

CAMZYOS (mavacamten) Echocardiogram Co-Pay Assistance Program

Reimbursement Guide for HEALTHCARE PROVIDERS

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.



CAMZYOS[®] (mavacamten) Echocardiogram Co-Pay Assistance Program*

This guide is designed to help you understand the **CAMZYOS Echocardiogram Co-Pay Assistance Program** and how to submit for reimbursement on behalf of your patient for their out-of-pocket costs for Risk Evaluation and Mitigation Strategy (REMS) required echocardiograms. The program includes a medical benefit offer for reimbursement of your patient's out-of-pocket costs for required echocardiogram procedures where the full cost is not covered by their insurance.

Patients may pay as little as \$0 in out-of-pocket costs per each echocardiogram procedure, subject to an annual maximum benefit of \$2,500. Patients are responsible for any costs that exceed the maximum benefit.

The program does not reimburse for other associated costs such as supplies, office visits, or physician-related services including interpretation of echocardiograms.

Your office or your patient can submit for reimbursement of their echocardiogram procedure out-of-pocket costs after insurance coverage has been applied.



For more information about the program please call **855-CAMZYOS**, 8 AM to 8 PM ET, Monday–Friday.

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.



CAMZYOS[®] (mavacamten) Echocardiogram Co-Pay Assistance Program Terms & Conditions

Eligibility Requirements

- Patients must have commercial (private) insurance and must be treated with CAMZYOS for an on-label indication
- Patients must be 18 years of age or older
- Patients must live in the United States or United States territories
- Patients are not eligible if they have medical insurance coverage through a state or federal healthcare program, including but not limited to Medicare, Medicaid, MediGap, CHAMPUS, TRICARE, Veterans Affairs (VA), or Department of Defense (DoD) programs; patients who move from commercial plans to state or federal healthcare programs will no longer be eligible
- Patients residing in Massachusetts, Minnesota, or Rhode Island are not eligible

Program Benefits

- The Program includes a medical benefit offer for reimbursement of patient's out-of-pocket costs for required echocardiogram procedures where the full cost is not covered by the patient's insurance; program does not reimburse for other associated costs such as supplies, office visits or physician related services including interpretation of echocardiograms
- Patients may pay as little as \$0 in out-of-pocket costs per echocardiogram procedure, subject to an annual maximum benefit of \$2,500. Patients are responsible for any costs that exceed the maximum benefit
- To receive the Program benefits, a claim must be submitted within 180 days from the date of the Explanation of Benefits (EOB)
- The program may apply retroactively to out-of-pocket costs for echocardiograms that occurred within 180 days prior to the date of enrollment
- All Program payments are for the benefit of the patient only

Program Timing

• Patients will be evaluated for ongoing eligibility and will continue enrollment in the program if all eligibility requirements are met

Additional Terms & Conditions

- Patients and prescribers may not seek reimbursement from health insurance, health savings, or flexible spending accounts, or any third party, for any part of the benefit received by the patient through this offer
- Acceptance of this offer confirms that this offer is consistent with patient's insurance. Patients and healthcare providers must report the receipt of co-pay assistance benefits if required by patient's insurance provider
- Offer valid only in the United States and United States Territories. Void where prohibited by law, taxed, or restricted
- The Program is not insurance, not transferable and not conditioned on any past, present, or future purchase
- No membership fees
- Bristol Myers Squibb reserves the right to rescind, revoke, or amend this offer at any time without notice





Once you have enrolled your patient into the program using the MyCAMZYOS enrollment form, you can submit for reimbursement on your patient's behalf for their echocardiogram procedure out-of-pocket costs after insurance coverage has been applied.

Be sure to have your documentation ready to submit using the online reimbursement portal. You will need to upload copies or a picture of the documentation to your computer or have ready on your mobile device.

Required documentation includes:

- An Explanation of Benefits (EOB) from your patient's insurance company with the following:
 - ^o Date of service
 - ^o CPT code or HCPCS code (echocardiogram procedure code)
 - ^o Patient financial responsibility once insurance has been applied
- CMS-1500 or UB-04 claim form

Claims may be submitted in 3 ways:

- 1. The online reimbursement portal at www.echocopayportal.com/hcp
- 2. Fax to: 800-889-2243
- 3. Mail to: Echocardiogram Co-Pay Assistance Program PO Box 2355 Morristown, NJ 07962





Sample Explanation of Benefits (EOB) Form

	ember Name: John Sample ember ID #: 12345678-01			Group Name: Provider: Smith		Group #: 123456 Group #: 9876543			
Dates of Service	Service Description	Billed Amount	Allowed Amount	Deductible Amount	Co-pay Amount	Co-insurance Amount	Paid Amount	Amount You Owe	Remark Code
10/14/22	Example Service 99205	\$493.28	\$109.13		\$35		\$74.13	\$35	R
10/5/22	Example Service 99214	\$198.00	\$98.66		\$35		\$63.66	\$35	
	Totals	\$691.28	\$207.79		\$70		\$137.79	\$70	

What are CPT and HCPCS codes and why are they being requested?

CPT and HCPCS codes are used by providers to identify a medical procedure for billing. A CPT code is a 5-digit numerical code that starts with the number 9. An HCPCS code is a 5-digit code that starts with a C followed by 4 numerical digits.

NOTE: This is a sample form intended for illustrative purposes only.



For additional assistance with the online portal or claims submissions, please contact the program at **800-830-1413**, 8 AM to 8 PM ET, Monday–Friday.

NOTE: If the EOB does not include this information, you may submit an itemized receipt of services that includes the information above. Claims should be itemized and should not be bundled.

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.





Instructions for Submitting a Claim in the Portal

- Step 1: Visit the online rebate portal at <u>www.echocopayportal.com/hcp</u>
- Step 2: Call the program at 800-830-1413 to set up your new account. The program will assist you with creating your account and linking your enrolled patients.

Sign In
Username (Email Address) *
Password *
Forgot password? Sign In
First time logging in? Please call 800-830-1413 to receive your temporary password.





Step 3: Your dashboard will display a list of your patients. To begin a claims submission, click on "Submit a Claim" next to the appropriate patient. If your patient is not listed, please call the program for assistance at 800-830-1413

submit new claims for				low, including patier below, please call		l program status. You can also 13.
Search Your F	Patients					
First Name		Last Name		Date of Birth (M	M/DD/YYYY)	Member ID
				mm/dd/yyyy		
Clear	ch					Export to Excel
Clear Searc	Date of Birth	Member ID	Product	Enroll Date	Status	Export to Excel
		Member ID 69878618062	Product Echocardiogram	Enroll Date 07/05/2023	Status Active	

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- Step 4: Click the radio button for the documentation (Claim document/EOB or Other/Misc) that you are uploading. Claim submission will not be delayed or rejected if the incorrect button is selected.
- Step 5: Upload the required documents by clicking the **"Browse"** button to locate your file.
- Step 6: Once all documents are uploaded, click the "Submit" button.

NOTE: This page provides important information about the documentation required for your claim to be successfully submitted.

Upload Documents Please upload the appropriate documents to	o submit.			
Patient				
Full Name Uat Patient Bms	Member ID 69878618062			
Document				
Please submit the required following documents: • Claim Form (CMS-1500 or UB-40) • Patient's Explanation of Benefits (EOB) OR an itemized receipt from your billing department Documents need to include all of the	Document Type: Claim document/EOB Other/Misc	Information: You can upload a maximum of 5 files at one time (max size per file is 5MB). Allowed file types: gif, jpgjreg, png, pdf, heic, heif		
following details: • Facility name • Patient's name		or drag it here Refresh Submit >		
 Date of service Patient financial responsibility once insurance has been applied CPT or HCPCS code (echocardiogram procedure code) 				
All fields are mandatory unless otherwise indicated.				

What happens after a claim is submitted?

If you or your patient submits the claim and it is approved, the party that submitted will receive a check in 7-10 business days. The other party will receive an approval notice to keep you both informed. If the claim is not approved, you will both receive a letter informing you of the reason why. You may also receive a call from the program to obtain any missing information to reprocess the claim. If you need assistance at any time, please call **800-830-1413** and ask to speak with a program representative.





Additional Features of the Portal

- Create and manage office user accounts for the portal
- Receive notifications of patients' status and communications
- View claims history
- · View patient and provider communications history
- View payment reports for your claims
- FAQs about the program
- Resources Patient Check Request Form for patient's mailed/faxed claims and a sample EOB

Payment Report

From your dashboard within the **"Payment Reports"** tab, you can view payments issued for claims submitted by your office.

Sent to Bank: F	Status: m has been approved unds are pending the pproved and check h	e bank-to-bank trans	fer for deposit				Export	to Exc
Check Tra	ansactions							
Product	Patient Name	Member ID	DOS	Payee Info	Amount	Check Confirmation	Status Date	State
Echocardiogram	Patient atBMS Program	19878399659	08/16/2023	Bms Danbury Townhall Danbury, CA 77777	\$150.00	3343400012	08/16/2023	Pai
Echocardiogram	UAT PatientBMS	69878618062	08/09/2023	Bms Danbury Townhall Danbury, CA 77777	\$100.00		08/16/2023	Ser to Ban

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Provider Profile

Within the **"Profile"** tab, you will be able to make updates to your address, phone number, and fax information.

Practice Name *		Specialty				
Bms Test						
Address *		Address 2				
Danbury Townhall		Address 2				
City *	State *		Zip Code *			
Danbury	California	*	77777			
Main Phone Number *	Fax Number		Email Address *			
222-222-2222			test@test.com			
NPI	Tax ID (Optional)					
8272480137	22-2222222					





Claims History

View the status of your patient's claims under the patient profile within the **"Patient Claims History"** tab. You will see if their claim was approved and the amount to be paid, or rejected with the reason for rejection.

Co-Pay Member ID	Details						Print card details	
69878618062		BIN 000000		PCN 00		Group Number EX75017001		
Submit a Claim 义								
Patient Profile De	tails P	atient Claims H	listory Patier	nt Messages Histo	<u>ry</u>			
Patient Clain	ns Histo	ry						
Product	Claim ID	Claim Type	Date of Service	Amount Paid	Claim Status	Payment Type	Payee	
Echocardiogram	1	Medical	08/09/2023	\$100.00	Accepted	Check	Bms Danbury Townhall Danbury, CA 77777	
Items per page: 10	-					1 – 1 of	1 < >	
						Sub	mit a Claim 🔉	



For additional assistance with the online portal or claims submissions, please contact the program at **800-830-1413**, 8 AM to 8 PM ET, Monday–Friday.

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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.

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 increase the risk of left ventricular systolic dysfunction and heart failure symptoms and clinical experience is limited.





ADDITIONAL IMPORTANT SAFETY INFORMATION (cont.) WARNINGS AND PRECAUTIONS (cont.)

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 overthe-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.

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ADDITIONAL IMPORTANT SAFETY INFORMATION (cont.) WARNINGS AND PRECAUTIONS (cont.)

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. CHCs containing a combination of ethinyl estradiol and norethindrone may be used with CAMZYOS. However, CAMZYOS may reduce the effectiveness of certain other combined hormonal contraceptives (CHC). 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 CAMZYOS.

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%). There were no new adverse reactions identified in VALOR-HCM.

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.





ADDITIONAL IMPORTANT SAFETY INFORMATION (cont.) 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:

- <u>Moderate to Strong CYP2C19 Inhibitors or Strong CYP3A4 Inhibitors:</u> Concomitant use increases CAMZYOS exposure, which may increase the risk of heart failure due to systolic dysfunction. Concomitant use is contraindicated.
- <u>Moderate to Strong CYP2C19 Inducers or Moderate to Strong 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.





ADDITIONAL IMPORTANT SAFETY INFORMATION (cont.) DRUG INTERACTIONS (cont.)

Potential for CAMZYOS to Affect Plasma Concentrations of Other Drugs CAMZYOS is an inducer of CYP3A4, CYP2C9, and CYP2C19. Concomitant use with CYP3A4, CYP2C9, or CYP2C19 substrates may reduce plasma concentration of these drugs. Closely monitor when CAMZYOS is used with concomitant CYP3A4, CYP2C9, or CYP2C19 substrates unless otherwise recommended in the Prescribing Information.

Certain Combined Hormonal Contraceptives (CHC): Progestin and ethinyl estradiol are CYP3A4 substrates. Concomitant use of CAMZYOS may decrease exposures of certain progestins, which may lead to contraceptive failure. CHCs containing a combination of ethinyl estradiol and norethindrone may be used with CAMZYOS, but if other CHCs are used, advise patients to add nonhormonal contraception (such as condoms) during concomitant use and 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 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.

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.





ADDITIONAL IMPORTANT SAFETY INFORMATION (cont.) 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 <u>www.bms.com</u>.

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. CHCs containing a combination of ethinyl estradiol and norethindrone may be used with CAMZYOS. However, CAMZYOS may reduce the effectiveness of certain other combined hormonal contraceptives (CHC). 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 CAMZYOS.

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Supporting Your Patients Every Step of the Way

Have questions or need assistance?

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

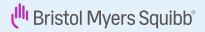


Call us at **855-CAMZYOS (855-226-9967)**, 8 AM to 8 PM ET, Monday–Friday, to speak with a live Patient Access Specialist



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

Please see Important Safety information on pages 12-17 and U.S. Full Prescribing Information, including **Boxed WARNING**, by <u>clicking here</u>.



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