

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

# Support Every Step of the Way

MyCAMZYOS® provides dedicated and personal support to appropriate patients throughout their treatment because we know how important access is.

## In this guide you will find:



How to enroll your patients (p.2)



Overview of access support programs (p.3-6)



An important checklist to provide to appropriate patients (p.10-11)

#### **INDICATION**

CAMZYOS® 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.

#### **SELECT 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 CAMZYOS REMS PROGRAM.

Please see Important Safety Information, including **Boxed WARNING**, throughout and U.S. Full Prescribing Information for CAMZYOS® here.





# **Two Ways to Enroll Your Patients**



## **Option 1: Enroll via the CoverMyMeds portal**

- 1. Log in to or create your CoverMyMeds account at account.covermymeds.com/signup
- 2. Select New Request and enter "CAMZYOS" and patient details
- 3. Select Enroll Patient. Fill out the online MyCAMZYOS® Enrollment Form



Scan the QR code with your device for easy access to the portal.



## **Option 2: Enroll via fax**

 Download and complete the MyCAMZYOS Enrollment Form, located at MyCAMZYOShcp.com. Fax the signed and completed forms to 833-302-1421



Be sure your patient reviews and signs the Patient Authorization and Agreement (PAA) within the Enrollment Form while they're in the office.



## What if your patient leaves the office before signing the PAA form?

MyCAMZYOS can reach out to your patient for a signature.

Include your patient's phone number and email address on the submitted MyCAMZYOS
 Enrollment Form so that the patient signature can be requested

If you have any questions about the enrollment process or the **MyCAMZYOS** program, please contact your local Access and Reimbursement Manager.

Please find enrollment forms at MyCAMZYOShcp.com



# **Help Patients Start Treatment**



## MyCAMZYOS® Free Trial Program

One-time, 35-day free trial for first-time patients\*

\*Program Terms, Conditions, and Eligibility Criteria, located at MyCAMZYOS.com/terms, apply.



Following MyCAMZYOS enrollment, all eligible patients will be enrolled in the Free Trial unless you check the box that you do not want patient to receive the FTO dispense.



## MyCAMZYOS Bridge Program

If there is a delay in coverage, commercially insured patients may be able to receive CAMZYOS 30 day prescriptions at no cost for up to 18 dispenses.

- The program begins when coverage is delayed 20 business days after the initial submission of prior authorization (PA)
- If PA is denied, you must file an appeal within 60 days to keep your patient in the program

<sup>\*</sup>Program Terms, Conditions, and Eligibility Criteria, located at MyCAMZYOS.com/terms, apply.



Check the box for the Bridge Program on page 2 of the MyCAMZYOS Enrollment Form.



## **MyNurse Navigator Patient Support**

Dedicated Nurse Navigators are available to support patients on CAMZYOS throughout treatment.

- Following enrollment, a dedicated Nurse Navigator will be assigned to your patient, and will reach out within 1 business day
- Nurse Navigators are available to provide information and answer questions about CAMZYOS, help your patient organize and stay on track for key appointments, and supply information about other resources that may be available

†Nurse Navigators can provide general information about CAMZYOS but cannot provide medical advice.



## Coverage Support<sup>‡</sup>

After your patient is enrolled, a MyCAMZYOS Patient Access Specialist will:



Conduct a benefits review,

which addresses:

- How CAMZYOS will be covered under your patient's insurance
- Additional coverage information for your patient's echocardiograms
- Which specialty pharmacy certified to distribute CAMZYOS is preferred based on your patient's insurance



Take additional action, such as:

- Reviewing and explaining PA requirements
- Offering electronic PA submission through the CoverMyMeds portal
- Providing PA forms specific to your patient's insurance
- Appeal assistance when PA is denied

<sup>‡</sup>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.



# **Co-Pay Assistance**

**MyCAMZYOS**<sup>®</sup> is committed to making treatment affordable by offering the following:



## **CAMZYOS®** co-pay program

Eligible, commercially insured patients may pay as little as \$10 for CAMZYOS prescriptions.\*

\*Eligibility requirements and Terms and Conditions apply. Prescription benefits are available to commercially insured patients, up to an annual maximum of \$15,000.



For CAMZYOS co-pay assistance, your patients can enroll themselves by calling 855-CAMZYOS (855-226-9967) or visiting MyCAMZYOS.com.



## **Echocardiogram co-pay program**

Eligible, commercially insured patients may pay as little as \$0 for required echocardiograms.\*

\*Eligibility requirements and Terms and Conditions apply. Echocardiogram benefits are available to commercially insured patients, up to an annual maximum of \$2,500.



Following enrollment, all eligible patients will be enrolled. Check the box for your patient to receive a full a medical benefit summary for echocardiograms.

# SELECT 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





# **Echocardiogram co-pay reimbursement process**

- Patients may submit for reimbursement in 1 of 3 ways:
- 1. Visit the online portal at: www.echocopayportal.com/patient
- 2. By Fax\* to: 800-889-2243
- 3. By Mail\* to: Echocardiogram Co-Pay Assistance Program PO Box 2355

  Morristown, NJ 07962
- Have the following documentation ready to upload with their submission:
  - Itemized Explanation of Benefits (EOB) from the patient's insurance provider OR
  - Itemized statement of the echocardiogram service from the echo provider

\*Check Request Form—for Mail and Fax submissions only found at www.echocopayportal.com/patient/resources

**IMPORTANT:** EOB must include the following to be approved:

- · Date of service
- CPT or HCPCS code for their echo procedure
- Patient financial responsibility

#### **Provider Reimbursement Process**

- You may submit for reimbursement in 1 of 3 ways:
- 1. Visit the online portal at: www.echocopayportal.com/hcp
- 2. By Fax to: 800-889-2243
- 3. By Mail to: Echocardiogram Co-Pay Assistance Program
  PO Box 2355
  Morristown, NJ 07962
- Have the following documentation ready to upload with their submission:
  - Itemized Explanation of Benefits (EOB) from the patient's insurance provider OR
  - Itemized statement of the echocardiogram service from the echo provider
  - o CMS-1500 or UB-04 Claim form

**IMPORTANT:** EOB must include the following to be approved:

- Date of service
- CPT or HCPCS code for their echo procedure
- Patient financial responsibility

Payment issued by check via mail.

For questions or assistance using the portals or on claims submissions, please call the program at **800-830-1413**.





# **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.



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

# **Specialty Pharmacy Limited Distribution Network**

#### **Accredo**

**PHONE** (877) 482-5927, Option 2 **FAX** (888) 302-1028 **ERX NCPDP:** 4436920 https://www.accredo.com/

#### **Alivia Health**

**PHONE** (888) 925-1989 **FAX** (787) 925-1015 **ERX NCPDP:** 4030057 https://www.aliviahealth.com/specialty

#### **Walgreens Specialty Pharmacy**

**PHONE** (855) 244-2555 **FAX** (877) 231-8302 **ERX NCPDP:** 3974157 https://www.walgreensspecialtyrx.com/

#### **CVS Specialty**

PHONE (888) 626-1145 FAX (888) 626-7660 ERX NCPDP: 1466033 http://www.cvsspecialty.com/

#### Rx Crossroads\*

**PHONE** (855) 393-3619 **FAX** 724-754-0289 **ERx NCPDP:** 4541416

#### **Optum**

PHONE (877) 576-1292 FAX (877) 342-4596 ERX NCPDP: 1564930 https://specialty.optumrx.com



- Prescription available on the Enrollment Form
- Specialty Pharmacy will call your patient to schedule shipments
- Rxs can be sent via fax or EHR
- Provide your patients the appropriate Specialty Pharmacy phone number

\*The dispensing Specialty Pharmacy for Free Trial Offer and Bridge is Rx Crossroads by McKesson.

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.



# SELECT IMPORTANT SAFETY INFORMATION 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.

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 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 <u>www.CAMZYOSREMS.com</u> 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%).

#### 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.

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# SELECT IMPORTANT SAFETY INFORMATION 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 <u>CYP3A4 Inducers</u>: 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.

#### **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.

Please see U.S. Full Prescribing Information, including **Boxed WARNING**, for CAMZYOS <u>here</u>.





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

# **Support Every Step of the Way**

For questions about MyCAMZYOS®:



**Contact a Bristol Myers Squibb Access and Reimbursement Manager** 



Visit MyCAMZYOShcp.com



Call 855-CAMZYOS (855-226-9967) to speak to a live Patient Access Specialist





# MyCAMZYOS® is here to help support you and answer questions during your treatment with CAMZYOS®.

## Before you leave your doctor's office today, be sure you are:



- 1. Enrolled in the CAMZYOS REMS program
- 2. Signed up for the MyCAMZYOS Patient Support program, if interested
  - Full program enrollment requires 2 signatures on the enrollment form. Please review and sign in both places



## **MyNurse Navigator**

Once your doctor prescribes CAMZYOS, and if you enroll in the MyCAMZYOS program, you'll be assigned a dedicated Nurse Navigator\* who will guide you through the services listed below:



Providing important information as you start treatment, getting to know your specific needs, and answering questions about CAMZYOS<sup>†</sup>



Helping you organize and stay on track for key appointments when you get started on CAMZYOS



Supplying information about other resources that may be available to you



## **MyAccess Specialist**

# Once your doctor and you enroll in MyCAMZYOS, the Patient Access Specialists will start working with your insurance company to:

- Determine your coverage for CAMZYOS
- Help you understand any out-of-pocket costs
- Inform you of resources that may be available for you, such ast:



A free trial offer:

 You may be eligible for your first month's prescription free



Financial resources, including:

- Co-pay program: Commercially insured patients may pay as little as \$10 per month
- Imaging co-pay program: Commercially insured patients may be eligible for co-pay assistance for their required imaging tests

Ask your doctor to enroll you in the program.

You may also sign up online at MyCAMZYOS.com or by calling 855-CAMZYOS (855-226-9967), 8 AM to 8 PM ET, Monday through Friday.

Scan the QR code to add MyCAMZYOS (855-CAMZYOS) to your contact list.



<sup>\*</sup>Available from 8 AM to 8 PM ET, Monday through Friday. At all other times, nurses will usually return your calls the following business day. Response times may vary in Puerto Rico.

<sup>†</sup>Nurse Navigators can provide general information about CAMZYOS but cannot provide medical advice. Your doctor is the best source of information about your health. ‡Eligibility requirements and Terms and Conditions apply.



# Getting Started With MY \*\*CAMZYOS\*\* PATIENT (mavacamten) SUPPORT

## After you enroll in the MyCAMZYOS Patient Support program, here's what you can expect:



#### Day 1

#### Within one business day, your dedicated Nurse Navigator\* will reach out and:

- Introduce themselves and welcome you to MyCAMZYOS
- Answer any CAMZYOS-related questions you may have
- Tell you about resources and tools that are available to you

\*Nurse Navigators can provide general information about CAMZYOS but cannot provide medical advice. Your doctor is the best source of information about your health.



#### Week 1

#### A Patient Access Specialist will call you to answer questions and provide updates on:

- Your insurance coverage Your out-of-pocket costs
- Potential financial resources that may be available for eligible patients<sup>†</sup>

#### You will receive your Getting Started Kit in the mail, including:

• Treatment brochure • Symptom tracker • FAQ document

Be sure to call your **Nurse Navigator** if you have any questions or would like to talk about any of the information in the **Getting Started Kit.** 

<sup>‡</sup>Eligibility requirements and Terms and Conditions apply. For Terms and Conditions, go to MyCAMZYOS.com/terms.



#### Once you start treatment

Make sure to call your doctor to schedule your required monitoring appointments.

- Tell your doctor about any new prescription or over-the-counter medicines, vitamins, and herbal supplements. Taking CAMZYOS with certain medicines or grapefruit juice may cause side effects. Do not stop or change the dose of a medicine or start a new medicine without telling your doctor
- Tell your healthcare provider right away if you become pregnant, think you may be pregnant, or plan to breastfeed during treatment with CAMZYOS. Talk to your doctor about effective forms of birth control while on treatment and for 4 months after your last dose



## Sign the patient section of the MyCAMZYOS Enrollment Form before leaving today.

Please be sure to provide 2 signatures to receive both MyNurse Navigator and MyAccess Specialist support through the MyCAMZYOS Patient Support program. If you need to sign the form and have already left the office, call 855-CAMZYOS (855-226-9967) and ask about e-sign, or sign up online at MyCAMZYOS.com

If you need assistance, ask your doctor to help you enroll.





Contact your BMS Access & Reimbursement
Manager to order more MyCAMZYOS® patient tear
pads to share information about MyCAMZYOS
with your patients.

Please see Important Safety Information, including **Boxed WARNING**, throughout and U.S. Full Prescribing Information for CAMZYOS® <u>here</u>.



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