09-J4000-31

Original Effective Date: 10/01/22

Reviewed: 07/10/24

Revised: 08/15/24

Subject: Mavacamten (Camzyos®) Capsule

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Mavacamten (Camzyos) is a first-in-class oral cardiac myosin inhibitor that was approved by the U.S. Food and Drug Administration (FDA) in April 2022 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. Mavacamten is the first disease-specific treatment for HCM. Hypertrophic cardiomyopathy (HCM) is a genetic heart disease in which the heart muscle wall thickens and stiffens making it more difficult for the heart to expand normally thus reducing the amount of blood the left ventricle can hold and pump. The current 2024 HCM guidelines from the AHA/ACC/AMSSM/HRS/PACES/SCMR state that a HCM diagnosis in adults is made with 2D echocardiography or cardiovascular magnetic resonance (CMR) showing a maximal end-diastolic wall thickness of ≥15 mm anywhere in the left ventricle, in the absence of another cause of hypertrophy. However, more limited hypertrophy (13 to 14 mm) can be diagnostic when present in family members of a patient with HCM or in conjunction with a positive genetic test. In many people with HCM, the thickened heart muscle wall can narrow the path for blood flow out of the heart and restrict blood flow to the rest of the body [i.e., left ventricular outflow tract (LVOT) obstruction]. The heart must pump harder to move blood through the narrowed pathway. This type of HCM is called obstructive HCM. Common symptoms of HCM include shortness of breath, tiredness, palpitations, chest pain, feeling light-headed, fainting, and fatigue or exercise intolerance. The prevalence of unexplained asymptomatic hypertrophy in young adults in the United States has been reported to range from 1:200 to 1:500. Symptomatic hypertrophy based on medical claims data has been estimated at less than 1:3000 adults in the United States; however, the true burden is much higher when unrecognized disease in the general population is considered. Clinical evaluation for HCM may be triggered by occurrence of symptoms, a cardiac event, detection of a heart murmur, an abnormal 12-lead EKG identified on routine examinations, or through cardiac imaging during family screening studies. Mavacamten modulates the

number of myosin heads that can enter “on actin” (power-generating) states, thus reducing the probability of cross-bridge formation. HCM is caused by too many cross-bridges between actin and myosin. In HCM patients, myosin inhibition with mavacamten reduces dynamic LVOT obstruction and improves cardiac filling pressures. The 2024 HCM guidelines include a statement that for patients with obstructive HCM who have persistent symptoms attributable to LVOT obstruction despite beta blockers or non-dihydropyridine calcium channel blockers, adding a myosin inhibitor (adult patients only), or disopyramide (in combination with an atrioventricular nodal blocking agent), or septal reduction therapy (SRT) performed at experienced centers, is recommended (class 1 recommendation).

The efficacy of mavacamten leading to FDA approval was evaluated in EXPLORER-HCM (NCT03470545) a Phase 3, double-blind, randomized, placebo-controlled, multicenter, international, parallel-group trial in 251 adults with symptomatic NYHA class II and III obstructive HCM, LVEF ≥55%, and Valsalva LVOT peak gradient ≥50 mmHg at rest or with provocation. Patients on dual therapy with beta blocker and calcium channel blocker treatment or monotherapy with disopyramide or ranolazine were excluded. Patients with a known infiltrative or storage disorder causing cardiac hypertrophy that mimicked obstructive HCM, such as Fabry disease, amyloidosis, or Noonan syndrome with left ventricular hypertrophy, were also excluded. Patients were randomized in a 1:1 ratio to receive either a starting dose of mavacamten 5 mg of or placebo once daily for 30 weeks. Treatment assignment was stratified by baseline disease severity NYHA functional class, baseline use of beta blockers, and type of ergometer (treadmill or exercise bicycle). Groups were well matched with respect to age (mean 59 years), BMI (mean 30 kg/m2), heart rate (mean 62 bpm), blood pressure (mean 128/76 mmHg), and race (90% Caucasian). Males comprised 54% of the mavacamten group and 65% of the placebo group. At baseline, approximately 73% of the randomized patients were NYHA class II and 27% were NYHA class III. The mean LVEF was 74%, and the mean Valsalva LVOT gradient was 73 mmHg. About 10% had prior septal reduction therapy, 75% were on beta blockers, 17% were on calcium channel blockers, and 14% had a history of atrial fibrillation. All patients were initiated on mavacamten 5 mg (or matching placebo) once daily, and the dose was periodically adjusted to optimize patient response (decrease in LVOT gradient with Valsalva maneuver) and maintain LVEF ≥50%. In the mavacamten group, at the end of treatment, 49% of patients were receiving the 5-mg dose, 33% were receiving the 10-mg dose, and 11% were receiving the 15-mg dose. Three patients temporarily interrupted their dose due to LVEF <50%, of whom two resumed treatment at the same dose and one had the dose reduced from 10 mg to 5 mg.

The primary composite functional endpoint, assessed at 30 weeks, was defined as the proportion of patients who achieved either improvement of mixed peak oxygen consumption (pVO2) by ≥1.5 mL/kg/min plus improvement in NYHA class by at least 1, or improvement of pVO2 by ≥3.0 mL/kg/min plus no worsening in NYHA class. The outcome was achieved in significantly more patients with mavacamten compared with placebo (37% vs. 17%; p=0.0005). Mavacamten was associated with significant improvement in the components of the outcome: 1.5 mL/kg/min or greater increase in pVO2 with at least 1 NYHA class reduction (33% vs. 14%), 3 mL/kg/min or greater increase in pVO2 with no worsening of NYHA class (24% vs. 11%), and 3 mL/kg/min or greater increase in pVO2 with at least 1 NYHA class reduction (20% vs. 8%). The benefit of mavacamten was smaller in patients on background beta blocker therapy compared to those who were not (attenuated improvement in pVO2), but analyses of other secondary endpoints (symptoms, LVOT gradient) suggest that patients might benefit from mavacamten treatment regardless of beta blocker use. In terms of secondary outcomes, mavacamten was associated with significant improvements from baseline to week 30 in mean post-exercise LVOT

gradient change (-47 vs. -10 mm Hg), mean pVO2 change (1.4 vs -0.1 mL/kg/min), at least 1 NYHA class reduction (65% vs 31%), change in Kansas City Cardiomyopathy Questionnaire-Clinical Symptom Score (13.6 vs. 4.2 [positive change better]), and change in Hypertrophic Cardiomyopathy Symptom Questionnaire Shortness-of-Breath subscore (-2.8 vs. -0.9 [negative change better]). Serious adverse events were reported in 8% with mavacamten and 9% with placebo and included atrial fibrillation (AF) (2% vs 3%), syncope (2% vs 1%), and stress cardiomyopathy (2% vs 0%). No serious events of heart failure occurred with mavacamten.

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

Initiation of mavacamten (Camzyos) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1" to "9"):

1. Member has a diagnosis of obstructive hypertrophic cardiomyopathy (HCM) as confirmed by **BOTH** of the following ("a" and "b") – *documentation from the member's medical record must be submitted*:
    a. **EITHER** of the following ("i" or "ii"):
        i. Maximal end-diastolic left ventricular wall thickness of greater than or equal to 15 mm
        ii. Maximal end-diastolic left ventricular wall thickness of 13 to 14 mm in members with family history of HCM or in conjunction with a positive genetic test (for example, MYH7, MYBPC3, TNNI3*, TNNT2, TPM1, MYL2, MYL3, ACTC1* gene variants)
    b. A baseline (within the past 6 months) left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg [at rest or after provocation (Valsalva maneuver or post exercise)]
2. Member has New York Heart Association (NYHA) class II or III symptoms, **AND** mavacamten is being used to improve functional capacity and symptoms – *documentation of the NYHA class from the member's medical record must be submitted*
3. Member has a baseline (within the past 6 months) left ventricular ejection fraction (LVEF) of greater than or equal to 55% - *documentation from the member's medical record must be submitted*
4. **EITHER** of the following ("a" or "b"):
    a. Member has had an inadequate response to treatment with **EITHER** a beta-blocker **OR** a non-dihydropyridine calcium channel blocker (diltiazem or verapamil)
    b. Member has intolerance(s), FDA-labeled contraindication(s), and/or is otherwise not an appropriate candidate for treatment with **BOTH** a beta-blocker **AND** a non-dihydropyridine calcium channel blocker (diltiazem or verapamil) – *the specific intolerance(s), FDA-labeled contraindication(s), and/or reason(s) for not being an appropriate candidate must be provided*

5. Mavacamten is being prescribed by a cardiologist or other specialist with experience in the management of HCM
6. The prescriber is enrolled in the CAMZYOS REMS Program, and will comply with all necessary echocardiogram assessments
7. Mavacamten will **NOT** be used in combination with **ANY** of the following:
    a. Disopyramide
    b. Ranolazine
    c. Diltiazem in combination with a beta blocker
    d. Verapamil in combination with a beta blocker
    e. Moderate to strong CYP2C19 inhibitors (including but not limited to fluconazole, fluoxetine, fluvoxamine, felbamate)
    f. Strong CYP3A4 inhibitors (including but not limited to clarithromycin, ketoconazole, itraconazole, ritonavir, nelfinavir, nefazodone)
    g. Moderate to strong CYP2C19 inducers (including but not limited to rifampin, efavirenz, phenytoin)
    h. Moderate to strong CYP3A4 inducers (including but not limited to carbamazepine, phenytoin, rifampin, St. John's wort, bosentan, efavirenz, phenobarbital)
8. The member is 18 years of age or older
9. Member will be initiated at a maximum dosage of 5 mg once daily, **AND** the maximum dosage after titration will not exceed 15 mg once daily [maximum quantity limit is one capsule across all strengths per day, for example the use of 7.5 mg (5 mg + 2.5 mg) is not permitted]

Approval duration: 12 months

Continuation of mavacamten (Camzyos) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1" to "7"):

1. An authorization or reauthorization for mavacamten (Camzyos) has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of obstructive hypertrophic cardiomyopathy (if another health plan, documentation of a health plan-paid claim for Camzyos during the 90 days immediately before the authorization request must be submitted), **OR** the member has previously met **ALL** indication-specific criteria (with the exception of requirements #2, #3, and #4)
2. Member has achieved, or is maintaining, a positive clinical response to mavacamten therapy [for example, NYHA class reduction, an increase in mixed venous oxygen tension (pVO2), or improvement in post-exercise left ventricular outflow tract [LVOT] gradient)
3. Member's most recent LVEF (must be within the 6 months) is greater than or equal to 50% - *documentation from the member's medical record must be submitted*
4. Mavacamten is being prescribed by a cardiologist or other specialist with experience in the management of HCM

5. The prescriber is enrolled in the CAMZYOS REMS Program, and will comply with all necessary echocardiogram assessments
6. Mavacamten will **NOT** be used in combination with **ANY** of the following:
    a. Disopyramide
    b. Ranolazine
    c. Diltiazem in combination with a beta blocker
    d. Verapamil in combination with a beta blocker
    e. Moderate to strong CYP2C19 inhibitors (including but not limited to fluconazole, fluoxetine, fluvoxamine, felbamate)
    f. Strong CYP3A4 inhibitors (including but not limited to clarithromycin, ketoconazole, itraconazole, ritonavir, nelfinavir, nefazodone)
    g. Moderate to strong CYP2C19 inducers (including but not limited to rifampin, efavirenz, phenytoin)
    h. Moderate to strong CYP3A4 inducers (including but not limited to carbamazepine, phenytoin, rifampin, St. John's wort, bosentan, efavirenz, phenobarbital)
7. The dosage of mavacamten does not exceed 15 mg once daily [maximum quantity limit is one capsule across all strengths per day, for example the use of 7.5 mg (5 mg + 2.5 mg) is not permitted]

Approval duration: 12 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- 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.
- The recommended starting dose is 5 mg once daily without regard to food; allowable subsequent doses with titration are 2.5, 5, 10, or 15 mg once daily.
    - Confirm absence of pregnancy and usage of effective contraception in females of reproductive potential.
    - Initiation or up-titration in patients with LVEF <55% is NOT recommended.
- Patients may develop heart failure while taking mavacamten. 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.
- Daily dosing takes weeks to reach steady-state drug levels and therapeutic effects, and genetic variation in metabolism and drug interactions may cause large differences in exposure

- When initiating or titrating, first consider LVEF then consider the Valsalva LVOT gradient and patient clinical status to guide appropriate dosing. Follow the algorithms in the product labeling for initiation and maintenance for appropriate dosing and monitoring schedules.
- If LVEF <50% while taking mavacamten, interrupt treatment. Follow the algorithm in the product labeling for Interruption for guidance on interrupting, restarting, or discontinuing therapy. If interrupted at 2.5 mg, either restart at 2.5 mg or discontinue permanently.
- Delay dose increases when there is intercurrent illness (e.g., serious infection) or arrhythmia (e.g., atrial fibrillation or other uncontrolled tachyarrhythmia) that may impair systolic function. Consider interruption of mavacamten in patients with intercurrent illness.

Dose Adjustments

- Renal Impairment - Specific guidelines for dosage adjustments in renal impairment are not available; it appears that no dosage adjustments are needed.
- Hepatic Impairment - Specific guidelines for dosage adjustments in hepatic impairment are not available; it appears that no dosage adjustments are needed.
- Adverse effects (e.g., LVEF reduction) – Refer to the product labeling for guidance on interrupting, restarting, or discontinuing therapy
- Drugs Interactions - Initiate at the recommended starting dosage of 5 mg orally once daily in patients who are on stable therapy with a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor. Reduce dosage of mavacamten by one level (i.e., 15 → 10 mg; 10 → 5 mg; or 5 → 2.5 mg) in patients who initiate a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor. Schedule clinical and echocardiographic assessment 4 weeks after inhibitor initiation, and do not up-titrate mavacamten until 12 weeks after inhibitor initiation. Avoid initiation of concomitant weak CYP2C19 and moderate CYP3A4 inhibitors in patients who are on stable treatment with 2.5 mg because a lower once-daily dose is not available.

Drug Availability

- 2.5 mg, 5 mg, 10 mg, and 15 mg capsules in 30-count bottles
- Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F)

PRECAUTIONS:

Boxed Warning

WARNING: 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. Interrupt Camzyos if LVEF is <50% at any visit or if the patient experiences heart failure symptoms or worsening clinical status.

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.

Contraindications

- Concomitant use of moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors
- Concomitant use of moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers

Precautions/Warnings

- **Heart Failure** - Mavacamten reduces systolic contraction and can cause heart failure or totally block ventricular function. Patients who experience a serious intercurrent illness (e.g., serious infection) or arrhythmia (e.g., atrial fibrillation or other uncontrolled tachyarrhythmia) are at greater risk of developing systolic dysfunction and heart failure. Assess the patient's clinical status and LVEF prior to and regularly during treatment and adjust the mavacamten dose accordingly. New or worsening arrhythmia, dyspnea, chest pain, fatigue, palpitations, leg edema, or elevations in N-terminal pro-B-type natriuretic peptide (NT-proBNP) may be signs and symptoms of heart failure and should also prompt an evaluation of cardiac function. Asymptomatic LVEF reduction, intercurrent illnesses, and arrhythmias require additional dosing considerations. Initiation of mavacamten in patients with LVEF <55% is not recommended. Avoid concomitant use in patients on disopyramide, ranolazine, verapamil with a beta blocker, or diltiazem with a beta blocker as these medications and combinations increase the risk of left ventricular systolic dysfunction and heart failure symptoms and clinical experience is limited.
- **CYP450 Drug Interactions Leading to Heart Failure or Loss of Effectiveness** - Mavacamten is primarily metabolized by CYP2C19 and CYP3A4 enzymes. Concomitant use of mavacamten and drugs that interact with these enzymes may lead to life-threatening drug interactions such as heart failure or loss of effectiveness. Advise patients of the potential for drug interactions, including with over-the-counter medications (such as omeprazole, esomeprazole, or cimetidine). Advise patients to inform their healthcare provider of all concomitant products prior to and during mavacamten treatment.
- **CAMZYOS REMS Program** - Mavacamten is only available through a restricted program called the CAMZYOS REMS Program because of the risk of heart failure due to systolic dysfunction. Notable requirements of the CAMZYOS REMS Program include the following:
    - Prescribers must be certified by enrolling in the CAMZYOS REMS Program.
    - Patients must enroll in the CAMZYOS REMS Program and comply with ongoing monitoring requirements

- Pharmacies must be certified by enrolling in the CAMZYOS REMS Program and must only dispense to patients who are authorized to receive mavacamten.
- Wholesalers and distributors must only distribute to certified pharmacies.

Further information is available at WWW.CAMZYOSREMS.COM or by telephone at 1-833-628-7367.

- **Embryo-Fetal Toxicity** - Mavacamten may cause fetal toxicity when administered to a pregnant female, based on findings in animal studies. Confirm absence of pregnancy in females of reproductive potential prior to treatment and advise patients to use effective contraception during treatment with mavacamten and for 4 months after the last dose. Combined hormonal contraceptives (CHCs) containing a combination of ethinyl estradiol and norethindrone may be used with mavacamten. However, mavacamten may reduce the effectiveness of certain other combined CHCs. If these CHCs are used, advise patients to add nonhormonal contraception (such as condoms) during concomitant use and for 4 months after the last dose of mavacamten.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J8499	Prescription drug, oral, non chemotherapeutic, NOS

ICD-10 Diagnosis Codes That Support Medical Necessity

I42.1	Obstructive hypertrophic cardiomyopathy

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

New York Heart Association (NYHA) Classification of Heart Failure

NYHA Class	Definition	Limitation	Example

I	Ordinary physical activity does not cause undue fatigue, dyspnea, or palpitations.	None	Can complete any activity requiring ≤7 MET: • Carry 11 kg up 8 steps • Carry objects weighing 36 kg • Shovel snow • Spade soil • Ski • Play squash, handball, or basketball • Jog or walk 8 km/hour
II	Ordinary physical activity causes fatigue, dyspnea, palpitations, or angina.	Mild	Can complete any activity requiring ≤5 MET: • Sexual intercourse without stopping • Garden • Roller skate • Walk 7 km/hour on level ground • Climb one flight of stairs at a normal pace without symptoms
III	Comfortable at rest; less than ordinary physical activity causes fatigue, dyspnea, palpitations, or angina.	Moderate	Can complete any activity requiring ≤2 MET: • Shower or dress without stopping • Strip and make a bed • Clean windows • Play golf • Walk 4 km/hour
IV	Symptoms occur at rest; any physical activity increases discomfort.	Severe	Cannot do or cannot complete any activity requiring ≥2 MET; cannot do any of the above activities
MET = metabolic equivalent of task, a measure of how much energy is expended compared to remaining at rest.			

RELATED GUIDELINES:

None

OTHER:

None

REFERENCES:

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6. Orphan Drug Designations and Approval [Internet]. Silver Spring (MD): US Food and Drug Administration; 2024. Accessed 06/21/24.
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 07/10/24.

GUIDELINE UPDATE INFORMATION:

10/01/22	New Medical Coverage Guideline.
08/15/23	Review and revision to guideline consisting of updating the Precautions/Warnings section and references.
08/15/24	Review and revision to guideline consisting of updating the description, Precautions/Warnings section, and references.