association (NYHA) class II-III symptoms
- Peak left ventricular outflow tract gradient at least 50 mm Hg at rest, after Valsalva maneuver, or post-exercise
- Inadequate benefit from or unable to use a non-vasodilating beta-blocker (e.g., bisoprolol, metoprolol, propranolol)
- Inadequate benefit from or unable to use a non-dihydropyridine calcium channel blocker (e.g., verapamil, diltiazem) ^2
- Patient and provider are enrolled in the CAMZYOS REMS program

Additional Inclusion Criteria *(Select if applicable)*

- For patients who can become pregnant: Pregnancy excluded prior to receiving mavacamten
- For patients who can become pregnant: Counseling provided on potential risks vs. benefits of treatment and the use of effective contraception ^3 during therapy and for 4 months after stopping treatment

1. Clinical trial inclusion criteria: unexplained left ventricular hypertrophy with maximal left ventricular wall thickness of \geq 15 mm (or \geq 13 mm if familial hypertrophic cardiomyopathy).
2. Recommended if inadequate benefit from or unable to use a non-vasodilating beta-blocker. Note: if current treatment includes a nondihydropyridine calcium channel blocker and a beta-blocker, it is recommended to discontinue one of these agents before initiating mavacamten.
3. Mavacamten may reduce the effectiveness of combined hormonal contraceptives. Advise patients using combined hormonal contraceptives to use an alternative contraceptive method not affected by CYP450 enzyme induction or to add nonhormonal contraception.

Supplemental Information

Refer to CAMZYOS REMS Drug Interaction and Counseling Checklist for Pharmacies

Examples of Drugs Contraindicated with Mavacamten (CAMZYOS)* – DO NOT DISPENSE CAMZYOS
<p>Moderate to Strong CYP2C19 Inhibitors: esomeprazole, fluconazole, fluoxetine, fluvoxamine, omeprazole (40 mg once daily), voriconazole</p> <p>Strong CYP3A4 Inhibitors: boceprevir, clarithromycin, cobicistat, grapefruit juice, idelalisib, itraconazole, ketoconazole, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, troleandomycin</p> <p>Moderate to Strong CYP2C19 Inducers or Moderate to Strong CYP3A4 Inducers: apalutamide, carbamazepine, efavirenz, enzalutamide, etravirine, fosphenytoin, mitotane, nafcillin, phenobarbital, phenytoin, primidone, rifampin, ritonavir, St. John’s wort</p>
Examples of Drugs that Interact with Mavacamten (CAMZYOS)* (Dose of CAMZYOS Must Be Adjusted)
<p>Weak CYP2C19 Inhibitors or Moderate CYP3A4 Inhibitors: cimetidine, ciprofloxacin, diltiazem, dronedarone, erythromycin, felbamate, isoniazid, omeprazole (20 mg once daily), verapamil</p>

*Select examples, not a comprehensive list