

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

214998Orig1s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document

CAMZYOS™ (mavacamten) REMS Program

I. Administrative Information

Application Number: NDA 214998

Application Holder: MyoKardia, Inc., a wholly owned subsidiary of Bristol Myers Squibb

Initial REMS Approval: 04/2022

II. REMS Goal

The goal of the CAMZYOS Risk Evaluation and Mitigation Strategy (REMS) program is to mitigate the risk of heart failure due to systolic dysfunction.

Objectives:

1. Monitor for detection of heart failure due to systolic dysfunction with periodic echocardiograms.
2. Screen for drug interactions prior to each dispense.

III. REMS Requirements

MyoKardia, Inc. must ensure that healthcare providers, patients, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare providers who prescribe CAMZYOS must:

To become certified to prescribe

1. Review the drug's Prescribing Information.
2. Review the [Program Overview](#) and the [Education Program for Healthcare Providers and Pharmacies](#).
3. Successfully complete the [Healthcare Provider Knowledge Assessment](#) and submit it to the REMS.
4. Enroll by completing the [Healthcare Provider Enrollment Form](#) and submitting it to the REMS.

Before treatment initiation (first dose)

5. Counsel the patient using the [Patient Brochure](#) on the risk of heart failure due to systolic dysfunction.
6. Counsel the patient using the [Patient Brochure](#) on the risk of drug-drug interactions with CYP2C19 and CYP3A4 inhibitors and inducers and the need to inform healthcare providers of all the prescription and nonprescription medications they take.
7. Provide the patient with the [Patient Brochure](#).

8. Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Document and submit confirmation of an echocardiogram and authorization for treatment to the REMS using the [Patient Enrollment Form](#).
9. Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions. Document and submit to the REMS using the [Patient Enrollment Form](#).
10. Enroll the patient by completing and submitting the [Patient Enrollment Form](#) to the REMS.

During treatment: 4, 8, and 12 weeks after treatment initiation and every 12 weeks thereafter unless dose change, initiating a weak CYP2C19 inhibitor, or initiating a moderate CYP3A4 inhibitor

11. Counsel the patient on the risks of heart failure due to systolic dysfunction and drug-drug interactions with CYP2C19 and CYP3A4 inhibitors and inducers, and the related safe-use requirements using the [Patient Brochure](#).
12. Assess the patient's cardiovascular status and the appropriateness of continuing treatment by echocardiogram. Document and submit confirmation of an echocardiogram and authorization for treatment to the REMS using the [Patient Status Form](#).
13. Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions. Document and submit authorization for continuing treatment to the REMS using the [Patient Status Form](#).

During treatment: 4 and 12 weeks after any dose change, initiating a weak CYP2C19 inhibitor, or initiating a moderate CYP3A4 inhibitor, and every 12 weeks thereafter

14. Counsel the patient on the risks of heart failure due to systolic dysfunction and drug-drug interactions with CYP2C19 and CYP3A4 inhibitors and inducers, and the related safe-use requirements using the [Patient Brochure](#).
15. Assess the patient's cardiovascular status and the appropriateness of continuing treatment by echocardiogram. Document and submit confirmation of an echocardiogram and authorization for continuing treatment to the REMS using the [Patient Status Form](#).
16. Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions. Document and submit authorization for continuing treatment to the REMS using the [Patient Status Form](#).

At all times

17. Report adverse events of heart failure due to systolic dysfunction to Bristol Myers Squibb.

2. Patients who are prescribed CAMZYOS:

Before treatment initiation (first dose)

1. Receive counseling from the healthcare provider on the risk of heart failure due to systolic dysfunction (when the heart is unable to pump enough blood to the body) using the [Patient Brochure](#).
2. Receive counseling from the healthcare provider on the risk of drug-drug interactions and the need to inform healthcare providers of all prescription and over-the-counter medicines and supplements they take, using the [Patient Brochure](#).

	- Get an echocardiogram to check their heart. - Enroll in the REMS by completing the Patient Enrollment Form with the healthcare provider. Enrollment information will be provided to the REMS.
During treatment: 4, 8, and 12 weeks after treatment initiation and every 12 weeks thereafter unless dose change or starting certain new medicines	- Receive counseling from the healthcare provider on the risk of heart failure due to systolic dysfunction (when the heart is unable to pump enough blood to the body). - Receive counseling from the healthcare provider on the risk of drug-drug interactions and the need to inform healthcare providers of all the prescription and over-the-counter medicines and supplements they take, using the Patient Brochure. - Get an echocardiogram to check their heart.
During treatment: 4 and 12 weeks after dose changes and starting certain new medicines and every 12 weeks thereafter	- Receive counseling from the healthcare provider on the risk of heart failure due to systolic dysfunction. - Receive counseling from the healthcare provider on the risk of drug-drug interactions and the need to inform healthcare providers of all the prescription and over-the-counter medicines and supplements they take, using the Patient Brochure. - Get an echocardiogram to check their heart.
Before each prescription dispense	- Review all prescriptions and over-the-counter medicines and supplements with the pharmacist. - Receive counseling from the pharmacist on drug-drug interactions.
At all times	- Inform the healthcare provider or seek other medical attention if there are new or worsening symptoms of heart failure. - Inform other healthcare providers about treatment with CAMZYOS. - Inform healthcare providers of all medicines and any changes, including over-the-counter medicines and supplements.

3. Pharmacies that dispense CAMZYOS must:

To become certified to dispense	- Designate an authorized representative to complete the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. - Have the authorized representative review the Prescribing Information, the Education Program for Healthcare Providers and Pharmacies, and the Program Overview. - Have the authorized representative successfully complete the Pharmacy Authorized Representative Knowledge Assessment and submit it to the REMS.
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4. Have the authorized representative enroll in the REMS on behalf of the pharmacy by completing the [Pharmacy Enrollment Form](#) and submitting it to the REMS.
5. Train all relevant staff involved in dispensing CAMZYOS using the [Program Overview](#) and [Education Program for Healthcare Providers and Pharmacies](#).

Before dispensing

6. Counsel the patient on drug-drug interactions.
7. Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions. Document and submit to the REMS using the [Drug Interaction and Counseling Checklist for Pharmacies](#).
8. Document the prescribed dose.
9. Obtain authorization to dispense each prescription by contacting the REMS to verify that the prescriber is certified, the patient is enrolled, the healthcare provider has authorized the patient to receive the drug, the patient is counseled, and the pharmacy identified and resolved any drug-drug interactions.
10. Provide the patient with the [Patient Brochure](#).
11. Dispense no more than a 35-day supply of CAMZYOS.

To maintain certification to dispense

12. Have the new authorized representative enroll in the REMS by successfully completing the [Pharmacy Authorized Representative Knowledge Assessment](#) and completing the [Pharmacy Enrollment Form](#) if the authorized representative changes.

At all times

13. Report adverse events of heart failure due to systolic dysfunction to Bristol Myers Squibb.
 14. Do not distribute, transfer, loan, or sell CAMZYOS, except to a certified pharmacy.
 15. Maintain records of dispensing information.
 16. Maintain records of completion of the REMS training by relevant staff.
 17. Maintain records that all processes and procedures are in place and are being followed.
 18. Comply with audits conducted by MyoKardia, Inc. or a third party acting on behalf of MyoKardia, Inc. to ensure that all processes and procedures are in place and are being followed.
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4. Wholesalers-distributors that distribute CAMZYOS must:

To be able to distribute

1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies.
 2. Train all relevant staff involved in distributing CAMZYOS on the REMS requirements.
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At all times	3. Distribute only to certified pharmacies. 4. Maintain records of drug distribution for all CAMZYOS shipments. 5. Comply with audits conducted by MyoKardia, Inc. or a third party acting on behalf of MyoKardia, Inc. to ensure that all processes and procedures are in place and are being followed.
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MyoKardia, Inc. must provide training to healthcare providers who prescribe CAMZYOS.

The training includes the following educational materials:

- [Program Overview](#)
- [Education Program for Healthcare Providers and Pharmacies](#)
- [Healthcare Provider Knowledge Assessment](#)

The training must be available online, via email, and in a hard-copy format via mail.

MyoKardia, Inc. must provide training to pharmacies that dispense CAMZYOS.

The training includes the following educational materials:

- [Program Overview](#)
- [Education Program for Healthcare Providers and Pharmacies](#)
- [Pharmacy Authorized Representative Knowledge Assessment](#)

The training must be available online, via email, and in a hard-copy format via mail.

To support REMS operations, MyoKardia, Inc. must:

1. Authorize dispensing for each patient based on receipt of a [Patient Enrollment Form](#), [Patient Status Form](#), and [Drug Interaction and Counseling Checklist for Pharmacies](#) on the following schedule:
 - For the initial dispense: If the [Patient Enrollment Form](#) and [Drug Interaction and Counseling Checklist for Pharmacies](#) are not completed, the patient is not authorized to receive drug until the completed forms are received.
 - For subsequent dispenses: If the [Patient Status Form](#) is not received within 3 calendar days of the last day of the week the echocardiogram is due (as described in the [Education Program for Healthcare Providers and Pharmacies](#)) and the [Drug Interaction and Counseling Checklist for Pharmacies](#) is not completed before each dispense, the patient is not authorized to receive the drug until the completed forms are received.
2. Establish and maintain a [REMS Website](#), [CAMZYOSREMS.com](#). The [REMS Website](#) must include the capability to complete healthcare provider and pharmacy certification and enrollment online; the capability to enroll and manage patients online, including completion of the [Drug Interaction and Counseling Checklist for Pharmacies](#) and [Patient Status Form](#); the capability to review patient enrollment and authorization status and healthcare provider certification status, as well as obtaining authorization to dispense; and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website(s).
3. Make the [REMS Website](#) fully operational and all REMS materials available through [CAMZYOSREMS.com](#) and the CAMZYOS REMS Call Center at the time that CAMZYOS first becomes commercially available.
4. Establish and maintain a REMS Call Center for REMS participants at 833-628-7367.

5. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the CAMZYOS REMS.
6. Ensure healthcare providers and pharmacies are able to complete the certification process online and by fax.
7. Ensure healthcare providers are able to complete the patient enrollment process online and by fax.
8. Ensure healthcare providers are able to complete the [Patient Status Form](#) online and by fax.
9. Ensure pharmacies are able to document the prescribed dose and complete the [Drug Interaction and Counseling Checklist for Pharmacies](#) online and by fax.
10. Ensure pharmacies are able to obtain authorization to dispense online and by phone.
11. Provide the [Program Overview](#), [Education Program for Healthcare Providers and Pharmacies](#), and the [Healthcare Provider Enrollment Form](#) or [Pharmacy Enrollment Form](#) to healthcare providers who (1) attempt to prescribe or dispense CAMZYOS and are not yet certified or (2) inquire about how to become certified.
12. Notify healthcare providers and pharmacies within 1 business day when they become certified in the REMS.
13. Notify healthcare providers within 1 business day when patient enrollment is complete.
14. Provide certified healthcare providers access to the database of their enrolled patients and certified pharmacies.
15. Provide certified pharmacies access to the database of certified healthcare providers and enrolled patients.
16. Provide authorized wholesalers-distributors access to the database of certified pharmacies.

To ensure REMS participants' compliance with the REMS, MyoKardia, Inc. must:

17. Annually verify that the authorized representative's name and contact information correspond to those of the current designated authorized representative for the pharmacy. If different, the pharmacy must recertify a new authorized representative.
18. Maintain adequate records to demonstrate that the REMS requirements have been met, including but not limited to records of the following: CAMZYOS distribution and dispensing, certification of healthcare providers and pharmacies, enrolled patients, completed [Patient Status Forms](#) and [Drug Interaction and Counseling Checklist for Pharmacies](#), and audits of certified pharmacies and wholesalers-distributors. These records must be readily available for FDA inspections.
19. Establish and maintain a plan for addressing noncompliance with the REMS requirements.
20. Monitor healthcare providers, pharmacies, and wholesalers-distributors on an ongoing basis to ensure the REMS requirements are being met. Take corrective action if noncompliance is identified, including decertification.
21. Audit pharmacies and wholesalers-distributors no later than 180 calendar days after they become certified and annually to ensure all REMS processes and procedures are in place, functioning, and support the REMS requirements.
22. Take reasonable steps to improve operations of and compliance with the REMS requirements based on monitoring and evaluation of the CAMZYOS REMS.

IV. REMS Assessment Timetable

MyoKardia, Inc. must submit REMS assessments annually from the date of the initial approval of the REMS program (04/28/2022). To facilitate the inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. MyoKardia, Inc must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the CAMZYOS REMS:

Enrollment Forms

Healthcare Providers:

1. [Healthcare Provider Enrollment Form](#)

Patients:

2. [Patient Enrollment Form](#)

Pharmacy:

3. [Pharmacy Enrollment Form](#)

Training and Educational Materials

Healthcare Providers:

4. [Education Program for Healthcare Providers and Pharmacies](#)
5. [Program Overview](#)
6. [Healthcare Provider Knowledge Assessment](#)

Patients:

7. [Patient Brochure](#)

Pharmacy:

8. [Education Program for Healthcare Providers and Pharmacies](#)
9. [Program Overview](#)
10. [Pharmacy Authorized Representative Knowledge Assessment](#)

Patient Care Forms

11. [Patient Status Form](#)
12. [Drug Interaction and Counseling Checklist for Pharmacies](#)

Other Materials

13. [REMS Website](#)

CAMZYOS™ REMS Healthcare Provider Enrollment Form

Instructions:

1. Review the [Prescribing Information](#), the [Education Program for Healthcare Providers and Pharmacies](#), and the [Program Overview](#)
2. Successfully complete and submit the [Healthcare Provider Knowledge Assessment](#) and the [Healthcare Provider Enrollment Form](#) to the CAMZYOS REMS:
 - ▶ Online at CAMZYOSREMS.com, or
 - ▶ By fax at 833-299-9539

Complete all required fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS will notify you of your successful certification within 1 business day.

Healthcare Provider Information (Fields marked * are REQUIRED)			
*First Name:	Middle Initial:	*Last Name:	
*Credentials: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other (please specify):			
*Specialty: ☐ Cardiology ☐ Electrophysiology ☐ Genetics ☐ Other (please specify):			
*Healthcare Provider NPI #:			
*Practice/Facility Name:			
*Address:	*City:	*State:	*ZIP Code:
*Phone: Area Code/Telephone Number		*Fax: Area Code/Fax Number	
*Email:		Preferred Method of Contact: (please select one) ☐ Phone ☐ Email ☐ Fax	
Preferred Time of Contact: ☐ AM ☐ PM			

Healthcare Provider Responsibilities

I have:

- Reviewed the drug's [Prescribing Information](#), the [Program Overview](#), and the [Education Program for Healthcare Providers and Pharmacies](#)
- Successfully completed the [Healthcare Provider Knowledge Assessment](#) and submitted it to the CAMZYOS REMS

Before treatment initiation (first dose), I must:

- Counsel the patient, using the [Patient Brochure](#), on the:
 - risk of heart failure due to systolic dysfunction, including how to recognize and respond to the symptoms of heart failure due to systolic dysfunction
 - risk of drug-drug interactions with CYP2C19 and CYP3A4 inhibitors and inducers and the need to inform healthcare providers of all the prescription and nonprescription medication they take



CAMZYOS™ REMS

Healthcare Provider Enrollment Form

- Provide the patient with the [Patient Brochure](#)
- Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining a baseline echocardiogram
- Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions
- Document and submit confirmation of an echocardiogram, assessment of drug-drug interactions, and authorization for treatment to the CAMZYOS REMS using the [Patient Enrollment Form](#)
- Enroll the patient by completing the [Patient Enrollment Form](#) and submitting the form to the CAMZYOS REMS

During treatment (4, 8, and 12 weeks after treatment initiation and every 12 weeks thereafter, unless dose change, initiating a weak CYP2C19 inhibitor, or initiating a moderate CYP3A4 inhibitor), I must:

- Counsel the patient on the risks of heart failure due to systolic dysfunction and drug-drug interactions with CYP2C19 and CYP3A4 inhibitors and inducers, and the related safe-use requirements using the [Patient Brochure](#)
- Assess the patient's cardiovascular status and the appropriateness of continuing treatment by echocardiogram
- Assess the patient's prescription and nonprescription medications for drug-drug interactions
- Document and submit confirmation of an echocardiogram, assessment of drug-drug interactions, and authorization for continuing treatment to the CAMZYOS REMS using the [Patient Status Form](#)

During treatment (4 and 12 weeks after any dose change, initiating a weak CYP2C19 inhibitor, or initiating a moderate CYP3A4 inhibitor, and every 12 weeks thereafter), I must:

- Counsel the patient on the risks of heart failure due to systolic dysfunction and drug-drug interactions with CYP2C19 and CYP3A4 inhibitors and inducers, and the related safe-use requirements using the [Patient Brochure](#)
- Assess the patient's cardiovascular status and the appropriateness of continuing treatment by echocardiogram
- Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions
- Document and submit confirmation of an echocardiogram, assessment of drug-drug interactions, and authorization for continuing treatment to the CAMZYOS REMS using the [Patient Status Form](#)

At all times, I must:

- Report adverse events of heart failure due to systolic dysfunction to Bristol Myers Squibb

***Healthcare Provider Signature:** _____ ***Date:** _____
Month/Day/Year



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Bristol Myers Squibb™

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Phone: 833-628-7367
Fax: 833-299-9539
CAMZYOSREMS.com

CAMZYOS™ REMS Patient Enrollment Form

- Complete this form online at **CAMZYOSREMS.com**, or
- Print and complete this form and submit by fax to the CAMZYOS REMS at 833-299-9539

Patient Information (Fields marked * are REQUIRED)			
*First Name:	Middle Initial:	*Last Name:	
*Date of Birth: _____ Month/Day/Year		*Gender: ☐ Female ☐ Male ☐ Neutral ☐ Prefer Not to Say	
*Address:	*City:	*State:	*ZIP Code:
*Phone: _____ Area Code/Telephone Number	Alternate Phone (optional): _____ Area Code/Telephone Number		
*Email:	Preferred Method of Contact: ☐ Phone ☐ Email		
Person to Contact if Patient Is Not Available/Secondary Contact:	Phone Number for Secondary Contact: _____ Area Code/Telephone Number		

Certified Healthcare Provider Information (Fields marked * are REQUIRED)	
*First Name:	*Last Name:
*Healthcare Provider NPI #:	*Phone: _____ Area Code/Telephone Number

For patients who are participating or have finished participation in a clinical trial for CAMZYOS
Will the patient now be enrolling in the REMS on a dose higher than expected for new patients? ☐ Yes ☐ No



CAMZYOS™ REMS

Patient Enrollment Form

Patient Agreement

- I have received, read, and understand the **Patient Brochure** that my healthcare provider has given me

Before treatment, I will:

- Enroll in the CAMZYOS REMS by completing this **Patient Enrollment Form** with my healthcare provider
- Get an echocardiogram (echo) to check my heart as directed by my doctor

My healthcare provider has counseled me, using the **Patient Brochure**, on:

- The risk of heart failure due to systolic dysfunction (when the heart cannot pump enough blood to the body)
- The risk of drug-drug interactions and the need to inform healthcare providers of all the prescription and over-the-counter medicines and supplements I take
- The need for echos during my treatment with CAMZYOS

I understand the symptoms of heart failure, including:

- shortness of breath
- chest pain
- fatigue
- a racing sensation in your heart (palpitations)
- swelling in your legs
- rapid weight gain

During treatment, I will:

- Continue to receive counseling from my healthcare provider using the **Patient Brochure** on:
 - the risk of heart failure due to systolic dysfunction (when the heart cannot pump enough blood to the body)
 - the risk of drug-drug interactions and the need to inform healthcare providers of all the prescription and over-the-counter medicines and supplements I take
- Get echos to check my heart as directed by my doctor

Before I receive each prescription:

- I will review all my prescription and over-the-counter medicines and supplements with the pharmacist
- The pharmacist will counsel me on drug-drug interactions

At all times, I will:

- Inform my healthcare provider or seek other medical attention if I have new or worsening symptoms of heart failure
- Inform all my healthcare providers that I am taking CAMZYOS
- Inform healthcare providers of all medicines, including over-the-counter medicines and supplements and any changes to my medicines



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Phone: 833-628-7367
Fax: 833-299-9539
CAMZYOSREMS.com

CAMZYOS™ REMS

Patient Enrollment Form

Patient Agreement (continued)

- I understand that my protected health information will be stored in a secure and confidential database of all patients who receive CAMZYOS in the United States
- Bristol Myers Squibb and its agents will use and share my protected health information for the CAMZYOS REMS program and for FDA reporting
- I agree that Bristol Myers Squibb and its agents may contact me by phone, mail, or email to manage the CAMZYOS REMS

***Patient/Legal**

Guardian Signature: _____ ***Date:** _____
Month/Day/Year

Print Name: _____

Healthcare Provider Acknowledgment

- I have reviewed the echocardiogram result for this patient and confirmed that it is appropriate to initiate treatment with CAMZYOS (LVEF $\geq 55\%$): Echo Performed Date: _____)
Month/Day/Year
- The VLVOT for this patient is: ☐ <20 mmHg ☐ ≥ 20 mmHg and <30 mmHg ☐ ≥ 30 mmHg
- I have reviewed the patient's prescription and nonprescription medications and supplements for drug-drug interactions
 - After reviewing the patient's prescription and nonprescription medications and supplements, does the patient require a lower starting dose due to a potential drug-drug interaction?
☐ Yes ☐ No
- I have provided the **Patient Brochure** to the patient
- The patient is authorized to begin treatment

***Healthcare Provider**

or Designee Signature: _____ ***Date:** _____
Month/Day/Year

Print Name: _____



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Phone: 833-628-7367
Fax: 833-299-9539
CAMZYOSREMS.com

CAMZYOS™ REMS Pharmacy Enrollment Form

Instructions:

- Review the [Prescribing Information](#), the [Education Program for Healthcare Providers and Pharmacies](#), and the [Program Overview](#)
- Successfully complete and submit the [Pharmacy Authorized Representative Knowledge Assessment](#) and the [Pharmacy Enrollment Form](#) to the CAMZYOS REMS:

- ▶ Online at CAMZYOSREMS.com, or
- ▶ By fax at 833-299-9539

Complete all required fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS will notify you of your successful certification within 1 business day.

Pharmacy Information (Fields marked * are REQUIRED)			
*Pharmacy Name:	*Pharmacy NPI #:	*Pharmacy DEA #:	
*Pharmacy Address:	*City:	*State:	*ZIP Code:
*Phone: _____	*Fax: _____		
Area Code/Telephone Number	Area Code/Fax Number		

Authorized Representative Information (Fields marked * are REQUIRED)		
*First Name:	Middle Initial:	*Last Name:
*Title/Position:		
*Phone: _____	*Fax: _____	
Area Code/Telephone Number	Area Code/Fax Number	
*Email:		
Preferred Method of Contact (please select one): ☐ Phone ☐ Email ☐ Fax		

*Secondary Contact (Fields marked * are REQUIRED)		
*First Name:	Middle Initial:	*Last Name:
*Phone: _____	*Fax: _____	
Area Code/Telephone Number	Area Code/Fax Number	
*Email:		



CAMZYOS™ REMS

Pharmacy Enrollment Form

Pharmacy Responsibilities

As the Authorized Representative, I must:

- Review the [Prescribing Information](#), the [Education Program for Healthcare Providers and Pharmacies](#), and the [Program Overview](#)
- Successfully complete the [Pharmacy Authorized Representative Knowledge Assessment](#) and submit it to the CAMZYOS REMS
- Train all relevant staff involved in dispensing CAMZYOS using the [Program Overview](#) and the [Education Program for Healthcare Providers and Pharmacies](#)

Before dispensing, all pharmacy staff must:

- Counsel the patient on drug-drug interactions
- Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions. Document and submit to the CAMZYOS REMS using the [Drug Interaction and Counseling Checklist for Pharmacies](#)
- Document the prescribed dose of CAMZYOS
- Obtain authorization to dispense each prescription by contacting the CAMZYOS REMS to verify that the:
 - prescriber is certified and the patient is enrolled
 - healthcare provider has authorized the patient to receive the drug, the patient is counseled, and the pharmacy has identified and resolved any drug-drug interactions
- Provide the patient with the [Patient Brochure](#)
- Dispense no more than a 35-day supply of CAMZYOS

At all times, all pharmacy staff must:

- Report adverse events of heart failure due to systolic dysfunction to Bristol Myers Squibb
- Not distribute, transfer, loan, or sell CAMZYOS except to a certified pharmacy
- Maintain records of dispensing information
- Maintain records of completion of the REMS training by relevant staff
- Maintain records that all processes and procedures are in place and are being followed
- Comply with audits carried out by MyoKardia or a third party acting on behalf of MyoKardia to ensure that all processes and procedures are in place and are being followed
- Have a new authorized representative enroll in the CAMZYOS REMS by successfully completing the [Pharmacy Authorized Representative Knowledge Assessment](#) and completing the [Pharmacy Enrollment Form](#)

***Authorized Representative Signature:** _____ ***Date:** _____
Month/Day/Year



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Phone: 833-628-7367
Fax: 833-299-9539
CAMZYOSREMS.com

CAMZYOS™ (mavacamten) REMS

Education Program

for Healthcare Providers and Pharmacies



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Welcome to the CAMZYOS™ REMS Education Program for Healthcare Providers and Pharmacies



To prescribe CAMZYOS, healthcare providers must become certified in the CAMZYOS Risk Evaluation Mitigation Strategy (REMS), which includes reviewing this education program. Only certified healthcare providers are eligible to prescribe CAMZYOS to patients.



CAMZYOS can only be dispensed by certified pharmacies.



Patients must be enrolled in the CAMZYOS REMS to receive CAMZYOS.

CAMZYOS™ Risk Information



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CAMZYOS™ Indication and Mechanism of Action



Indication

CAMZYOS is a cardiac myosin inhibitor 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.



Mechanism of Action

Excess cross-bridge formation between myosin and actin and dysregulation of the super-relaxed state are mechanistic hallmarks of HCM.

CAMZYOS modulates the number of myosin heads that can enter “on actin” (power-generating) states, thus reducing the probability of force-producing (systolic) and residual (diastolic) cross-bridge formation. CAMZYOS shifts the overall myosin population towards an energy-sparing, recruitable, super-relaxed state. In HCM patients, myosin inhibition with CAMZYOS reduces dynamic left ventricular outflow tract (LVOT) obstruction and improves cardiac filling pressures.

BOXED WARNING:

Risk of Heart Failure Due to Systolic Dysfunction



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.

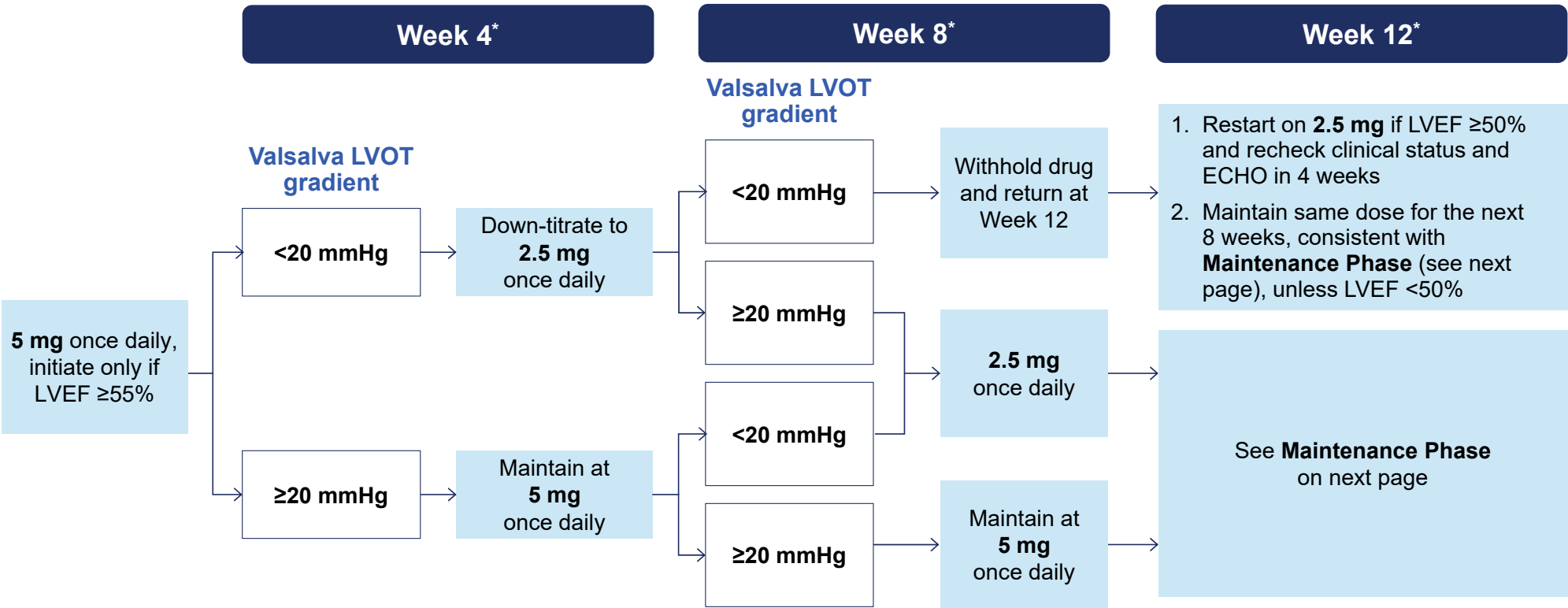
The Use of Echocardiography in CAMZYOS™ Dosing and Administration

Regular LVEF and Valsalva LVOT gradient assessment is required for careful titration to achieve an appropriate target Valsalva LVOT gradient, while maintaining LVEF $\geq 50\%$ and avoiding heart failure symptoms.

From the CAMZYOS Prescribing Information

- Initiation or up-titration of CAMZYOS in patients with LVEF $< 55\%$ is not recommended
- When initiating or titrating CAMZYOS, first consider LVEF, then consider the Valsalva LVOT gradient and the patient's clinical status to guide appropriate CAMZYOS dosing. Follow the algorithms for **Initiation** and **Maintenance** (see next pages) for appropriate CAMZYOS dosing and monitoring schedules
- If LVEF $< 50\%$ while taking CAMZYOS, interrupt treatment. Follow the algorithm for **Treatment Interruption** (see next pages) for guidance on interrupting, restarting, or discontinuing CAMZYOS
- Permanently discontinue treatment if LVEF $< 50\%$ twice on 2.5 mg daily (the lowest dose level of CAMZYOS)

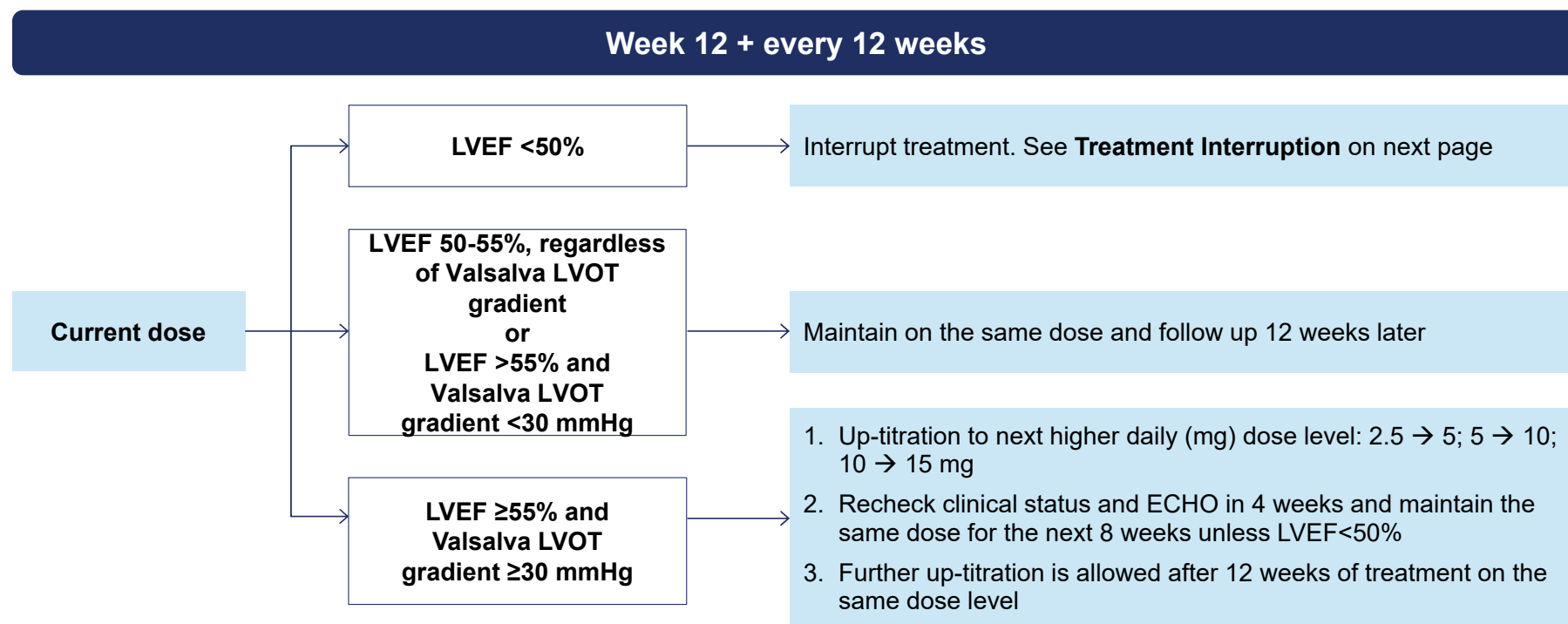
CAMZYOS™ Dosing and Administration: Initiation Phase



* Interrupt treatment if LVEF <50% at any clinic visit; restart treatment after 4 weeks if LVEF ≥50%. See **Treatment Interruption**.

ECHO=echocardiogram; LVEF=left ventricular ejection fraction; LVOT=left ventricular outflow tract.

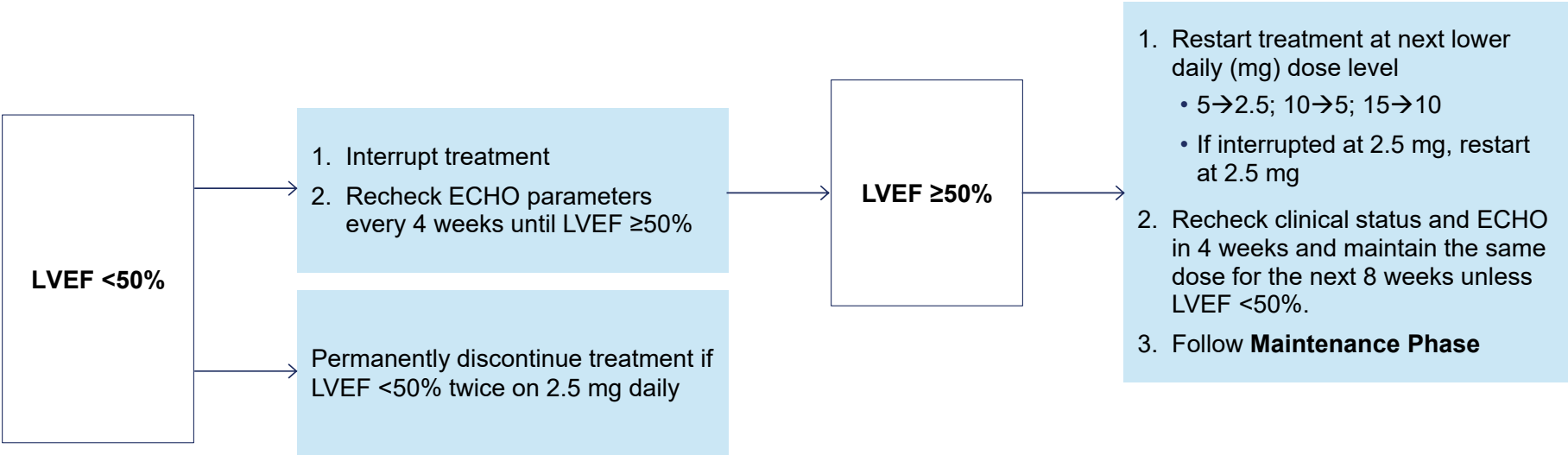
CAMZYOS™ Dosing and Administration: Maintenance Phase



ECHO=echocardiogram; LVEF=left ventricular ejection fraction; LVOT=left ventricular outflow tract.

CAMZYOS™ Dosing and Administration: Treatment Interruption

At Any Clinical Visit If LVEF <50%



ECHO=echocardiogram; LVEF=left ventricular ejection fraction

BOXED WARNING: CYP 450 Drug Interactions Leading to Heart Failure or Loss of Effectiveness (I)

CAMZYOS™ is primarily metabolized by cytochrome P450 (CYP) enzymes CYP2C19 and (to a lesser extent) CYP3A4.



- Concomitant use of CAMZYOS with **moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors** can increase CAMZYOS exposure and may increase the risk of heart failure due to systolic dysfunction
- **Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers** can decrease CAMZYOS exposure which may reduce CAMZYOS' efficacy
 - The risk of heart failure due to systolic dysfunction may increase when these inducers are discontinued during CAMZYOS treatment, as a result of increased CAMZYOS exposure
- Weak CYP2C19 inhibitors or moderate CYP3A4 inhibitors can increase CAMZYOS exposure, which may increase the risk of adverse drug reactions

BOXED WARNING: CYP 450 Drug Interactions Leading to Heart Failure or Loss of Effectiveness (II)

CAMZYOS™ is **contraindicated** in patients using:

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

Patients that intend to initiate a weak CYP2C19 inhibitor or moderate CYP3A4 inhibitor while on CAMZYOS should reduce their dose of CAMZYOS by one level (see table).

- Schedule clinical and echocardiographic assessment 4 weeks after the initiation of an inhibitor, and do not up-titrate CAMZYOS until 12 weeks after 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 once-daily dose is not available

Stepwise Down-titration For Initiation of a Weak CYP2C19 Inhibitor or Moderate CYP3A4 Inhibitor

Starting Dose (mg)	New Dose (mg)
15	10
10	5
5	2.5
2.5	0 (treatment interruption)

Advise patients of the potential for drug interactions, including with over-the-counter medications (such as omeprazole, esomeprazole, or cimetidine), prior to and during treatment with CAMZYOS

CAMZYOS™ REMS Overview



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What is the CAMZYOS™ REMS?



The CAMZYOS REMS (Risk Evaluation and Mitigation Strategy) program is required by the US Food and Drug Administration (FDA) to ensure that the benefits of CAMZYOS outweigh the risks

Risk



The CAMZYOS REMS is a program to manage the risk of heart failure due to systolic dysfunction



Healthcare Provider Requirements



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How Does a Healthcare Provider Become Certified in the CAMZYOS™ REMS?



To become certified in the CAMZYOS REMS, healthcare providers must:



- 1 Review the CAMZYOS Prescribing Information
- 2 Review the following:
 - **Program Overview**
 - **Education Program for Healthcare Providers and Pharmacies (this presentation)**
- 3 Successfully complete the **Healthcare Provider Knowledge Assessment**
- 4 Enroll by completing the **Healthcare Provider Enrollment Form**
- 5 Certification can be completed online at CAMZYOSREMS.com or by printing and faxing the **Healthcare Provider Knowledge Assessment** and the **Healthcare Provider Enrollment Form** to the CAMZYOS REMS at 833-299-9539. Healthcare providers will be notified within 1 business day when they are certified to prescribe CAMZYOS

What are the Requirements of the CAMZYOS™ REMS for Certified Healthcare Providers?



To prescribe CAMZYOS, you must:



- 1 Provide counseling to the patient using the **Patient Brochure** about CAMZYOS prior to initiating treatment and enroll them into the CAMZYOS REMS
- 2 Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram
- 3 Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions
- 4 Document and submit the confirmation of an echocardiogram, assessment of drug-drug interactions, and authorization for treatment to the REMS using the **Patient Enrollment Form**
- 5 Counsel the patient, assess drug-drug interactions, and assess the patient's cardiovascular status during treatment, including obtaining echocardiograms at the frequency described in the Prescribing Information
- 6 Document and submit the **Patient Status Form**, confirming that:
 - The patient has been counseled
 - The echocardiogram for the required time interval based on the Prescribing Information has been performed
 - Assessment of drug-drug interactions has been performed
 - Based on the above, it is appropriate to continue treatment
- 7 Promptly report adverse events of heart failure due to systolic dysfunction to Bristol Myers Squibb at 833-628-7367



Healthcare Provider Designees

- Certified healthcare providers can designate members of their staff who are **licensed medical professionals** to be their REMS Designee
- The healthcare provider is responsible for all information entered and activities performed in the CAMZYOS REMS by their designees
- The designee must complete and submit the **Healthcare Provider Designee Enrollment Form** together with the healthcare provider, online through CAMZYOSREMS.com or by fax

Designee Activities

REMS Designees can perform these REMS activities for the certified healthcare provider:

- **Counsel** the patient using the **Patient Brochure** and provide the brochure to the patient
- Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions
- **Enroll** the patient, **confirm** the initial echocardiogram, and **authorize treatment** by completing and submitting the **Patient Enrollment Form**
- Assess the patient's cardiovascular status and the appropriateness of continuing treatment by echocardiograms
- **Complete and submit the Patient Status Form** during treatment

Initial and subsequent prescriptions can only be written by the certified healthcare provider.



Required Patient Counseling by the Healthcare Provider

- Before and during treatment, healthcare providers must use the **Patient Brochure** to counsel their patients on:
 - The risk of heart failure due to systolic dysfunction
 - How to recognize and respond to the symptoms of heart failure due to systolic dysfunction
 - Risk of drug-drug interactions with CYP2C19 or CYP3A4 inhibitors and inducers and the need to inform their healthcare provider of all prescription and over-the-counter medications they take
- Provide the patient with a copy of the **Patient Brochure** to take with them
- After the initial patient counseling, complete the **Patient Enrollment Form** with the patient and submit to the REMS



Timing and Completion of Patient Status Forms

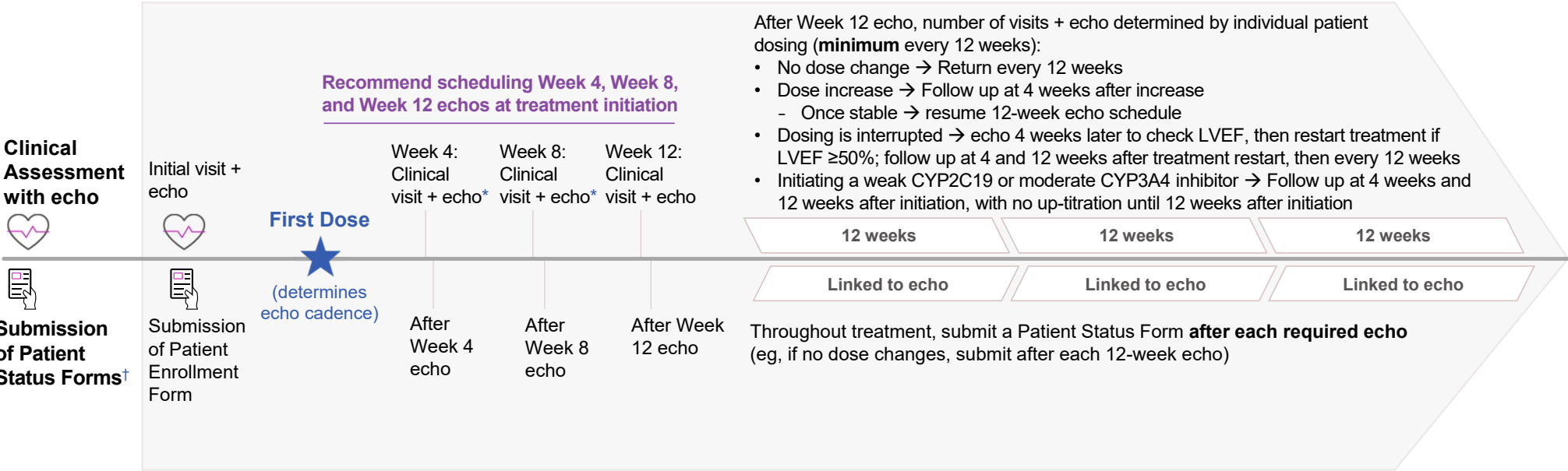
Submission of a **Patient Status Form** to the REMS is required after echocardiograms to confirm that the patient has been counseled, the echocardiogram for the required time interval based on the Prescribing Information has been performed, assessment of drug-drug interactions has been performed, and it is appropriate for the patient to continue treatment with CAMZYOS™

- **Patient Status Forms** include:
 - Confirmation that you have completed the required steps with each submission (see above)
 - The date on which the associated echocardiogram was performed
 - An indication of whether the patient has experienced LVEF <50%
 - An indication of what action was taken with the patient's dose based on this clinical visit
 - An indication of whether the patient has experienced a clinical heart failure event requiring hospitalization
- Submit a **Patient Status Form** as soon as possible but no later than **3 calendar days after the last day of the week that the echocardiogram was due**
- Failure to submit the **Patient Status Form** according to the required schedule may result in dispensing holds and potentially treatment interruptions



Echo Assessments and Patient Status Form Submissions: Year 1

Year 1



*For early clinical response.

[†]Required by the CAMZYOS™ REMS; failure to complete and submit **Patient Status Forms** may lead to interruptions in dosing.

Echo=echocardiogram; LVEF=left ventricular ejection fraction.

Echo Assessments and Patient Status Form Submissions: Year 2 and Beyond



Year 2+

Number of visits + echo determined by individual patient dosing (**minimum** every 12 weeks):

- No dose change → Return every 12 weeks
- Dose increase → Follow up at 4 weeks after increase
 - Once stable → resume 12-week echo schedule
- Dosing is interrupted → echo 4 weeks later to check LVEF, then restart treatment if LVEF ≥50%; follow up at 4 and 12 weeks after treatment restart, then every 12 weeks
- Initiating a weak CYP2C19 or moderate CYP3A4 inhibitor → Follow up at 4 weeks and 12 weeks after initiation, with no up-titration until 12 weeks after initiation

Clinical Assessment with echo



12 weeks

12 weeks

12 weeks

12 weeks

12 weeks



Submission of Patient Status Forms*

Linked to echo

Linked to echo

Linked to echo

Linked to echo

Linked to echo

Throughout treatment, submit a Patient Status Form **after each required echo** (eg, if no dose changes, submit after each 12-week echo)

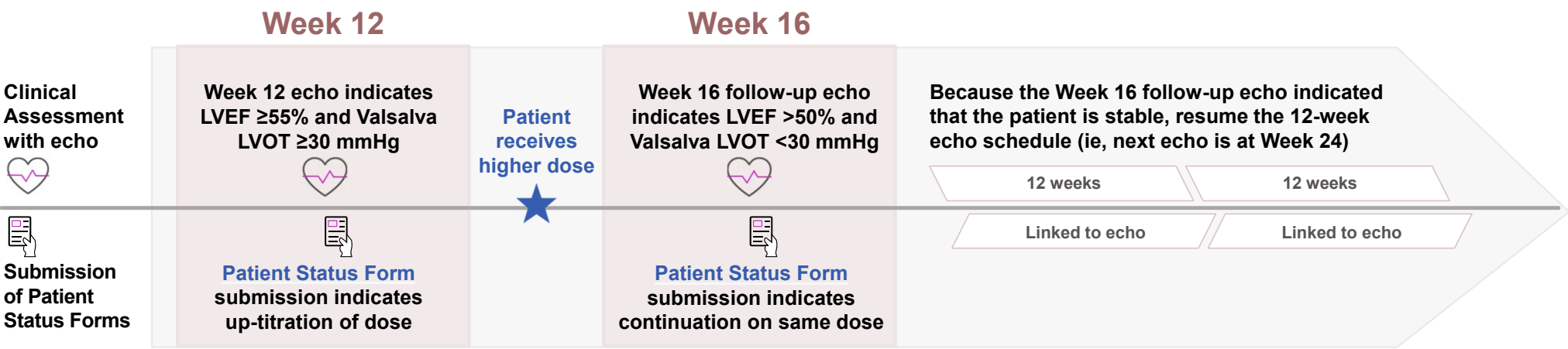
*Required by REMS; failure to complete and submit **Patient Status Forms** may lead to interruptions in dosing.

Echo=echocardiogram; LVEF=left ventricular ejection fraction.



Echo Assessments and Patient Status Form Submissions: Case Scenarios (I)

Scenario 1: Dose increase

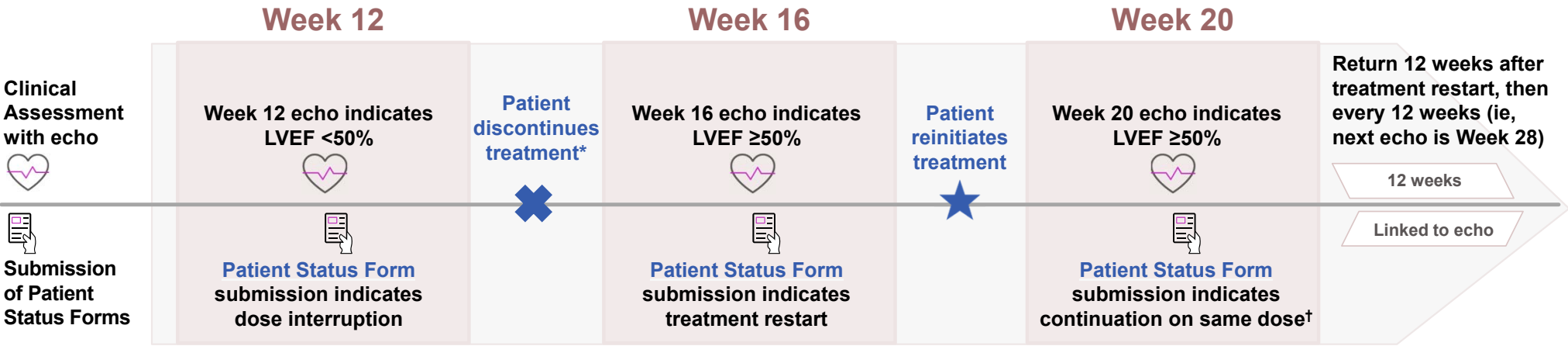


Echo=echocardiogram; LVEF=left ventricular ejection fraction; LVOT=left ventricular outflow tract.



Echo Assessments and Patient Status Form Submissions: Case Scenarios (II)

Scenario 2: Discontinuation due to LVEF <50%



*Permanently discontinue treatment if LVEF <50% twice on 2.5 mg daily (the lowest dose level of CAMZYOS™).

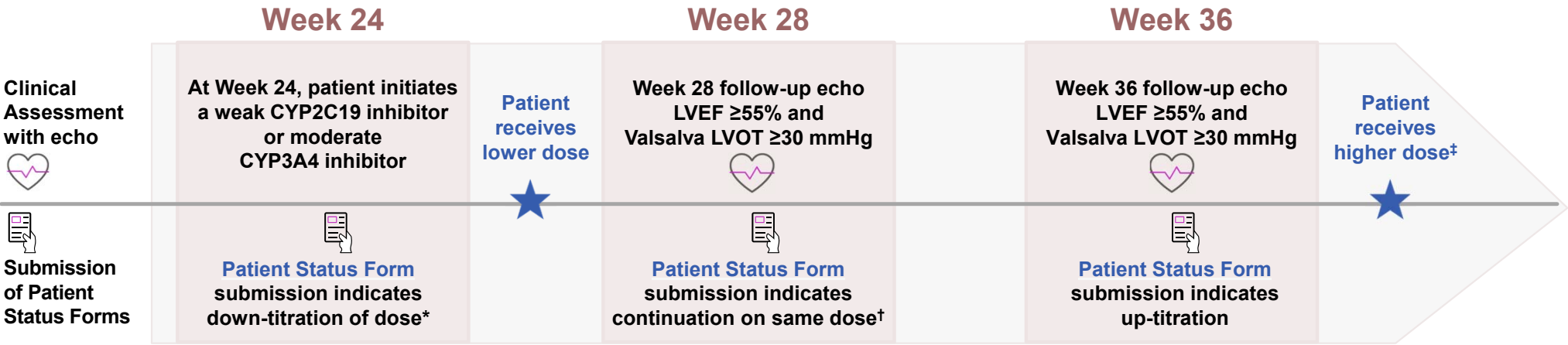
†Maintain the same dose for the next 8 weeks unless LVEF <50%.

Echo=echocardiogram; LVEF=left ventricular ejection fraction; LVOT=left ventricular outflow tract.



Echo Assessments and Patient Status Form Submissions: Case Scenarios (III)

Scenario 3: Initiation of a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor



*Patients who are on CAMZYOS™ therapy and intend to initiate a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor should reduce dose of CAMZYOS by one level (ie, 15 → 10 mg; 10 → 5 mg; or 5 → 2.5 mg). Avoid initiation of concomitant weak CYP2C19 and moderate CYP3A4 inhibitors in patients who are on stable therapy with 2.5 mg of CAMZYOS because a lower dose is not available.

†The patient cannot be up-titrated until 12 weeks after inhibitor initiation.

*Following up-titration, the patient requires a Week 40 follow-up echo; if the patient is stable, resume 12-week echo schedule (ie, next echo is Week 48).

Echo=echocardiogram; LVEF=left ventricular ejection fraction; LVOT=left ventricular outflow tract.



Pharmacy Requirements



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How Does a Pharmacy Become Certified in the CAMZYOS™ REMS?

CAMZYOS can only be dispensed by certified pharmacies.

To become certified to dispense, pharmacies must designate an authorized representative to complete the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.



- 1 Have the authorized representative review the Prescribing Information, the **Program Overview**, and this presentation
- 2 Have the authorized representative successfully complete the **Pharmacy Authorized Representative Knowledge Assessment**
- 3 Have the authorized representative enroll in the REMS on behalf of the pharmacy by completing the **Pharmacy Enrollment Form**
- 4 Submit both the **Knowledge Assessment** and **Enrollment Form** to the CAMZYOS REMS.

Certification can be completed online at CAMZYOSREMS.com or by faxing the **Pharmacy Authorized Representative Knowledge Assessment** and the **Pharmacy Enrollment Form** to the CAMZYOS REMS.

Pharmacies will be notified within 1 business day if they are certified to dispense CAMZYOS.



What Are the Pharmacy Responsibilities?

Authorized Representatives must:

- Train all relevant staff involved in dispensing CAMZYOS using the [Program Overview](#) and this presentation



Pharmacies must:

- Report any adverse events of heart failure due to systolic dysfunction to Bristol Myers Squibb at 833-628-7367
- Not distribute, transfer, loan or sell CAMZYOS except to a certified pharmacy
- Maintain records of dispensing information
- Maintain records documenting completion of the REMS training by relevant staff
- Maintain records that all processes and procedures are in place and being followed
- Have any new representatives enroll in the REMS by successfully completing the [Pharmacy Authorized Representative Knowledge Assessment](#) and completing the [Pharmacy Enrollment Form](#)



What are the Dispensing Requirements for Pharmacies?

Before dispensing CAMZYOS, the certified pharmacy will:



- 1 Counsel the patient on drug-drug interactions
- 2 Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions. Complete and submit the [Drug Interaction and Counseling Checklist for Pharmacies](#) to the CAMZYOS REMS
- 3 Document the prescribed dose
- 4 Obtain authorization to dispense CAMZYOS by contacting the REMS to verify that the:
 - Prescriber is certified and the patient is enrolled
 - Healthcare provider has authorized the patient to receive the drug, the patient was counseled, and the pharmacy identified and resolved any drug-drug interactions



With each dispense of CAMZYOS:

- 1 Provide a [Patient Brochure](#) with each shipment of CAMZYOS
- 2 Dispense no more than a 35-day supply of CAMZYOS

CAMZYOS must be shipped overnight or dispensed, as applicable within 24 hours of logging a dispense for a patient. All product shipments must ship for next business day or next calendar day delivery.

This concludes the CAMZYOS™ REMS Education Program for Healthcare Providers and Pharmacies

If you are a potential healthcare provider or pharmacist, you will need to successfully complete your respective **Knowledge Assessment** and complete your **Enrollment Form** to become certified in the CAMZYOS REMS.

For more information or to obtain any REMS materials,
visit **CAMZYOSREMS.com** or call **833-628-7367**.



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CAMZYOS™ REMS

Program Overview

This overview describes the requirements of the CAMZYOS REMS and the responsibilities of healthcare providers, pharmacists, and patients.

What is the CAMZYOS REMS?

A **R**isk **E**valuation and **M**itigation **S**trategy (**REMS**) is a strategy to manage known or potential risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure the benefits of a drug outweigh its risks.

Because of the serious risk of heart failure due to systolic dysfunction, CAMZYOS is available only through a restricted program called the CAMZYOS REMS.

CAMZYOS may increase the risk of heart failure due to systolic dysfunction; patients may experience heart failure at any time during treatment with CAMZYOS.

What are the requirements of the CAMZYOS REMS?

In order for patients to receive CAMZYOS, healthcare providers, pharmacies, and patients must comply with the requirements of the CAMZYOS REMS.

CAMZYOS™ REMS

Program Overview

Healthcare Provider Requirements

Only healthcare providers certified in the CAMZYOS REMS are authorized to prescribe CAMZYOS.

Become Certified (One Time)

Before prescribing CAMZYOS:

1. Review the Prescribing Information
2. Review the following educational materials:
 - **Program Overview** (this document)
 - **Education Program for Healthcare Providers and Pharmacies**
3. Successfully complete and submit the following to become certified:
 - **Healthcare Provider Knowledge Assessment**
 - **Healthcare Provider Enrollment Form**
4. Receive confirmation of CAMZYOS REMS certification

Enroll Patients

Before starting each patient on CAMZYOS:

1. Counsel the patient, using the **Patient Brochure**, on the:
 - Risk of heart failure due to systolic dysfunction, including how to recognize and respond to the symptoms of heart failure due to systolic dysfunction
 - Risk of drug-drug interactions with CYP2C19 or CYP3A4 inhibitors and inducers and the need to inform healthcare providers of all the prescription and nonprescription medications they take
2. Provide the patient with the **Patient Brochure**
3. Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram
4. Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions
5. Enroll the patient by completing the **Patient Enrollment Form** together with the patient and documenting and submitting the confirmation of the echocardiogram, screening for drug-drug interactions, and authorization for treatment to the REMS

Phone: 833-628-7367
Fax: 833-299-9539
CAMZYOSREMS.com

CAMZYOS™ REMS

Program Overview

Healthcare Provider Requirements (continued)

At All Times for Each Patient

Once the patient is on CAMZYOS:

1. Counsel the patient on the risk of heart failure due to systolic dysfunction and drug-drug interactions with CYP2C19 and CYP3A4 inhibitors and inducers, and the related safe-use requirements using the [Patient Brochure](#)
2. Assess the patient's cardiovascular status, including obtaining echocardiograms at the frequency described in the Prescribing Information:
 - i. 4, 8, and 12 weeks after treatment initiation, then every 12 weeks thereafter
 - ii. 4 weeks after interruption of treatment
 - iii. 4 and 12 weeks after any dose change (including restart of treatment)
 - iv. 4 and 12 weeks after initiating a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor
3. Assess the patient's current prescription and nonprescription medications and supplements for drug-drug interactions
4. Complete, sign, and submit a [Patient Status Form](#) to the CAMZYOS REMS, documenting that the patient has been counseled, the echocardiogram for the required time interval based on the Prescribing Information has been performed, assessment of drug-drug interactions has been performed, and it is appropriate for the patient to continue treatment
5. Report adverse events of heart failure due to systolic dysfunction to Bristol Myers Squibb at 833-628-7367

The CAMZYOS REMS will send reminders to the certified healthcare provider to submit the [Patient Status Form](#). Completed forms should be submitted to the CAMZYOS REMS online at CAMZYOSREMS.com or via fax to 833-299-9539.

Failure to submit the [Patient Status Form](#) at the required intervals could result in a delay in dispensing of CAMZYOS to the patient.

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CAMZYOS™ REMS

Program Overview

Pharmacy Requirements

Only pharmacies certified in the CAMZYOS REMS can dispense CAMZYOS.

Become Certified

Before dispensing CAMZYOS:

1. Designate an authorized representative to complete the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy
2. Have the authorized representative review the following educational materials:
 - Prescribing Information
 - [Education Program for Healthcare Providers and Pharmacies](#)
 - [Program Overview](#) (this document)
3. Have the authorized representative successfully complete the [Pharmacy Authorized Representative Knowledge Assessment](#) and submit it to the REMS
4. Have the authorized representative enroll the pharmacy by completing the [Pharmacy Enrollment Form](#) and submitting it to the REMS
5. Train all relevant staff involved in dispensing CAMZYOS using the [Program Overview](#) and the [Education Program for Healthcare Providers and Pharmacies](#)
6. Establish processes and procedures to comply with the CAMZYOS REMS

Ensure Compliance With the CAMZYOS REMS Requirements

When dispensing CAMZYOS:

1. Counsel the patient on drug-drug interactions
2. Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions. Document and submit to the REMS using the [Drug Interaction and Counseling Checklist for Pharmacies](#)
3. Document the prescribed dose
4. Obtain authorization to dispense each prescription by contacting the REMS to verify that the:
 - Prescriber is certified and the patient is enrolled
 - Healthcare provider has authorized the patient to receive the drug, the patient was counseled, and the pharmacy identified and resolved any drug-drug interactions
5. Provide a [Patient Brochure](#) with each shipment of CAMZYOS
6. Dispense no more than a 35-day supply of CAMZYOS
7. If the authorized representative of the pharmacy changes, have the new representative enroll in the REMS by successfully completing the [Pharmacy Authorized Representative Knowledge Assessment](#) and completing the [Pharmacy Enrollment Form](#)
8. Report adverse events of heart failure due to systolic dysfunction to Bristol Myers Squibb at 833-628-7367
9. Do not distribute, transfer, loan, or sell CAMZYOS, except to a certified pharmacy
10. Maintain records of dispensing information
11. Maintain records documenting completion of the REMS training by relevant staff
12. Maintain records that all processes and procedures are in place and are being followed
13. Comply with audits conducted by MyoKardia, Inc. or a third party acting on behalf of MyoKardia, Inc. to ensure that all processes and procedures are in place and are being followed

CAMZYOS is not available to all pharmacies. If you have questions about the CAMZYOS REMS or how to obtain CAMZYOS, call 833-628-7367.

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Fax: 833-299-9539
CAMZYOSREMS.com

CAMZYOS™ REMS

Program Overview

Patient Requirements

Only patients enrolled in the CAMZYOS REMS can receive CAMZYOS.

Become Enrolled

Before starting CAMZYOS:

1. Receive counseling from the healthcare provider, using the [Patient Brochure](#), on the:
 - a. Risk of heart failure due to systolic dysfunction (when the heart is unable to pump enough blood to the body)
 - b. Risk of drug-drug interactions and the need to inform healthcare providers of all prescription and over-the-counter medicines and supplements they take
2. Get an echocardiogram to check their heart
3. Enroll in the REMS by completing the [Patient Enrollment Form](#) with the healthcare provider. Enrollment information will be provided to the REMS

At All Times

After starting CAMZYOS:

1. Receive counseling from the healthcare provider on the:
 - a. Risk of heart failure due to systolic dysfunction
 - b. Risk of drug-drug interactions and the need to inform healthcare providers of all prescription and over-the-counter medicines and supplements they take
2. Get echocardiograms to check their heart
3. Inform their healthcare providers or seek other medical attention if there are new or worsening symptoms of heart failure
4. Inform their healthcare providers about their treatment with CAMZYOS
5. Inform their healthcare providers of all concomitant products, including over-the-counter medicines and supplements. Patients must be advised not to take medicines contraindicated with CAMZYOS
6. Review all prescription and over-the-counter medicines and supplements with their healthcare provider and pharmacist

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CAMZYOS™ REMS

Program Overview

Resources

The resources listed below are available for download at CAMZYOSREMS.com.

Healthcare Provider	Pharmacy	Patient
• Prescribing Information • Program Overview • Education Program for Healthcare Providers and Pharmacies • Healthcare Provider Knowledge Assessment • Healthcare Provider Enrollment Form • Patient Status Form • Healthcare Provider Designee Enrollment Form	• Prescribing Information • Program Overview • Education Program for Healthcare Providers and Pharmacies • Pharmacy Authorized Representative Knowledge Assessment • Pharmacy Enrollment Form • Drug Interaction and Counseling Checklist for Pharmacies	• Medication Guide • Patient Brochure • Patient Enrollment Form

For more information about the CAMZYOS REMS, visit CAMZYOSREMS.com or call the CAMZYOS REMS at 833-628-7367.

Please see Important Safety Information, including **Boxed WARNING**, and US Full Prescribing Information for CAMZYOS [here](#).

CAMZYOS™ REMS

Healthcare Provider Knowledge Assessment

Instructions:

- Complete and submit this *Healthcare Provider Knowledge Assessment* to the REMS:
 - Online at **CAMZYOSREMS.com**, or
 - Print and fax the form to the CAMZYOS REMS at 833-299-9539
 - To complete certification, enroll in the REMS by completing and submitting the *Healthcare Provider Enrollment Form*
- Complete all required fields on this form to avoid a delay in the enrollment process. You will be notified by email of the status of your certification within 1 business day once the *Healthcare Provider Enrollment Form* has also been submitted.

Healthcare Provider Information (Fields marked * are REQUIRED)		
*First Name:	Middle Initial:	*Last Name:
*Healthcare Provider NPI #:		
*Phone: _____ Area Code/Telephone Number	*Fax: _____ Area Code/Fax Number	
*Email:		

For Questions 1–10, select the correct answer. All questions must be answered correctly.

Question 1

The risk being mitigated in the CAMZYOS REMS is:

- ☐ A. Liver function test elevations (>3 times the upper limit of normal)
- ☐ B. Neutropenia
- ☐ C. Heart failure due to systolic dysfunction
- ☐ D. Severe skin reactions

Question 2

Which of the following **is** an objective of the CAMZYOS REMS?

- ☐ A. Monitor for detection of heart failure due to systolic dysfunction with periodic echocardiograms
- ☐ B. Reduce liver toxicity caused by CAMZYOS
- ☐ C. Screen for drug interactions prior to each dispense
- ☐ D. Options A and B only
- ☐ E. Options A and C only
- ☐ F. None of the above

Question 3

What is the recommended starting dose of CAMZYOS?

- ☐ A. 2.5 mg once daily
- ☐ B. 5 mg once daily
- ☐ C. 10 mg every other day



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CAMZYOS™ REMS

Healthcare Provider Knowledge Assessment

Question 4

Prior to and during treatment with CAMZYOS, each individual patient needs to receive counseling from their healthcare provider, using the **Patient Brochure**, on:

- ☐ A. The risk of drug-drug interactions with CYP2C19 or CYP3A4 inhibitors and inducers
- ☐ B. The risk of heart failure due to systolic dysfunction
- ☐ C. How to recognize and respond to the symptoms of heart failure due to systolic dysfunction
- ☐ D. The need to inform healthcare providers of all the prescription and nonprescription medications they take
- ☐ E. The need for echocardiograms during treatment with CAMZYOS
- ☐ F. All of the above

Question 5

Echocardiograms are required at each of the following time points while on CAMZYOS, **except**:

- ☐ A. Prior to initiation of treatment
- ☐ B. 4 weeks after initiation of treatment
- ☐ C. 8 weeks after initiation of treatment
- ☐ D. 12 weeks after initiation of treatment
- ☐ E. Every 6 months in the second year
- ☐ F. 4 weeks after a dose increase or decrease

Question 6

Patients can elect not to enroll in the REMS and still receive treatment with CAMZYOS.

- ☐ A. TRUE
- ☐ B. FALSE

Question 7

A prescription for CAMZYOS must be sent to a certified pharmacy to be dispensed. Pharmacies certified in the REMS can dispense CAMZYOS.

- ☐ A. TRUE
- ☐ B. FALSE

Question 8

If during treatment with CAMZYOS a patient has an LVEF <50%, the following step(s) should be followed:

- ☐ A. Treatment should be interrupted for 4 weeks
- ☐ B. Echocardiogram should be repeated after 4 weeks
- ☐ C. Once LVEF is ≥50%, treatment may be reinitiated at the next lower dose level
- ☐ D. All of the above

Question 9

In order for patients to continue treatment with CAMZYOS, the healthcare provider or designee is required to submit a **Patient Status Form** after each required echocardiogram.

- ☐ A. TRUE
- ☐ B. FALSE

Question 10

If a patient must begin to use a moderate CYP3A4 or a weak CYP2C19 inhibitor during CAMZYOS therapy, what must occur?

- ☐ A. CAMZYOS must be discontinued
- ☐ B. The dose of CAMZYOS must be increased by one level
- ☐ C. The moderate CYP3A4 or weak CYP2C19 inhibitor must be discontinued
- ☐ D. The dose of CAMZYOS must be decreased by one level



For internal use only

CAMZYOS™ REMS Patient Brochure



CAMZYOS™
(mavacamten)^{2.5, 5, 10, 15mg}
capsules

What Is CAMZYOS™?

CAMZYOS is a prescription medicine used to treat adult patients with symptomatic obstructive hypertrophic cardiomyopathy, a heart condition.

What Is the Most Serious Risk of Treatment With CAMZYOS?

In some patients, CAMZYOS can cause heart failure due to systolic dysfunction, when the heart is unable to pump enough blood to the body.

Tell your healthcare provider right away if you have new or worsening symptoms of heart failure while taking CAMZYOS. If you cannot reach your healthcare provider, seek urgent or emergency healthcare right away.

Symptoms of heart failure include:

- Shortness of breath
- Chest pain
- Fatigue
- A racing sensation in your heart (palpitations)
- Swelling in your legs
- Rapid weight gain

Drug Interactions

The risk of heart failure can increase for people who are taking certain medicines or supplements with CAMZYOS. These medicines can affect the amount of CAMZYOS in their blood. Your healthcare provider will discuss these interactions with CAMZYOS, including examples of which over-the-counter medicines and supplements to avoid.

Tell your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements, even if you don't take them every day. Do not start taking a new medicine, stop existing medicines, or change the dose of any of your medicines without talking to your healthcare provider. CAMZYOS and other medicines may affect each other, causing side effects.

What Do I Need to Do to Take CAMZYOS?

Before Taking CAMZYOS

1. **Receive and review** this brochure with your healthcare provider and ask any questions you may have.
2. **Discuss** with your healthcare provider and understand the:
 - Risk of heart failure due to systolic dysfunction, when your heart is unable to pump enough blood to the body

- Symptoms of heart failure
- Need to report new or worsening symptoms of heart failure to your healthcare provider or to seek other medical attention
- Risks of CAMZYOS interacting with other medicines, including over-the-counter medicines and supplements
- Need to get regular echocardiograms

3. **Tell** your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements.
 - Do not start taking a new medicine or change the dose of any of your medicines without talking to your healthcare provider
 - On the next page are **some examples** of medicines and supplements that can affect the amount of CAMZYOS in your blood and that should be avoided. These examples are a guide and not a complete list of all possible drugs that may fit this category
 4. **Get** an echocardiogram to see if you are eligible for treatment with CAMZYOS.
 5. **Complete** the [Patient Enrollment Form](#) with your healthcare provider.
- While Taking CAMZYOS**
6. **Get** regular echocardiograms as directed on the next page. Your healthcare provider will decide if your CAMZYOS dose needs to be changed. If you do not get these echocardiograms, you will not be able to continue to receive CAMZYOS.

Where Will I Get My CAMZYOS Medicine?

CAMZYOS is only dispensed by pharmacies that participate in the REMS. CAMZYOS is not available through local retail pharmacies.

The pharmacy will contact you to fill your prescription and ship it to your home.

Be sure to tell the pharmacist about any new medicine or changes in the dose of the medicines you are taking, including over-the-counter medicines and supplements.

Phone: 833-628-7367
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CAMZYOSREMS.com

Examples of Drug Interactions for CAMZYOS

Over-the-counter

Grapefruit juice	Prilosec (omeprazole)	Tagamet (cimetidine)
Nexium (esomeprazole)	St. John's wort	

Prescription

Biaxin (clarithromycin)	Ketek (telithromycin)	Norvir (ritonavir)	Tagamet (cimetidine)
Boceprevir	Luminal (phenobarbital)	Noxafil (posaconazole)	Tegretol (carbamazepine)
Diflucan (fluconazole)	Luvox (fluvoxamine)	Prilosec (omeprazole)	Ticlid (ticlopidine)
Dilantin (phenytoin)	Lysodren (mitotane)	Prozac (fluoxetine)	Tracleer (bosentan)
Erleada (apalutamide)	Mysoline (primidone)	Rifadin (rifampin)	Vfend (voriconazole)
Felbatol (felbamate)	Nefazodone	Sporanox (itraconazole)	Viracept (nelfinavir)
Incivek (telaprevir)	Nexium (esomeprazole)	Sustiva (efavirenz)	Xtandi (enzalutamide)
Intelence (etravirine)	Nizoral (ketoconazole)	Tao (troleandomycin)	Zydelig (idelalisib)

Echocardiogram Requirements for CAMZYOS



Before
treatment
starts



At 4 weeks
after treatment
is started



At 8 weeks
after treatment
is started



At 12 weeks
after treatment
is started



Every 12 weeks
thereafter

Echocardiograms may also be needed:

- 4 weeks after a change in the dose of CAMZYOS
- After a break in treatment (as directed by your healthcare provider)
- 4 weeks and 12 weeks after starting certain medicines that are known to affect CAMZYOS

Your healthcare provider will let you know if these echocardiograms are required.

What Is the CAMZYOS REMS?

A **R**isk **E**valuation and **M**itigation **S**trategy (**REMS**) is a drug safety program that the US Food and Drug Administration (FDA) can require for certain medicines to ensure they are used safely. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are greater than the risks. FDA must approve these steps as part of the REMS.

CAMZYOS has a REMS because of the risk of heart failure due to systolic dysfunction.

Where Can I Get More Information on CAMZYOS?

You can find additional information at [CAMZYOSREMS.com](https://www.camzyosrems.com) or call CAMZYOS REMS at 833-628-7367.

CAMZYOS™ REMS

Pharmacy Authorized Representative Knowledge Assessment

Instructions:

1. Complete and submit this **Pharmacy Authorized Representative Knowledge Assessment** to the REMS:

- ▶ Online at **CAMZYOSREMS.com**, or
- ▶ Print and fax the form to the CAMZYOS REMS at 833-299-9539

2. To complete certification, enroll in the REMS by completing and submitting the **Pharmacy Enrollment Form**

Complete all required fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS will notify you of your successful certification within 1 business day.

Pharmacy Authorized Representative Information (Fields marked * are REQUIRED)		
*First Name:	Middle Initial:	*Last Name:
*Title:		
*Pharmacy NPI #:		
*Pharmacy Name:		
*Phone: Area Code/Telephone Number	*Fax: Area Code/Fax Number	
*Email:		



CAMZYOS™ REMS

Pharmacy Authorized Representative Knowledge Assessment

For Questions 1–10, select the correct answer. All questions must be answered correctly.

Question 1

The risk being mitigated in the CAMZYOS REMS is:

- ☐ A. Liver function test elevations (>3 times upper limit of normal)
- ☐ B. Neutropenia
- ☐ C. Heart failure due to systolic dysfunction
- ☐ D. Severe skin reactions

Question 2

Which of the following **are** objectives of the CAMZYOS REMS?

- ☐ A. Monitor for detection of heart failure due to systolic dysfunction with periodic echocardiograms
- ☐ B. Reduce liver toxicity caused by CAMZYOS
- ☐ C. Screen for drug interactions prior to each dispense
- ☐ D. Options A and B only
- ☐ E. Options A and C only

Question 3

What is the recommended starting dose of CAMZYOS?

- ☐ A. 2.5 mg once daily
- ☐ B. 5 mg once daily
- ☐ C. 10 mg every other day

Question 4

With every prescription of CAMZYOS dispensed, the pharmacy needs to:

- ☐ A. Obtain authorization to dispense CAMZYOS
- ☐ B. Document the prescribed dose on the CAMZYOS REMS website or by calling the REMS Call Center
- ☐ C. Complete and submit the ***Drug Interaction and Counseling Checklist for Pharmacies*** to the REMS
- ☐ D. Provide the ***Patient Brochure*** with each shipment of CAMZYOS
- ☐ E. All of the above

Question 5

If the authorized representative of the pharmacy changes, the new representative needs to enroll in the CAMZYOS REMS.

- ☐ A. TRUE
- ☐ B. FALSE

Question 6

Patients can elect not to enroll in the REMS and still receive treatment with CAMZYOS.

- ☐ A. TRUE
- ☐ B. FALSE



CAMZYOS™ REMS

Pharmacy Authorized Representative Knowledge Assessment

Question 7

All of the following must be completed as part of the *Drug Interaction and Counseling Checklist for Pharmacies*:

- ☐ A. Review and document prescription and nonprescription medications and supplements with the patient
- ☐ B. Instruct the patient to contact their healthcare provider if new or worsening symptoms of heart failure occur
- ☐ C. Counsel the patient to notify their healthcare provider and pharmacist prior to starting any new prescription or nonprescription medications or supplements
- ☐ D. Options A and B
- ☐ E. All of the above

Question 8

A certified pharmacy may dispense up to how many days' supply of CAMZYOS?

- ☐ A. 14
- ☐ B. 35
- ☐ C. 95
- ☐ D. 120

Question 9

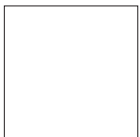
The pharmacist needs to verify which of the following to obtain authorization for the **first** dispense of CAMZYOS:

- ☐ A. The prescriber is certified in the CAMZYOS REMS
- ☐ B. The patient is enrolled in the CAMZYOS REMS
- ☐ C. The *Drug Interaction and Counseling Checklist for Pharmacies* has been completed and submitted to the CAMZYOS REMS
- ☐ D. The patient has completed a liver function test
- ☐ E. Options A, B, and C

Question 10

Which of the following are contraindications for CAMZYOS?

- ☐ A. Concomitant use of moderate to strong CYP2C19 inhibitors
- ☐ B. Concomitant use of moderate to strong CYP2C19 inducers
- ☐ C. Concomitant use of strong CYP3A4 inhibitors
- ☐ D. Concomitant use of moderate to strong CYP3A4 inducers
- ☐ E. Options A and C only
- ☐ F. All of the above



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CAMZYOS™ REMS Patient Status Form

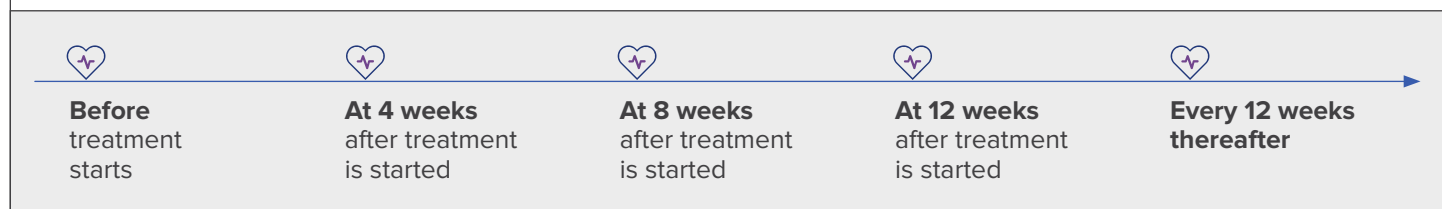
To Be Completed by a Certified Healthcare Provider or a Designee

Submit this form to the CAMZYOS REMS after each required echocardiogram based on the **Prescribing Information**.

- ▶ Complete the form online at **CAMZYOSREMS.com**, or
- ▶ Print and fax the completed form to the CAMZYOS REMS at 833-299-9539

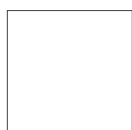
This form must be submitted in its entirety on the appropriate REMS program schedule in order for your patient to receive CAMZYOS. Failure to submit the Patient Status Form may result in dispensing holds and potentially treatment interruptions.

Echocardiograms must be done:



Alternative echocardiogram schedules may be implemented based on the below scenarios.

- With any dose change:
 - Perform an echocardiogram 4 weeks later
 - Resume monitoring per the **Prescribing Information**
- With any treatment discontinuation due to LVEF <50%, perform an echocardiogram 4 weeks later
 - If treatment is reinitiated, perform an echocardiogram 4 and 12 weeks later
 - Continue performing echocardiograms every 12 weeks thereafter
- With initiation of a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor:
 - Perform an echocardiogram 4 weeks after initiation
 - Perform an echocardiogram 12 weeks after initiation
 - Continue performing echocardiograms every 12 weeks thereafter



CAMZYOS™ REMS

Patient Status Form

Patient Information

(Fields marked * are REQUIRED)

*Patient First Name:	Middle Initial:	*Last Name:
*Birthdate (MM/DD/YYYY):		Phone: _____ Area Code/Telephone Number

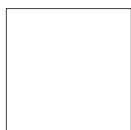
Healthcare Provider Information

(Fields marked * are REQUIRED)

*Healthcare Provider First Name:	*Last Name:
*Healthcare Provider NPI #:	*Phone: _____ Area Code/Telephone Number
*Fax: _____ Area Code/Fax Number	*Email:

*Healthcare Provider Agreement

- ☐ I acknowledge that I have counseled the patient on the:
- Risk of heart failure due to systolic dysfunction, including how to recognize and respond to the symptoms of heart failure due to systolic dysfunction
 - Risk of drug-drug interactions with CYP2C19 and CYP3A4 inhibitors and inducers and the need to inform healthcare providers of all the prescription and nonprescription medication they take
- ☐ I acknowledge that the **Prescribing Information** states that the patient should receive echocardiograms.
- ☐ I acknowledge that I have assessed the patient's prescription and nonprescription medications and supplements for drug-drug interactions.



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CAMZYOS™ REMS

Patient Status Form

*Patient Monitoring

1. I have reviewed the patient's echocardiogram report (Echo Performed Date: _____).
☐ Yes ☐ No (If no, the patient cannot receive CAMZYOS) Month/Day/Year
2. What is the patient's VLVOT?
☐ <20 mmHg ☐ ≥20 mmHg and <30 mmHg ☐ ≥30 mmHg
3. Did the patient experience a decrease in LVEF to <50%?
☐ Yes (If yes, CAMZYOS therapy must be interrupted) ☐ No
4. For this clinical visit, what action was taken with the patient's dose of CAMZYOS?
☐ No change ☐ Dose decrease ☐ Dose increase ☐ Dose interruption
5. Did the patient experience a clinical heart failure event requiring hospitalization?
☐ Yes ☐ No
6. After review of the patient's prescription and nonprescription medications and supplements, does the patient require a dose adjustment due to a potential drug-drug interaction?
☐ Yes ☐ No
7. Is the patient authorized to continue treatment?
☐ Yes ☐ No

*Healthcare Provider

or Designee Signature: _____ *Date: _____
Month/Day/Year

Print Name: _____

Note: A CAMZYOS REMS–certified healthcare provider or healthcare provider designee may complete and submit this form on behalf of the certified healthcare provider of record. The certified healthcare provider of record is responsible for compliance with the REMS requirements, including monitoring, evaluation, and management of each patient under his/her care.

If you have questions about the REMS, please call the CAMZYOS REMS Call Center at 833-628-7367, 8:00 AM–8:00 PM ET.

To report SUSPECTED ADVERSE REACTIONS, contact Bristol Myers Squibb at 800-721-5072 and medical.communications@bms.com.



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Phone: 833-628-7367
Fax: 833-299-9539
CAMZYOSREMS.com

CAMZYOS™ REMS

Drug Interaction and Counseling Checklist for Pharmacies

Instructions:

Complete this form prior to each dispense of CAMZYOS. Complete online at CAMZYOSREMS.com or fax the completed form to the CAMZYOS REMS at 833-299-9539. Do not dispense CAMZYOS until the authorization to dispense is received.

Step 1:

Patient Information (Fields marked * are REQUIRED)		
*First Name:	Middle Initial:	*Last Name:
*Date of Birth: Month/Day/Year		

Healthcare Provider Information (Fields marked * are REQUIRED)	
*First Name:	*Last Name:
NPI #:	Phone: Area Code/Telephone Number

Pharmacy Information (Fields marked * are REQUIRED)			
*Pharmacy Name:	*Pharmacy NPI #:		
*Pharmacy Address:	*City:	*State:	*ZIP Code:
Phone: Area Code/Telephone Number			

This is a: ☐ New prescription ☐ Refill at the same dose ☐ Restart after temporary interruption ☐ Dose increase ☐ Dose decrease (rationale): ☐ LVEF <50% ☐ VLVOT <20 mmHg ☐ Drug interaction ☐ Other not listed on <i>Patient Status Form</i>



CAMZYOS™ REMS

Drug Interaction and Counseling Checklist for Pharmacies

Step 2: Drug Interaction Screening

- ☐ I have reviewed the patient's current medical conditions for which they are under a healthcare provider's care.
List current medical conditions for which they are under a healthcare provider's care.

- ☐ I have reviewed with the patient their current prescription and nonprescription medications and supplements.
List the current prescription and nonprescription medications and supplements that the patient is currently taking.

List any new prescription or nonprescription medications or supplements since the last fill of CAMZYOS.
(If this is the first prescription, move to Question 1.)

1. Check ALL current medications and supplements for contraindications. **If contraindicated medication(s) are found, do not fill CAMZYOS and contact the healthcare provider.**

a. Is the patient taking a contraindicated medication? ☐ Yes ☐ No

If yes, please provide the contraindicated medication(s): _____

2. Check for drug interactions that require dose adjustment (moderate CYP3A4 inhibitor or weak CYP2C19 inhibitor).
If found, do not fill CAMZYOS, and contact the healthcare provider for dose adjustment. (Note: patients who are on stable therapy with a moderate CYP3A4 inhibitor or a weak CYP2C19 inhibitor prior to initiating CAMZYOS should initiate CAMZYOS at the recommended 5-mg starting dose)

a. Is the patient taking a medication that requires a dosage adjustment? ☐ Yes ☐ No

If yes, please provide the medication(s) that require(s) a dosage adjustment: _____

3. The interacting medication/supplement was prescribed/recommended by:

- ☐ A CAMZYOS-certified healthcare provider/designee
☐ Other healthcare provider/designee
☐ Purchased over the counter by patient

☐ Contacted healthcare provider via _____ on _____

Month/Day/Year

☐ Action taken for contraindicated medication(s):

☐ CAMZYOS discontinued ☐ Other medication(s) discontinued

☐ Action taken for medication(s) requiring dosage adjustment:

☐ CAMZYOS discontinued ☐ CAMZYOS dose decreased ☐ Other medication(s) discontinued



CAMZYOS™ REMS

Drug Interaction and Counseling Checklist for Pharmacies

Step 3: Counseling

- ☐ I have instructed the patient to notify their healthcare provider of new or worsening symptoms of heart failure such as shortness of breath, chest pain, fatigue, palpitations, leg swelling, and rapid weight gain.
- ☐ I have instructed the patient to notify their healthcare provider and pharmacy prior to the use of any new prescription or over-the-counter medication or supplement or prior to stopping any medication.

Pharmacist Name: _____ Date: _____
Month/Day/Year

Examples of Drugs Contraindicated With CAMZYOS—DO NOT DISPENSE CAMZYOS*

Moderate to Strong CYP2C19 Inhibitors or Strong CYP3A4 Inhibitors

Biaxin (clarithromycin)	Nexium (esomeprazole)	Serzone (nefazodone)
Boceprevir	Nizoral (ketoconazole)	Sporanox (itraconazole)
Diflucan (fluconazole)	Norvir (ritonavir)	Tao (troleandomycin)
Grapefruit juice	Noxafil (posaconazole)	Ticlid (ticlopidine)
Incivek (telaprevir)	Prilosec (omeprazole)	Vfend (voriconazole)
Ketek (telithromycin)	40 mg once daily	Viracept (nelfinavir)
Luvox (fluvoxamine)	Prozac (fluoxetine)	Zydelig (idelalisib)

Moderate to Strong CYP2C19 Inducers or Moderate to Strong CYP3A4 Inducers

Dilantin (phenytoin)	Norvir (ritonavir)	Tegretol (carbamazepine)
Erleada (apalutamide)	Rifadin (rifampin)	Xtandi (enzalutamide)
Intelence (etravirine)	St. John's wort	
Lysodren (mitotane)	Sustiva (efavirenz)	

Examples of Drugs That Interact With CAMZYOS—Dose of CAMZYOS Must Be Adjusted*

Weak CYP2C19 Inhibitors or Moderate CYP3A4 Inhibitors

Calan (verapamil)	Felbatol (felbamate)	Tagamet (cimetidine)
Cardizem (diltiazem)	Nydrazid (isoniazid)	
Cipro (ciprofloxacin)	Prilosec (omeprazole)	
	20 mg once daily	

*These tables contain select examples and are not comprehensive.



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Fax: 833-299-9539
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CAMZYOS™ REMS: 833-628-7367 Monday-Friday, 8:00 AM-8:00 PM ET

Prescribing Information

Medication Guide

CAMZYOS™

(mavacamten) 2.5, 5, 10, 15mg capsules

REMS

Healthcare Provider Login

Pharmacy Login

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Resources

Welcome to the CAMZYOS™ REMS

(Risk Evaluation and Mitigation Strategy)

Healthcare Providers: Log into the REMS portal to complete certification in the program. Once certified, use the portal to manage REMS tasks and patients, and to enroll a REMS designee.

Healthcare Provider Login

Pharmacies: The Pharmacy Authorized Representative may log into the REMS portal to complete certification. Once certified, use the portal to invite authorized staff members to manage REMS tasks and patients.

Pharmacy Login

NOTE: This portal cannot be opened in Internet Explorer (IE) or the legacy version of Microsoft Edge available before 2020. The portal can be opened in the version of Microsoft Edge available in January 2020. You can also copy and paste the link into a different browser.



Healthcare Providers

Healthcare providers must be certified in the CAMZYOS REMS in order to prescribe CAMZYOS.

Learn About Healthcare Provider Certification



Patients

Patients must be enrolled in the CAMZYOS REMS in order to receive CAMZYOS.

Learn About Patient Enrollment



Pharmacies

Pharmacies must be certified in the CAMZYOS REMS in order to dispense CAMZYOS.

Learn About Pharmacy Certification

A REMS is a strategy to manage known or potential serious risks associated with a drug. It is required by the US Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks. Due to the risk of heart failure due to systolic dysfunction, CAMZYOS is only available through a restricted program called the CAMZYOS REMS.

The objectives of the CAMZYOS REMS are to:

- Monitor for detection of heart failure due to systolic dysfunction with periodic echocardiograms
- Screen for drug interactions prior to each dispense

INDICATION

CAMZYOS is a cardiac myosin inhibitor 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.

Please see full [Prescribing Information](#).

⬆ Back to top

Healthcare providers must report adverse events of heart failure due to systolic dysfunction associated with CAMZYOS at 833-628-7367.

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REMS

Healthcare Provider Login Pharmacy Login

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Healthcare Providers

Log into the REMS portal to complete certification in the program. Once certified, use the portal to manage REMS tasks and patients.

[Healthcare Provider Login](#)

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CAMZYOS™ is only available through the CAMZYOS REMS. In order for healthcare providers to prescribe CAMZYOS, they must become certified in the REMS.

To become certified in the CAMZYOS REMS, healthcare providers must:

1. Complete the CAMZYOS REMS training program, which includes reviewing the following materials:

[Prescribing Information](#)

[Program Overview](#)

[Education Program for Healthcare Providers and Pharmacies](#)

2. Successfully complete the [Healthcare Provider Knowledge Assessment](#) and submit it to the REMS.

[Online](#) OR by [printing and faxing](#) to 833-299-9539

3. Enroll by completing the [Healthcare Provider Enrollment Form](#) and submitting it to the REMS.

[Online](#) OR by [printing and faxing](#) to 833-299-9539



The CAMZYOS REMS will send confirmation of your enrollment in the CAMZYOS REMS. You will not be able to prescribe CAMZYOS without completing your certification in the CAMZYOS REMS. If you fail to comply with the CAMZYOS REMS requirements, you will no longer be certified in the CAMZYOS REMS.

Patient Management



Counseling before treatment:

Counsel the patient, using the [Patient Brochure](#), on the:

- Risk of heart failure due to systolic dysfunction, including how to recognize and respond to the symptoms of heart failure due to systolic dysfunction
- Risk of drug-drug interactions with CYP2C19 and CYP3A4 inhibitors and inducers and the need to inform healthcare providers of all the prescription and nonprescription medications they take

Provide the patient with the [Patient Brochure](#).



Assessments before treatment:

Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Additionally, assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions. Document confirmation of an echocardiogram, assessment of drug-drug interactions, and authorization for treatment using the [Patient Enrollment Form](#). Enroll the patient by completing and submitting the [Patient Enrollment Form](#) to the REMS. Retain a copy for the patient's medical record.



During treatment:

- Assess the patient's cardiovascular status and the appropriateness of continuing treatment by obtaining echocardiograms at the frequency described in the [Prescribing Information](#)
- Counsel the patient as described above
- Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions

Document and submit that the patient has been counseled, the echocardiogram has been performed, the patient's medications have been assessed for drug-drug interactions, and it is appropriate to continue treatment using the [Patient Status Form](#).



At all times:

Report any adverse events of heart failure due to systolic dysfunction, including full details of the patient's medical status and dose of CAMZYOS at the time of the event, to Bristol Myers Squibb

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REMS

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Pharmacies

The Pharmacy Authorized Representative may log into the REMS portal to complete certification. Once certified, use the portal to invite authorized staff members to manage REMS tasks and patients.

[Pharmacy Login](#)

NOTE: This portal cannot be opened in Internet Explorer (IE) or the legacy version of Microsoft Edge available before 2020. The portal can be opened in the version of Microsoft Edge available in January 2020. You can also copy and paste the link into a different browser.

To become certified in the CAMZYOS™ REMS, pharmacies must:

1. Designate an authorized representative to complete the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.

2. Have the authorized representative do the following:

- A. Complete the CAMZYOS REMS training program, which includes reviewing the following materials:



[Prescribing Information](#)



[Program Overview](#)



[Education Program for Healthcare Providers and Pharmacies](#)

- B. Successfully complete the [Pharmacy Authorized Representative Knowledge Assessment](#) and submit it to the REMS



[Online](#)



by [printing and faxing](#) to 833-299-9539

- C. Enroll in the CAMZYOS REMS on behalf of the pharmacy by completing the [Pharmacy Enrollment Form](#) and submitting it to the REMS



[Online](#)



by [printing and faxing](#) to 833-299-9539

- D. Train all relevant staff involved in dispensing CAMZYOS using the Program Overview and the Education Program for Healthcare Providers and Pharmacies

3. Before dispensing **each dose** of CAMZYOS

- A. Counsel the patient on drug-drug interactions and review all prescription and nonprescription medications and supplements with the patient. Complete and submit the [Drug Interaction and Counseling Checklist for Pharmacies](#) to the REMS
- B. Document the prescribed dose
- C. Obtain authorization to dispense each CAMZYOS prescription by contacting the [CAMZYOS REMS online](#) or calling the REMS Call Center at **833-628-7367** to verify that the:
 - I. Prescriber is certified and the patient is enrolled
 - II. Healthcare provider has authorized the patient to receive the drug, the patient was counseled, and the pharmacy identified and resolved any drug-drug interactions
- D. Provide the patient with the [Patient Brochure](#)

4. Dispense no more than a 35-day supply of CAMZYOS.

5. Report any adverse events of heart failure due to systolic dysfunction to Bristol Myers Squibb.

6. Any time the authorized representative changes, the new authorized representative must:

- A. Successfully complete the [Pharmacy Authorized Representative Knowledge Assessment](#)
- B. Complete and submit the [Pharmacy Enrollment Form](#) to the CAMZYOS REMS to re-certify the pharmacy to dispense



The CAMZYOS REMS will send confirmation of the pharmacy's enrollment in the CAMZYOS REMS. A pharmacy will not be able to dispense CAMZYOS without completing pharmacy certification in the CAMZYOS REMS. If the pharmacy fails to comply with the CAMZYOS REMS requirements, the pharmacy will no longer be certified in the CAMZYOS REMS.

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REMS

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Patients

A **Risk Evaluation and Mitigation Strategy (REMS)** is a drug safety program that the US Food and Drug Administration (FDA) can require for certain medicines to ensure they are used safely. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are greater than the risks. The FDA must approve these steps as part of the REMS.

In some patients, CAMZYOS™ can cause heart failure due to systolic dysfunction, when the heart is unable to pump enough blood to the body. CAMZYOS has a REMS because of the risk of heart failure due to systolic dysfunction.

The risk of heart failure due to systolic dysfunction can increase for people who are taking certain medicines or supplements with CAMZYOS. These medicines can affect the amount of CAMZYOS in their blood. As part of the REMS, your healthcare provider will discuss these interactions with CAMZYOS, including examples of which over-the-counter medicines and supplements to avoid.

Tell your healthcare provider about **all** the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements, even if you don't take them every day. Do not start taking a new medicine, stop taking existing medicines, or change the dose of any of your medicines without talking to your healthcare provider. CAMZYOS and other medicines may affect each other, causing side effects.

To enroll in the CAMZYOS REMS and receive CAMZYOS, you must:

Before taking CAMZYOS:

1. **Receive and review the [Patient Brochure](#).** Your doctor will provide you with a copy of the brochure.
2. **Discuss** with your healthcare provider whether treatment with CAMZYOS is right for you. You should discuss the:
 - Risk of heart failure due to systolic dysfunction, when your heart is unable to pump enough blood to the body
 - Symptoms of heart failure, including shortness of breath, chest pain, fatigue, a racing sensation in your heart (palpitations), swelling in your legs, and rapid weight gain
 - Need to report new or worsening symptoms of heart failure to your healthcare provider or to seek other medical attention
 - Risks of CAMZYOS interacting with other medicines, including over-the-counter medicines and supplements
 - Need to get regular echocardiograms (an echocardiogram is a test that uses sound waves to create pictures of your heart)
3. **Get an echocardiogram** to see if you are eligible for treatment with CAMZYOS.
4. **Complete** the [Patient Enrollment Form](#) with your healthcare provider.

While taking CAMZYOS:

5. **Get echocardiograms** as directed below. Echocardiograms will be done:



Echocardiograms may also be needed:

- 4 weeks after a change in the dose of CAMZYOS
- After a break in treatment (as directed by your healthcare provider)
- 4 weeks and 12 weeks after starting certain medicines that are known to affect CAMZYOS

Your healthcare provider will let you know if these echocardiograms are required.

6. **During treatment**, discuss with your healthcare provider:
 - The risk of heart failure due to systolic dysfunction
 - The symptoms of heart failure
 - The need to report new or worsening symptoms of heart failure to your healthcare provider or to seek other medical attention
 - Any changes to the medicines you take in addition to CAMZYOS, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements
 - The need to get regular echocardiograms
7. **Discuss** with your pharmacist the risks of CAMZYOS interacting with other medicines, including over-the-counter medicines and supplements.

At all times:

8. **Report** new or worsening symptoms of heart failure to your healthcare provider or seek other medical attention.
9. **Let all your healthcare providers and pharmacists know** that you are taking CAMZYOS and all other products you are taking, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements.

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CAMZYOS

CAMZYOS

CAMZYOS[™] REMS: 833-628-7367 Monday-Friday, 8:00 AM-8:00 PM ET

Prescribing Information

Medication Guide

CAMZYOS[™]

(mavacamten) capsules

2.5, 5, 10, 15mg

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Contact Us

REMS Call Center

Phone: 833-628-7367
Fax: 833-299-9539
Email: REMSSupport@bms.com

Adverse Event Reporting

Phone: 800-721-5072
Email: worldwide.safety@bms.com

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Resources

NOTE: Some of the PDF resources below can be edited and Docu-signed to be submitted. Healthcare providers and pharmacies may complete these tasks online via the Healthcare providers and Pharmacy Login.

Healthcare Provider Resources

[Prescribing Information](#) ↓

[Education Program for Healthcare Providers and Pharmacies](#) ↓

[Healthcare Provider Enrollment Form](#) ↓

[Program Overview](#) ↓

[Healthcare Provider Knowledge Assessment](#) ↓

[Patient Status Form](#) ↓

[Healthcare Provider Designee Enrollment Form](#) ↓

Pharmacy Resources

[Prescribing Information](#) ↓

[Education Program for Healthcare Providers and Pharmacies](#) ↓

[Pharmacy Enrollment Form](#) ↓

[Program Overview](#) ↓

[Pharmacy Authorized Representative Knowledge Assessment](#) ↓

[Drug Interaction and Counseling Checklist for Pharmacies](#) ↓

Patient Resources

[Medication Guide](#) ↓

[Patient Brochure](#) ↓

[Patient Enrollment Form](#) ↓

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