

## Supporting Your Patients Every Step of the Way

# A Guide for the CoverMyMeds.com User



Questions? Call your MyCAMZYOS<sup>™</sup> Patient Access Specialist at 855-CAMZYOS (226-9967), 8 AM to 8 PM ET, Monday–Friday

Please see <u>Important Safety Information</u> on pages 23-26 and the <u>U.S. Full Prescribing Information</u>, including **Boxed WARNING**.





## Welcome

**MyCAMZYOS**<sup>™</sup> has partnered with **CoverMyMeds.com** to provide an online portal to help healthcare provider offices with enrolling patients being treated with CAMZYOS<sup>™</sup> (mavacamten) in services offered by **MyCAMZYOS**. This user guide explains how to register your office and help patients enroll. It also provides an overview of the basic features within the portal.

Once registered, you will be able to check the status of a request, view a patient's specific research results, and manage your patient, provider, and facility profiles. You can also manage cases for your currently enrolled patients, including electronically submitting requests for benefits reviews, co-pay assistance, patient assistance, prior authorization assistance, and claims assistance.

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

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#### **CASES** Overview

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PATIENT SUPPORT

#### **GETTING STARTED**

### **Account Access & Creation**

As a central location for patient support services, the CoverMyMeds provider portal enables prescribers to simultaneously submit a valid prescription by way of the program enrollment form within **CASES**.

If you do not have a CoverMyMeds account, follow the proceeding steps:

- 1 Visit covermymeds.com and click "CREATE FREE ACCOUNT"
- 2 Enter the required information in the form fields

sights Support Careers Enter Key CREATE A FREE ACCO	DUNT
log in	
Username	
Password	
LOG IN	
FORGOT USERNAME OR PASSWORD?	

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# Starting a Patient Case

If you are accessing CoverMyMeds for the first time, you will select the **"New Request"** button in the top left corner of your screen. This will direct you to the form pick menu.



### Cases

If you have previously accessed **CASES**, you can navigate to it now with the navigation tabs on the left side of the page.



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## MY I CAMZYOS

Starting a Patient Case, cont'd

If you are a new user, select the **"START NEW"** button, which will take you to the "Find the Request You Need" page, where you will enter "CAMZYOS" (mavacamten) as the medication name.

REQUESTS	covermymeds*				
	O START NEW O EN	TER KEY	Search by patient name or date o	of birth (ex: 12/31/1980)	
	$\uparrow_{\downarrow}$ sort by: most recent	r.		S EXPAND ALL   💥 COLLAPS	SE ALL
	Jane Doe CASE KEY E-123DEF DOB 01/01/1981 RX BRAND X	enrollment Complete	PRIOR AUTH. New (Not Sent to Plan)	ACTION REQUIRED     Prior Authorization	~

### Starting a Patient Case Menu

Once you select CAMZYOS as the medication name, you can choose to start a new patient case any of the following ways from the menu that populates:

- Enrollment into MyCAMZYOS™
- Initiating a prior authorization request
- Beginning a patient benefits verification

These actions can be taken at any time. You will also have the opportunity to go back and complete any previous actions.

Name of Medication Brand X	Q	
Patient Services Available for Brand X		
Please select the action you would like to take.		
Enrollment Form Enroll your patient in hub assistance.	START ENROLLMENT	
Enroll your patient in hub assistance.		
Prior Authorization Initiate a prior authorization for your patient.	START PA	
Benefits Verification Instantly learn more about your patient's coverage details.	CHECK BENEFITS	

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#### PATIENT ENROLLMENT

### Enrolling a Patient in MyCAMZYOS™

If you are opting to enroll the patient in **MyCAMZYOS**, you will select the **"START ENROLLMENT"** button. From there, the appropriate enrollment form will open for you to begin completing.

> **NOTE:** BV will be performed and ePA assistance will be available within the patient case.

Name of Medication Brand X	Q	
Patient Services Available for Brand X Please select the action you would like to take.		
Enrollment Form Enroll your patient in hub assistance.	START ENROLLMENT	0
Prior Authorization Initiate a prior authorization for your patient.	START PA	
Benefits Verification Instantly learn more about your patient's coverage details.	CHECK BENEFITS	

### Completing the MyCAMZYOS Enrollment Form in the CoverMyMeds Provider Portal

Once the enrollment form is open, all fields within the form should be completed. The enrollment form also includes the opportunity to capture patient preferences for additional services like co-pay assistance, free trial and bridge programs.

**NOTE:** Please check that all information for the patient and medication are correct.

<b>•</b>	covermymed	S°	
REQUESTS			DOWNLOAD/PRINT SAVE SUBMIT ENROLLMENT FORM
CASES	ENROLLMENT Medication: Brand X Form: Hub Enrollment Description: Enrollment	ī	Patient Information First Name Jane
	form for Brand X		Last Name Doe
	FORM STATUS New (Not Sent to Plan)	<u>(</u> )	Date of Birth 01/01/1981 MM/DD/YYYY
			Gender V
			Street Address 1234 West Main Street Columbus Ohio, 43214

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### Capturing Patient Authorization

The top of the enrollment form includes an area for the patient's and/or caregiver's signature, allowing you to capture patient authorization while the patient is still in the office.

By signing, the patient is acknowledging their information and preferences outlined in the enrollment form, along with authorizing (or choosing to not authorize) TCPA (Telephone Consumer Protection Act) consent and consent to participate in financial assistance programs.

If patient authorization is not captured in the office, CoverMyMeds will reach out to the patient to capture the patient's or caregiver's signature.

- You will need to include the patient's email address on the enrollment form if you intend to have authorization captured via email
- Additionally, the PAA portion

   of the paper enrollment form
   containing the patient's signature
   can be faxed to MyCAMZYOS<sup>™</sup>
   or electronically uploaded to the
   enrollment form. Enrollment forms
   will either be provided to you from
   your ARM (Access & Reimbursement
   Manager) or Field Representative,
   or are available for download at
   MyCAMZYOShcp.com. The program
   fax number can be found on the
   enrollment form

NOTE: No new technology is needed for e-signature capture.

	(No patient info) Key: AP668PRJ	DOWNLOAD/PRINT	SAVE SUBMIT
REQUESTS		I HAVE READ THIS AUTHORIZATION AND AGRI	EE TO ITS TERMS:
		Patient or Patient Representative Signature	
CASES		June Doe	
		Date of Signature	
		06/20/2022	

## Other methods are available for capturing a patient signature aside from electronically.

**IN OFFICE via paper enrollment form:** The signed PAA section of the paper enrollment form can be uploaded to the enrollment form or faxed to **MyCAMZYOS**. Please see the enrollment form for the program fax number.

**EMAIL:** The provider will need to ensure they include the patient's email address on the enrollment form to capture the patient's signature. Upon submitting the enrollment form, the system will recognize if the patient signature was not captured and will automatically email the patient to obtain the patient's signature.

**MAIL:** If the patient does not sign the enrollment form after receiving the email, CoverMyMeds will mail the patient a paper enrollment form and request the patient to return the signed copy via mail or fax. Please see the enrollment form for the program fax number and/or mailing address.

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### Submitting the Enrollment Form to MyCAMZYOS<sup>™</sup>

Upon clicking the **"SUBMIT"** button to submit the form, **"CASES"** opens to your case list, where all your patient cases reside.

	Prescriber Signature		
	Doctor Abbie	×	
	Date 06/20/2022		
	 C	SUBMIT	
LOGOUT			

You may also submit a paper enrollment form via fax. Paper enrollment forms are available via **MyCAMZYOShcp.com** for download or by request through your ARM or Field Representative.

Once **MyCAMZYOS** receives the paper enrollment form, the Patient Access Specialist enters the information into the electronic form which you can complete within **CASES** inside your CoverMyMeds account. If necessary, they will reach out to you for any missing information. The form is then available for you to access within the specific patient's case in your case list.

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#### INITIATING A PRIOR AUTHORIZATION (PA) REQUEST

### **PA Request**

To initiate a PA request, select the "**START PA**" button on the "Find the Request You Need" page, which will take you to the PA form to complete.

**NOTE:** Initiating a PA can also be done within a patient case once an enrollment form has been submitted.

	Find Your Medication	
	Name of Medication Brand X	Q
_		
	Patient Services Available for Brand X	
	Please select the action you would like to take.	
	Enrollment Form	ART ENROLLMENT
	Enroll your patient in hub assistance.	
	Prior Authorization	START PA
	Initiate a prior authorization for your patient.	
	Benefits Verification	
	Instantly learn more about your patient's coverage details.	CHECK BENEFITS

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## PATIENT SUPPORT

#### Completing a PA Complete all patient, prescription, and

Complete all patient, prescription, and diagnosis information.

over <b>my</b> m	eds		Verify Prescribers	Help	Privacy & Terms	Logged in as Joyce Doe	Log Out
Send to Plan	(Key:L-122VNC Brand X	ā)	Form Insurance Commercial Elec	tronic PA	Form		
Save		Created 1 Day ago	Sent to	o Plan		Determina	tion
Archive Other Actions			ut not sent to plan. Please f	ill out the	required fields and c	lick "Send to Plan."	
otes days age lewed by you	First Name	Jane					
days age							
lewed by you	Last Name	Doe					
dewed by you	Last Name Date of Birth	Doe 01/01/1981					
iewed by you							

Once all information on the PA form is complete, select the "**Send to Plan**" button.

	Provider Next	Steps	
	?	Click the "send to plan" button to submit this information to OptumRx. If it is disabled, be sure all required fields have been completed. This electronic electronic submission does not require a signature. Optum Rx will respond automatically with your next steps.	
		Send to Plan	
2			

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### ePA Submission Confirmation

Upon submitting the PA request, a confirmation will pop up on screen that the request has been sent to the plan. If no response is received, a **MyCAMZYOS**<sup>™</sup> Patient Access Specialist will follow up.

**NOTE:** The status of the PA can be found in the patient's case.

Untitled Requ	est (Key: APTRPFA2)	×
	This request has been approved Please note any additional information p within this request	rovided by [the plan]
Form If you would like to	services avacamten) Support Program Enrollment o submit an enrollment request for this ck on the "Start Enrollment" button.	Start Enrollment
		Close

Please see <u>Important Safety Information</u> on pages 23-26 and the <u>U.S. Full Prescribing Information</u>, including **Boxed WARNING**.





#### PERFORMING A BENEFITS VERIFICATION (BV)

### Initiating a BV

To perform a benefits verification, select the **"CHECK BENEFITS"** button on the "Find the Request You Need" page, which will take you to the BV form to complete.

> NOTE: If a patient enrollment form has been submitted, the BV will be initiated through MyCAMZYOS<sup>™</sup> and will not need to be re-initiated here.

Find Your Medication	-	
Brand X	Q	
Patient Services Available for Brand X Please select the action you would like to take.		
Enrollment Form Enroll your patient in hub assistance.	START ENROLLMENT	
Prior Authorization Initiate a prior authorization for your patient.	START PA	
Benefits Verification Instantly learn more about your patient's coverage details.	CHECK BENEFITS	
	0	

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## MY CAMZYOS

# Completing the BV Form

Complete all the patient, insurance, and medication information in the BV form.

<b>•</b> -	cover <b>my</b> meds <sup>®</sup>	
REQUESTS CASES	Electronic Benefits Verification Complete the fields below to instantly check patient coverage, PA requirements, and cost information. PATIENT INFORMATION	
	Patient First Name (Required) Patient Last Name (Required)	
	Patient Gender (Required) Female Male Other	
	Date of Birth (Required) MM/DD/YYYY Patient Zip Code (Required) Patient State (Required)	

Once all information on the BV form is complete, select the **"CHECK BENEFITS"** button. You can also choose to opt in to run a benefits investigation by selecting the check box at the end of the form.

PRESCRIBER INFORMATION	
Prescriber NPI 1234567890	
MEDICATION INFORMATION	
Brand X :	
ADDITIONAL SERVICES	
I acknowledge by selecting this option I am agreeing to have CoverMyMeds perfor a benefits investigation, when necessary, for this patient on my behalf.	m
 CANCEL CHECK BENEFITS	,
-	

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## PATIENT SUPPORT

### **BV** Confirmation

Upon running the benefits check, you will be taken to a new screen confirming coverage details.

If a PA request has not been completed to this point, this page will populate the appropriate form for you to complete. The PA request will be auto-populated with patient demographic information from the BV form.

This page may also display estimated pharmacy costs to share with your patient.

•	cover <b>my</b> meds <sup>*</sup>	
REQUESTS	Jane Doe         D.O.B. 01/01/1981           CASE KEY E-123DEF         Brand X	
CASES	Pharmacy Coverage Details	
	Results Returned: 03/02/2020       Insurance     Prescription Insurance     PA Requirement     O       Humana Preferred Open Access Plan     Commercial     PA Required       We found the appropriate Prior Authorization form and started it on your behalf:	
	PHARMACY BENEFIT      Humana General Prior Authorization Request Form      Prior Authorization Request Form used for members who belong to a Humana pharmacy plan. Note: The member will usually have one ID card for both medical and pharmacy identified as Humana.	

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#### **CASES OVERVIEW**

### Navigating Cases

Unlike **"REQUESTS," "CASES"** is organized by patient case. Each case in your list shows basic demographic information, such as name and date of birth.

The status of any task within the patient case is featured here, alongside the patient's name and alerts for any actions needed.



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## MY I CAMZYOS

Case List Functionality

Within **"CASES"** you can expand a single patient case from your case list to see details like prescription and pharmacy information without having to leave your list to view an individual case. To expand a single case, select the blue arrow function to the right in the patient case task line.

covermymeds <sup>®</sup>			
• START NEW • ENT	ER KEY	Search by patient name or da	ate of birth (ex: 12/31/1980)
$^{\uparrow}_{\downarrow}$ sort by: most recent			器 EXPAND ALL   ) 送 COLLAPSE ALI
Jane Doe CASE KEY E-123DEF DOB 01/01/1981 RX BRAND X	enrollment Complete	prior auth. New (Not Sent to Plan)	ACTION REQUIRED     Prior Authorization
Prescription Insurance Type	: Commercial		
Case History			Rx Status
Enrollment Form	COMPLETE	>	Program Pharmacy
Prior Authorization	NEW (NOT SEN	IT TO PLAN)	Initial Dose
			Specialty Pharmacy
	• START NEW • ENT	START NEW     ENTER KEY     Q       \$         f_\$ SORT BY: MOST RECENT         Jane Doe       CASE KEY-E-123DEF       DOB 01/01/391 RX BRAND X       Enrollment Form       Complete	START NEW       ENTER KEY       Q. Search by patient name or data and the second secon

Additionally, you can directly access the tasks under "Case History" within the expanded view without clicking into the case.

Each of the items under "Case History" will take you directly to that task, bypassing the patient case page. Hover over a task and when the arrow appears, you can select that option.

<b>•</b>	covermymeds		
REQUESTS	START NEW SENTER KEY	Q. Search by patient name or date	of birth (ex: 12/31/1980)
CASES	$\uparrow_{\downarrow}$ sort by: most recent		器 EXPAND ALL   涎 COLLAPSE ALI
	Jane Doe CASE KEY E-123DEF ENROLLMENT DOB 01/01/1981 RX BRAND X Complete	prior Auth. New (Not Sent to Plan)	ACTION REQUIRED     Prior Authorization
	Prescription Insurance Type: Commercial		
c	Case History		Rx Status
	Enrollment Form COMPLETE	e >	Program Pharmacy
	Prior Authorization NEW (NOT	r sent to plan)	Initial Dose
	Prior Authorization NEW (NOT	r sent to plan)	Initial Dose Specialty Pharmacy

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## MY I CAMZYOS

### Case List Functionality, cont'd

There will also be an option for you to expand all your cases within your case list view. You will simply select the **"EXPAND ALL"** feature at the top right of your case list. To close all cases, you will select the **"COLLAPSE ALL"** feature, also at the top right of your case list.

ESTS	START NEW SEN	TER KEY	Search by patient name or c	late of birth (ex: 12/31/1980)	
ES	$\uparrow_{\downarrow}$ sort by: most recent	т		⊠ EXPAND ALL    COLLA	PSE ALL
	Jane Doe CASE KEY E-123DEF DOB 01/01/1981 RX BRAND X	enrollment Complete	PRIOR AUTH. New (Not Sent to Plan)	ACTION REQUIRED     Prior Authorization	^
	Prescription Insurance Typ	e: Commercial			
	Case History			Rx Status	
	Enrollment Form	COMPLETE	>	Program Pharmacy	
	Prior Authorization	NEW (NOT SEE	NT TO PLAN)	Initial Dose	
				Specialty Pharmacy	

You can access all other patient requests not associated with this medication via the **"REQUESTS"** list by using the navigation on the left side of the page.



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#### MANAGING A PATIENT CASE

### Accessing Patient Cases

Once inside **"CASES"** you will select the desired patient case from your case list.

Your case list is organized by patient case. Each case shows basic demographic information, such as name and date of birth, along with the patient's unique Case Key.

The status of any task within the patient case is featured here, alongside the patient's name and alerts for any actions needed.

If applicable to CAMZYOS<sup>™</sup> (mavacamten), the status of their enrollment and PA will be shown here. If an action is required by your office, the **"ACTION REQUIRED**" tag along with the respective task will be shown on the far right of the screen. If a case does not require your attention, the most recent case status will be displayed.



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## MY I CAMZYOS

Accessing Patient Cases, cont'd

To open a specific patient case, click on the name of the desired patient case.

	<b>•</b>	cover <b>my</b> meds <sup>。</sup>				
R	EQUESTS	START NEW SENTE	R KEY	Q. Search by patient name or date	of birth (ex: 12/31/1980)	
	ČASES	Î↓ SORT BY: MOST RECENT			🛿 EXPAND ALL   ※ COLLAPS	EALL
c	,	CASE KEY E-123DEF	enrollment Complete	prior auth. New (Not Sent to Plan)	ACTION REQUIRED     Prior Authorization	~

You can expand any case with the "Quick View" option by clicking the blue arrow.

To go directly into an individual patient case, select **"OPEN CASE"** from the expanded view. Additional details on **"CASES"** and your case list functionality are included in a later section.

Jane Doe CASE KEY E-123DEF DOB 01/01/1981 RX BRAND X	ENROLLMENT PRIOR AUTH. Complete New (Not Sen	it to Plan)	ACTION REQUIRED     Prior Authorization
Prescription Insurance	ype: Commercial		
Case History			Rx Status
Enrollment Form	COMPLETE	>	Program Pharmacy
Prior Authorization	NEW (NOT SENT TO PLAN)	>	Initial Dose Specialty Pharmacy
			Rx Transferred

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### Managing Status of Patient Cases

Once you've opened an individual patient case, you will see your tasks available to manage or view. The status prompts on the right side of the task lines will indicate:

- If action is needed by displaying "START"
- If the task is in progress by displaying "CONTINUE"
- If the task is complete by displaying "VIEW"

Tasks will be organized into two lists to clearly indicate if action is required from you or your Patient Access Specialist.

_						
	<b>•</b>	cover <b>my</b> meds <sup>®</sup>				
	REQUESTS	Jane Doe D.O.B. 01/ CASE KEY E-123DEF Brand X	01/1981			
	CASES	SPECIALTY PHARMACY Dispensing Pharmacy	YOUR TASKS			
		Dispensing pharmacy will be displayed upon transfer of	Enrollment Form	Ov K-678HAZ	Complete	VIEW
		prescription to the dispensing pharmacy.	Prior Authorization	Ov L-122VNG	Sent to Plan	VIEW
			PATIENT SERVICES TASKS			
		ADDITIONAL SUPPORT ()	Benefit Verification/Investigation		Complete	VIEW
		III Portal User Guide	Prior Authorization Support		Complete	
			Appeal Support		Complete	
			Financial Assistance Enrollment		Not Started	
			Coordinate Order Fulfillment		Not Started	

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MYMCAMZY

PATIENT SUPPORT



## MYMCAMZY

Accessing **Financial** Assistance **Options** 

Within the portal, your Patient Access Specialist will enroll your patients who have opted into the MyCAMZYOS™ financial assistance program for which they are eligible.

The additional support section will provide links to additional resources.

accessing inancial		over <b>my</b> me	eds∘				
ssistance		Jane Doe CASE KEY E-123DEF	<b>D.O.B.</b> 01/03 Brand X	1/1981			
ptions	CASES	SPECIALTY PHARM	ACY	YOUR TASKS			
		Dispensing pharmacy will b displayed upon transfer of	be	Enrollment Form	OT K-678HAZ	Complete	VIEW
thin the portal, your Patient Access		prescription to the dispensi pharmacy.	ing	Prior Authorization	Ov L-122VNG	Sent to Plan	VIEW
ecialist will enroll your patients who ve opted into the MyCAMZYOS™			_	PATIENT SERVICES TASKS			
ancial assistance program for which	·····O	ADDITIONAL SUPP		Benefit Verification/Investigation		Complete	VIEW
ey are eligible.		III Portal User Guide	- I	Prior Authorization Support		Complete	
_				Appeal Support		Complete	
e additional support section will provide			•••••••	Financial Assistance Enrollment		Not Started	
ks to additional resources.				Coordinate Order Fulfillment		O Not Started	

### **Fulfilling Patient Cases**

Once all relevant tasks within a patient case have been successfully fulfilled, all steps within the patient case will display "VIEW" next to the step, indicating that step is completed.

You will have visibility into the prescription triage and pharmacy dispense date.

<b>•</b> -1	cover <b>my</b> meds <sup>,</sup>				
REQUESTS	Jane Doe D.O.B. 0 CASE KEY E-123DEF Brand X	01/01/1981			
CASES	SPECIALTY PHARMACY	YOUR TASKS			
	Dispensing Pharmacy Dispensing pharmacy will be displayed upon transfer of	Enrollment Form	Ov K-678HAZ	Complete	VIEW
	prescription to the dispensing pharmacy.	Prior Authorization	OT L-122VNG	Sent to Plan	VIEW
		PATIENT SERVICES TASKS			
	ADDITIONAL SUPPORT	Benefit Verification/Investigation	n	Complete	VIEW
	III Portal User Guide	Prior Authorization Support		Complete	
		Appeal Support		Complete	
		Financial Assistance Enrollmen	t	Not Started	
		Coordinate Order Fulfillment		Not Started	

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### covermymeds



#### INDICATION

CAMZYOS<sup>™</sup> (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.

#### **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.

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.

(continued on next page)

CAMZYOS<sup>™</sup> (mavacamten) capsules

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covermymeds



#### **ADDITIONAL IMPORTANT SAFETY INFORMATION**

#### WARNINGS AND PRECAUTIONS (cont'd)

#### Heart Failure (cont'd)

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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### Supporting Your Patients Every Step of the Way

Have questions or need assistance? There are three ways to get support:

Contact your BMS Access and Reimbursement Manager for general assistance or to schedule a visit

Call us at 855-CAMZYOS (855-297-9967), 8 AM to 8 PM ET, Monday–Friday, to speak with a live Patient Access Specialist

Visit **MyCAMZYOShcp.com** for information and resources, including the Enrollment Form, to help your patients with access to CAMZYOS

Please see <u>Important Safety Information</u> on pages 23-26 and the <u>U.S. Full Prescribing Information</u>, including **Boxed WARNING**.

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