MY CAMZYOS™
PATIENT SUPPORT

For your appropriate patients with symptomatic NYHA class II-III obstructive hypertrophic cardiomyopathy (HCM)

Supporting Your Patients Every Step of the Way

Access and Reimbursement Guide

INDICATION

CAMZYOS™ (mavacamten) is 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.

IMPORTANT SAFETY INFORMATION

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 the CAMZYOS REMS PROGRAM.

Please see additional Important Safety information throughout and U.S. Full Prescribing Information, including **Boxed WARNING**.

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Introduction

This guide is designed to help appropriate patients get access to CAMZYOS™ (mavacamten) by providing helpful reimbursement information for healthcare offices. Healthcare benefits vary significantly; therefore, it is important that healthcare-provider offices verify each patient's insurance coverage prior to initiating therapy.

In this guide, you will find information about:

- CoverMyMeds
- Billing and coding information for CAMZYOS
- CAMZYOS REMS
- **MyCAMZYOS**™ Patient Support Program

Questions? Contact your local Bristol Myers Squibb (BMS) Access and Reimbursement Manager (ARM)

BMS ARMs can:

- Educate about **MyCAMZYOS** resources
- Provide timely responses to access and reimbursement needs
- Assist with reimbursement claims and appeals support for pharmacy and medical benefits
- Share knowledge regarding local payer coverage

To request an in-person visit with a BMS ARM or for additional patient support, you can call 855-CAMZYOS (855-226-9967). Additional patient resources are available at MyCAMZYOShcp.com

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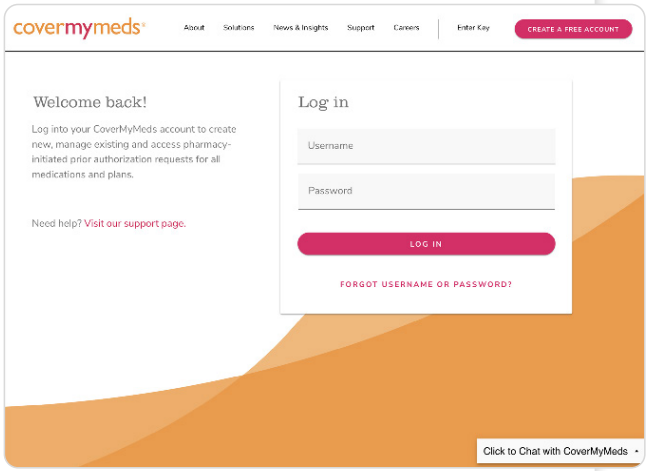
MyCAMZYOS™ Leverages CoverMyMeds to Assist Your Patients

With CoverMyMeds, you can:

- Enroll patients electronically
- Conduct electronic benefit reviews and prior authorizations (PAs)
- Access medical co-pay assistance for eligible, commercially insured patients*
- Track patient case status
- Request 35-day free trial offer and bridge coverage for eligible* patients
- Utilize e-signature capabilities
- Upload documents through the portal
- Access payer-specific PA forms and templates



How to get started on the CoverMyMeds portal

- Log into or create a new CoverMyMeds account at **account.covermymeds.com**
- Select **NEW REQUEST** and enter ‘CAMZYOS’
- Use your phone or tablet to scan the QR code for easy access to portal

You can also enroll patients via fax

- Download the enrollment form at **MyCAMZYOShcp.com**
- Fax signed and completed enrollment forms to **MyCAMZYOS** at **833-302-1421**

*Eligibility requirements and terms and conditions apply. Please **click here** for Program Terms, Conditions, and Eligibility Criteria.

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Billing and Coding Information for CAMZYOS™ (mavacamten)

ICD-10-CM codes are used to identify a patient's diagnosis.[1]

The ICD-10-CM codes for the labeled indications for CAMZYOS are provided below by BMS and should be verified with the payer. Some health plan and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record.

ICD-10-CM Code[1]

I42.1 for Obstructive Hypertrophic Cardiomyopathy	
I42.1	Obstructive Hypertrophic Cardiomyopathy

5010 Transaction Coding[2,3]

How Supplied	NDC	Billing NDC for NCPDP D.0 Pharmacy Claim Submission
2.5-mg Capsules, 30 Capsules/Bottle	73625-111-11	73625-0111-11
5-mg Capsules, 30 Capsules/Bottle	73625-112-11	73625-0112-11
10-mg Capsules, 30 Capsules/Bottle	73625-113-11	73625-0113-11
15-mg Capsules, 30 Capsules/Bottle	73625-114-11	73625-0114-11

Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and best coding practices. The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

ADDITIONAL IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

CAMZYOS is contraindicated with concomitant use of:

- Moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors
- Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers

WARNINGS AND PRECAUTIONS

Heart Failure

CAMZYOS 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.

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CAMZYOS™ (mavacamten) Risk Evaluation and Mitigation Strategy (REMS)

CAMZYOS is available only through a restricted program called the CAMZYOS REMS. Patients are required to enroll in the CAMZYOS REMS program prior to beginning therapy and must comply with ongoing monitoring requirements.[3]

Further information is available at **CAMZYOSREMS.com** or by telephone at **833-628-7367**

CAMZYOS Certified Specialty Pharmacies

CAMZYOS is only available from certified pharmacies. Please provide patients with the pharmacy contact information.

Accredo
(800) 803-2523 **PHONE**
(888) 302-1028 **FAX**
https://www.accredo.com/

Alivia Health Specialty Pharmacy
(888) 925-1989 **PHONE**
https://www.aliviahealth.com/specialty

AllianceRx Walgreens Prime
(855) 244-2555 **PHONE**
(877) 627-6337 **FAX**
https://www.alliancerxwp.com/

CVS Specialty
(888) 626-1145 **PHONE**
(888) 626-7660 **FAX**
http://www.cvsspecialty.com/

Optum SP (formerly BriovaRx)
(855)-312-9074 **PHONE**
(877) 342-4596 **FAX**
https://specialty.optumrx.com

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ADDITIONAL IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Heart Failure (cont'd)
Assess the patient's clinical status and LVEF prior to and regularly during treatment and adjust the CAMZYOS 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 CAMZYOS in patients with LVEF <55% is not recommended. Avoid concomitant use of CAMZYOS in patients on disopyramide, ranolazine, verapamil with a beta blocker, or diltiazem with a beta blocker as these medications and combinations were excluded from EXPLORER-HCM. Concomitant use of CAMZYOS with disopyramide in combination with verapamil or diltiazem has been associated with left ventricular systolic dysfunction and heart failure symptoms in patients with obstructive HCM.

CYP 450 Drug Interactions Leading to Heart Failure or Loss of Effectiveness
CAMZYOS is primarily metabolized by CYP2C19 and CYP3A4 enzymes. Concomitant use of CAMZYOS 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 CAMZYOS treatment.

CAMZYOS Risk Evaluation and Mitigation Strategy (REMS) Program
CAMZYOS 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 REMS Program.
- Patients must enroll in the REMS Program and comply with ongoing monitoring requirements.
- Pharmacies must be certified by enrolling in the REMS Program and must only dispense to patients who are authorized to receive CAMZYOS.
- 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
CAMZYOS may cause fetal toxicity when administered to a pregnant female, based on animal studies. 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 combined hormonal contraceptives (CHCs). Advise patients using CHCs to use an alternative contraceptive method that is not affected by CYP 450 enzyme induction or to add nonhormonal contraception. Advise females of reproductive potential about the potential risk to the fetus with maternal exposure to CAMZYOS during pregnancy.

ADVERSE REACTIONS
In the EXPLORER-HCM trial, adverse reactions occurring in >5% of patients and more commonly in the CAMZYOS group than in the placebo group were dizziness (27% vs 18%) and syncope (6% vs 2%).

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ADDITIONAL IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (cont'd)

Effects on Systolic Function

In the EXPLORER-HCM trial, mean (SD) resting LVEF was 74% (6) at baseline in both treatment groups. Mean (SD) absolute change from baseline in LVEF was -4% (8) in the CAMZYOS group and 0% (7) in the placebo group over the 30-week treatment period. At Week 38, following an 8-week interruption of trial drug, mean LVEF was similar to baseline for both treatment groups. In the EXPLORER-HCM trial, 7 (6%) patients in the CAMZYOS group and 2 (2%) patients in the placebo group experienced reversible reductions in LVEF <50% (median 48%: range 35-49%) while on treatment. In all 7 patients treated with CAMZYOS, LVEF recovered following interruption of CAMZYOS.

DRUG INTERACTIONS

Potential for Other Drugs to Affect Plasma Concentrations of CAMZYOS

CAMZYOS is primarily metabolized by CYP2C19 and to a lesser extent by CYP3A4 and CYP2C9. Inducers and inhibitors of CYP2C19 and moderate to strong inhibitors or inducers of CYP3A4 may affect the exposures of CAMZYOS.

Impact of Other Drugs on CAMZYOS:

- Moderate to Strong CYP2C19 Inhibitors or Strong CYP3A4 Inhibitors: Concomitant use increases CAMZYOS exposure, which may increase the risk of heart failure due to systolic dysfunction. Concomitant use is contraindicated.
- Moderate to Strong CYP2C19 Inducers or Moderate to Strong CYP3A4 Inducers: Concomitant use decreases CAMZYOS exposure, which may reduce CAMZYOS' efficacy. The risk of heart failure due to systolic dysfunction may increase with discontinuation of these inducers as the levels of induced enzyme normalizes. Concomitant use is contraindicated.
- Weak CYP2C19 Inhibitors or Moderate CYP3A4 Inhibitors: Concomitant use with a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor increases CAMZYOS exposure, which may increase the risk of adverse drug reactions. Initiate CAMZYOS at the recommended starting dose of 5 mg orally once daily in patients who are on stable therapy with a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor. Reduce dose of CAMZYOS by one level (i.e., 15 to 10 mg, 10 to 5 mg, or 5 to 2.5 mg) in patients who are on CAMZYOS treatment and intend to 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 CAMZYOS 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 of CAMZYOS because a lower dose is not available.

Potential for CAMZYOS to Affect Plasma Concentrations of Other Drugs

CAMZYOS is an inducer of CYP3A4, CYP2C9, and CYP2C19. Concomitant use with CYP3A4, CYP2C19, or CYP2C9 substrates may reduce plasma concentration of these drugs. Closely monitor when CAMZYOS is used in combination with CYP3A4, CYP2C19, or CYP2C9 substrates where decreases in the plasma concentration of these drugs may reduce their activity.

Hormonal Contraceptives: Progestin and ethinyl estradiol are CYP3A4 substrates. Concomitant use of CAMZYOS may decrease exposures of ethinyl estradiol and progestin, which may lead to contraceptive failure or an increase in breakthrough bleeding. Advise patients to use a contraceptive method that is not affected by CYP 450 enzyme induction (e.g., intrauterine system) or add nonhormonal contraception (such as condoms) during concomitant use and for 4 months after the last dose of CAMZYOS.

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ADDITIONAL IMPORTANT SAFETY INFORMATION

DRUG INTERACTIONS (cont'd)

Drugs That Reduce Cardiac Contractility

Expect additive negative inotropic effects of CAMZYOS and other drugs that reduce cardiac contractility. Avoid concomitant use of CAMZYOS with disopyramide in combination with verapamil or diltiazem. If concomitant therapy with a negative inotrope is initiated, or if the dose of a negative inotrope is increased, monitor LVEF closely until stable doses and clinical response have been achieved.

SPECIFIC POPULATIONS

Pregnancy

CAMZYOS may cause fetal harm when administered to a pregnant female. Advise pregnant females about the potential risk to the fetus with maternal exposure to CAMZYOS during pregnancy. There is a pregnancy safety study for CAMZYOS. If CAMZYOS is administered during pregnancy, or if a patient becomes pregnant while receiving CAMZYOS or within 4 months after the last dose of CAMZYOS, healthcare providers should report CAMZYOS exposure by contacting Bristol Myers Squibb at 1-800-721-5072 or www.bms.com.

Lactation

The presence of CAMZYOS in human or animal milk, the drug's effects on the breastfed infant, or the effects on milk production are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for CAMZYOS and any potential adverse effects on the breastfed child from CAMZYOS or from the underlying maternal condition.

Females and Males of Reproductive Potential

Confirm absence of pregnancy in females of reproductive potential prior to initiation of CAMZYOS. Advise females of reproductive potential to use effective contraception during treatment with CAMZYOS and for 4 months after the last dose. Use of CAMZYOS may reduce the effectiveness of CHCs. Advise patients using CHCs to use an alternative contraceptive method or add nonhormonal contraception.

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MY CAMZYOS™
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MyCAMZYOS™—supporting your patients every step of the way

Once you have prescribed CAMZYOS™ (mavacamten), we can assist with:

Patient access support

- Insurance benefits reviews
- Electronic prior authorizations
- Appeals process support
- Identification of programs that can help with treatment access
- Coordination with specialty pharmacies
- Dedicated local Access and Reimbursement Managers who can educate about patient access and affordability with the **MyCAMZYOS** program

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Getting patients started on CAMZYOS

- **Free trial program**: One-time, 35-day free trial for first-time patients
- **MyCAMZYOS Bridge program:** Commercially insured, first-time patients may initiate therapy with CAMZYOS at no cost during the insurance coverage determination process if there are prior authorization delays and/or if appeals are needed

Please click here for Program Terms, Conditions, and Eligibility Criteria.

Co-pay assistance

- **Prescription benefits:** Commercially insured patients may be eligible to pay **$10** for their CAMZYOS prescription
- **Echocardiogram co-pay program:** Commercially insured patients may be eligible for co-pay assistance for their required echocardiograms

Please click here for Program Terms, Conditions, and Eligibility Criteria.

Enroll your patients in MyCAMZYOS through CoverMyMeds at account.covermymeds.com or download an enrollment form at MyCAMZYOShcp.com.

Call 855-CAMZYOS (855-226-9967) or contact your Access and Reimbursement Manager for assistance.

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REFERENCES: 1. American Medical Association. *2020 ICD-10-CM: The Complete Official Codebook*. Chicago, IL: American Medical Association; 2020. **2.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 26 – Completing and Processing Form CMS-1500 Data Set. Revision 4388. September 6, 2020. Accessed November 3, 2021. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c26.pdf **3.** CAMZYOS [package insert]. Princeton, NJ: Bristol-Myers Squibb Company.

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