

CAMZYOS® REMS Frequently Asked Questions

Table of Contents

Topic Page(s)

REMS HCP Portal 4–8

What email address does the 2-factor authentication code get sent to?

What email address does the 2-factor authentication code come from?

Is there a way to disable the 2-factor authentication code?

What can cause a delay in receiving the 2-factor authentication code?

How can I whitelist email addresses and websites related to REMS communications for pharmacies?

How can I whitelist email addresses and websites related to REMS communications for HCPs?

Where can I find the patient treatment start date?

Why isn't my patient showing up on the Calendar/List View?

How can I disable and enable notifications received from the REMS system?

When a patient is being co-managed by multiple HCPs and/or a different HCP takes over the care of a patient I treated with CAMZYOS, will I still have access to the patient in the HCP Online Portal?

Where can I see my patient's full history and status in the HCP Portal?

How can I see a list of patients whose treatment I have interrupted through the portal?

HCP REMS Certification 9

Who can become certified as a CAMZYOS REMS HCP?

Can multiple HCPs in one clinic cover for one another in the REMS system?

HCP Designees 10–12

Who can be a Designee?

Is there a limit on the number of Designees my practice can have?

How do I remove a Designee from the portal?

Why can't an MA, LVN, or LPN be a Designee?

What can REMS support staff (eq, MAs, LVNs, LPNs, etc) do to assist the HCP with CAMZYOS?

CAMZYOS® REMS Frequently Asked Questions (cont'd)

Table of Contents (cont'd)

Topic Page(s)

HCP Designees (cont'd)

10-12

What can a certified HCP do that a Designee cannot?

I have the authority to write prescriptions as an NP. How can I become a certified HCP?

How am I able to be a Designee for just a few patients on behalf of the HCPs I work with?

CAMZYOS REMS Patient Enrollment

13-16

Do patients that were previously enrolled in a clinical trial need to restart their echocardiogram monitoring?

How do I find a partially enrolled patient?

How old can the baseline echocardiogram be for patient enrollment?

What if the patient does not have an email address to enter on the Patient Enrollment Form?

What if my practice does not know the exact treatment start date?

When enrolling a patient, can I select "Yes" and enter a patient's name on the enrollment form if the patient is not in the office to sign?

How can I see a history of Patient Enrollment Forms?

How do I reactivate a patient after a dose interruption? What are the next steps?

Patient Status Form 17–25

Does the next echocardiogram get scheduled based on when the last one was completed?

I made a mistake when entering the Patient Status Form responses and accidentally submitted it. How can I go back to fix it?

My patient will not start CAMZYOS within a 90-day period. Can my practice still update the start date?

My patient took a break in treatment, and now the Patient Status Form submission schedule is not aligned with their treatment. What can I do to fix it?

When a patient begins treatment with CAMZYOS, what is their initial Patient Status Form submission schedule?

Can you complete an echocardiogram earlier than the Patient Status Form eligible-to-submit date?

How do you submit an ad-hoc or unscheduled Patient Status Form, and what is it used for?

Is a prescription required for CAMZYOS, or will the Patient Status Form submission automatically trigger the pharmacy to dispense?

How long will a Patient Status Form remain overdue when not completed on time?

What responses on the submitted Patient Status Form would cause my patient to become deactivated?

How can I see future Patient Status Form submission due dates so that echocardiograms can be scheduled?

How can I see a history of all submitted Patient Status Forms?



CAMZYOS® REMS Frequently Asked Questions (cont'd)

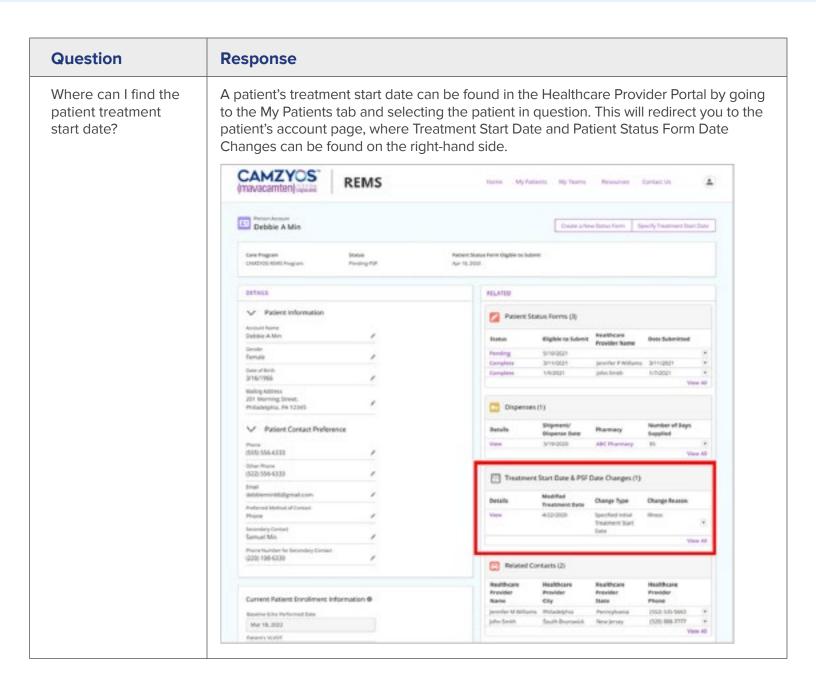
Table of Contents (cont'd)

Topic	Page(s)
Patient Status Form (cont'd)	17–25
How do I update a patient's treatment start date?	
My patient's treatment is going to be interrupted. When should echos be scheduled and how do I reinitiate treatment?	
My patient's dose is changing. How will this impact their current Patient Status Form submission schedule?	
Medication Dispensing	26
When can a pharmacy complete an override for more CAMZYOS? Where can the list of dispensing pharmacies be found? How can I view the dispensing pharmacy for my patient? How much time do I have to submit a Patient Status Form before it is considered overdue? If the pharmacy identifies a DDI, will they contact me directly? How do I know how many days' supply my patient has for every dispense?	
Product Information	27
Who should I contact for information regarding CAMZYOS?	

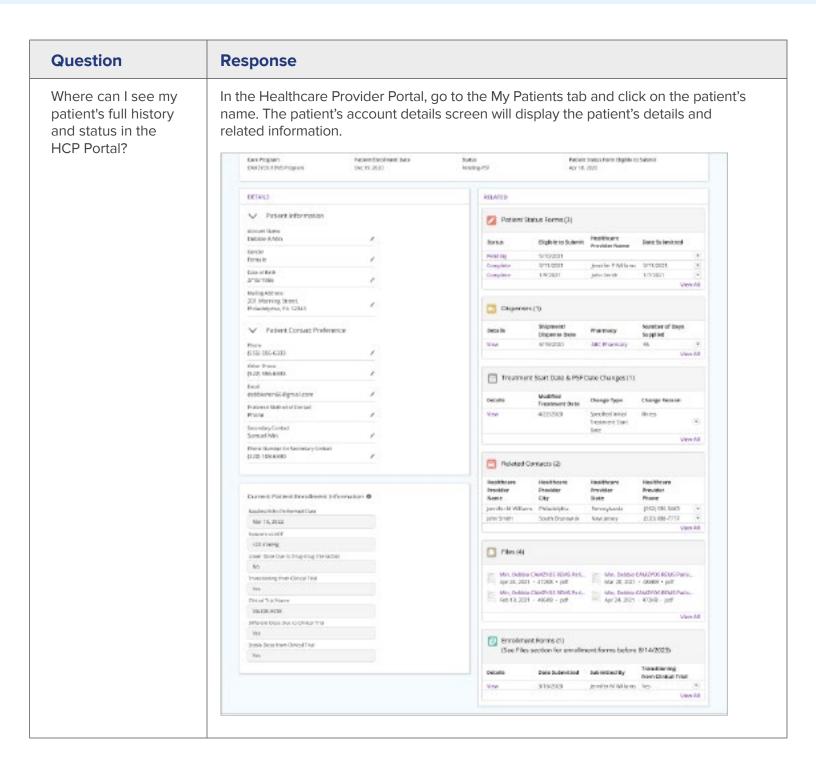
Glossary

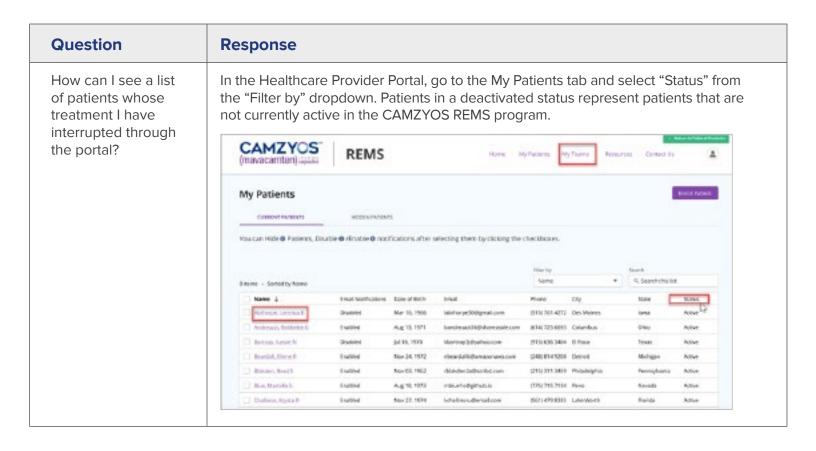
REMS HCP Portal

Question	Response		
What email address does the 2-factor authentication code get sent to?	The verification code is sent to the email address associated with the user's account.		
What email address does the 2-factor authentication code come from?	The email with the 2-factor authentication code comes from noreply@salesforce.com.		
Is there a way to disable the 2-factor authentication code?	The user can elect not to perform the 2-factor authentication in the future by selecting the "Don't ask again" radio button.		
What can cause a delay in receiving the 2-factor authentication code?	The 2-factor authentication code is immediately sent from the CAMZYOS REMS system. Delays in receiving the code may be associated with firewalls, connectivity issues, or recipient server issues. To prevent potential delays related to firewalls, it is recommended that you work with your system administrator to whitelist all email addresses related to REMS communications.		
How can I whitelist email addresses and websites related to REMS communications for pharmacies?	To ensure that you can access the online web portal available for the REMS program, please ensure the following website URLs are not blocked by your system's firewall, and that the email addresses and websites below are listed as a safe sender. • noreply@salesforce.com • REMSSupport@bms.com • https://www.camzyosrems.com • https://camzyosrems.bms.com/pharmacy Should you or IT staff at your site have any questions, please email MG-ACN-MAVREMS-Support@bms.com. They can provide you with further technical details if required.		
How can I whitelist email addresses and websites related to REMS communications for HCPs?	To ensure that you can access the online web portal available for the REMS program, please ensure the following website URLs are not blocked by your system's firewall, and that the email addresses and websites below are listed as a safe sender. • noreply@salesforce.com • REMSSupport@bms.com • https://www.camzyosrems.com • https://camzyosrems.bms.com/prescriber Should you or IT staff at your site have any questions, please email MG-ACN-MAVREMS-Support@bms.com. They can provide you with further technical details if required.		



Question	Response				
Why isn't my patient showing up on the Calendar/List View?	In the Healthcare Provider Portal, there are various reasons a patient may not appear within the Calendar/List View, including:				
Caleflual/List view:	 The patient may have been hidden The patient may have been deactivated The patient may not have a Patient Status Form eligible to submit within the calendar month that you are viewing 				
How can I disable and enable notifications received from the REMS system?	To disable and enable notifications, you can select the checkbox next to the applicable patient listed on the My Patients tab in the Healthcare Provider Portal. Then select Ena Notifications or Disable Notifications. When disabling notifications, a pop-up box will appear to confirm your request; you must click the checkbox acknowledgment, then cl on Disable Notifications.				
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When a patient is being co-managed by multiple HCPs and/or a different HCP takes over the care of a patient I treated with CAMZYOS, will I still have access to the patient in the HCP Online Portal?	Yes, you will have access to the patient in the "My Patients" tab. If you wish to no longe see the patient on your Calendar/List View on the Home page or the My Patients tab, you may hide the patient by clicking on the checkbox next to the patient's name followed by the Hide Patients button. You will no longer receive email reminders for Patient Status Forms when a patient is hidden.				





HCP REMS Certification

Question	Response						
Who can become certified as a CAMZYOS REMS HCP?	To become a certified HCP in the CAMZYOS REMS, you must be a licensed HCP with prescriptive authority (eg, MD, DO, NP, PA, etc).						
Can multiple HCPs in one clinic cover for one another in the REMS system?	Yes, each HCP will need to invite the other as a Designee from the My Teams tab on the Healthcare Provider Portal. Once the HCP accepts the invitation, they will be able see each other's patients in the My Patients tab.						
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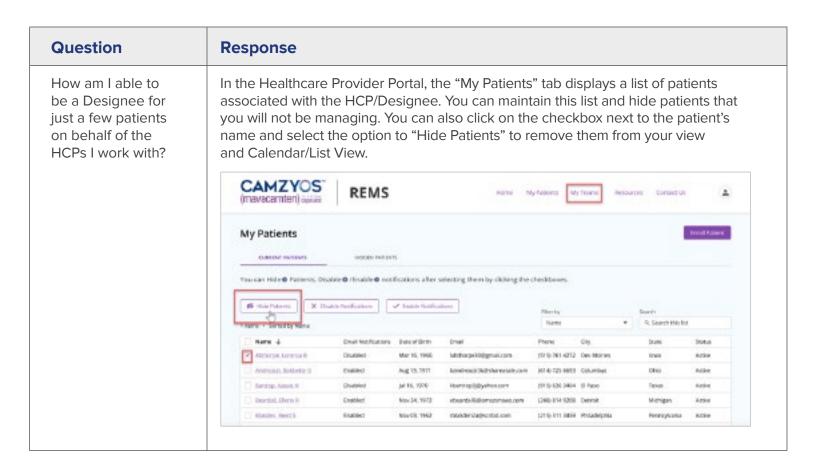
HCP Designees

Question	Response		
Who can be a Designee?	REMS Designees must be licensed medical professionals (RPh/PharmD, RN, NP, PA) on staff of the certified HCP. They must complete and submit the Healthcare Provider Designee Enrollment Form together with the HCP online through https://camzyosrems.bms.com/prescriber .		
Is there a limit on the number of Designees my practice can have?	Currently, there is no limit to the number of Designees for a certified HCP.		
How do I remove a Designee from the portal?	To remove a Designee from the portal, select the My Teams tab and select Deactivate from the drop-down menu to the right of the Designee's name to remove the association.		
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HCP Designees (cont'd)

Question	Response
Why can't an MA, LVN, or LPN be a Designee?	Certified HCPs cannot authorize these staff members to be REMS Designees. However, these staff members can be invited to become REMS Support Staff using the My Teams page in the HCP portal.
What can REMS support staff (eg, MAs, LVNs, LPNs, etc) do to assist the HCP with CAMZYOS?	Certified HCPs and Designees can invite members of their staff who cannot be Designees (eg, MAs, LVNs, LPNs) as REMS Support Staff. To assist the HCP, REMS Support Staff can: • Access the REMS portal to view patient REMS records and upcoming tasks due
	 Enter required data into the Patient Enrollment Form and Patient Status Form using the REMS portal with information provided by the certified HCP or Designee. The Patient Enrollment Form and Patient Status Form will not be submitted to the REMS until the HCP or Designee reviews the information entered, signs, and submits the form using their own REMS portal user credentials
What can a certified HCP do that a Designee cannot?	REMS Designees can perform most REMS activities for the certified HCP. However, the HCP is responsible for all information entered and activities performed in the CAMZYOS REMS by their Designees. In addition, initial and subsequent prescriptions of CAMZYOS can only be written by a certified HCP.
I have the authority	To become certified in the CAMZYOS REMS, an HCP must:
to write prescriptions as an NP. How can I become a certified HCP?	Review the CAMZYOS US Prescribing Information, Program Overview, and Education Program for Healthcare Providers and Pharmacies
	Successfully complete the Healthcare Provider Knowledge Assessment and submit it to the REMS
	Enroll by completing the Healthcare Provider Enrollment Form and submitting it to the REMS
	Within the "My Teams" screen in the REMS online portal, Designees can use the purple "Get Certified" button at the top righthand corner of the screen to complete the HCP certification process.

HCP Designees (cont'd)



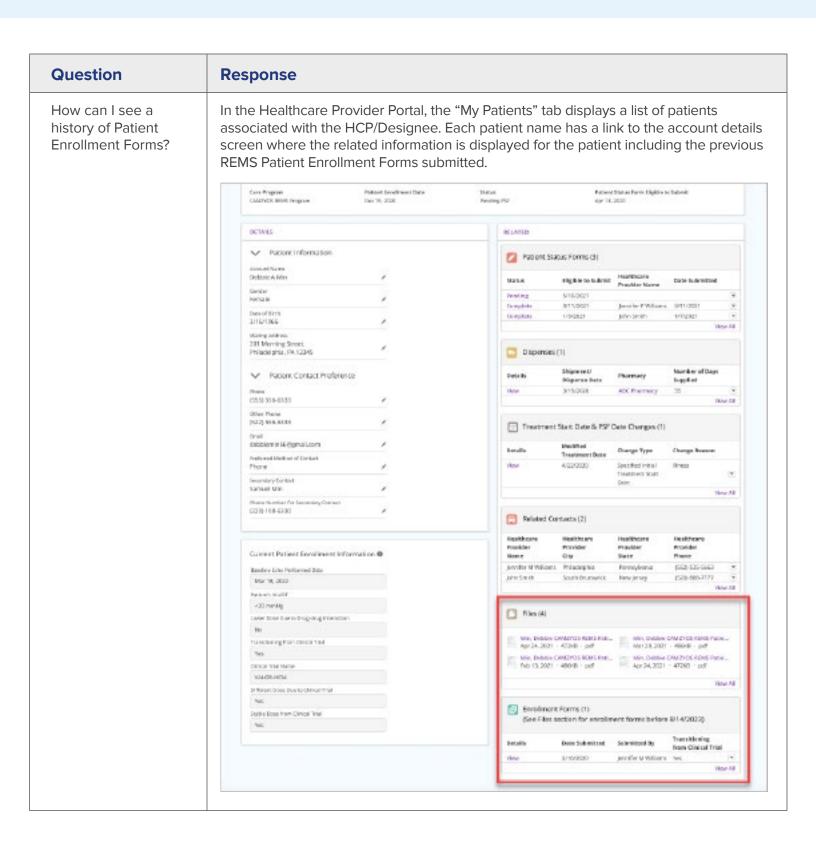
CAMZYOS REMS Patient Enrollment

Question	Response
Do patients that were previously enrolled in a clinical trial need to restart their echocardiogram	If a patient is transitioning from a CAMZYOS clinical trial and is on a stable dose of CAMZYOS, they can continue to take the same dose and follow the Maintenance Phase echocardiogram schedule (Figure 2 in the US Prescribing Information). Please ensure completion of the questions related to CAMZYOS clinical trial participation in the Patient Enrollment Form.
monitoring?	A patient is considered on a stable dose if they are on the same dose of CAMZYOS for the last 12 weeks of their clinical trial dosing and if there are 8 weeks or less between exit from the clinical trial and enrollment into the REMS.
	If the patient is not on a stable dose and/or it has been longer than 8 weeks between clinical trial exit and Patient Enrollment Form submission, the patient will need to restart their echocardiogram monitoring. The Patient Status Form submission schedule will be at Week 4, Week 8, and Week 12, and at a minimum of every 12 weeks thereafter (please see Figures 1 and 2 in the US Prescribing Information).
How do I find a partially enrolled patient?	You can find your partially enrolled patient in the REMS Portal by selecting Enroll Patient from the Home Screen and entering the patient's name and date of birth. The patient will populate below as a match since the enrollment was previously started. You can select continue enrollment, which can be found to the right of the patient's information, to complete the enrollment process.

CAMZYOS REMS Patient Enrollment (cont'd)

Question	Response
How old can the baseline echocardiogram be for patient enrollment?	For patients who have not taken CAMZYOS, clinical discretion should be used to determine the appropriate window of time between baseline echocardiogram and submission of the Patient Enrollment Form.
	If reinitiating treatment for a patient who has previously been on CAMZYOS but has discontinued treatment for >1 year, an HCP or Designee must submit a new Patient Enrollment Form indicating an echocardiogram was performed within 12 weeks of reinitiation. If treatment has been discontinued for ≤1 year, either a Patient Status Form or Patient Enrollment Form must be submitted indicating an echocardiogram was performed within 12 weeks of reinitiation.
What if the patient does not have an email address to enter on the Patient Enrollment Form?	If the patient does not have an email address, the HCP can substitute with noemail@patient.com.
What if my practice does not know the	If you do not know the exact treatment start date, the date will default to the date of the first dispense if the initial treatment start date is not manually specified.
exact treatment	The treatment start date can be manually modified only if:
start date?	The first Patient Status Form has not been submittedThe patient has been enrolled for 90 days or less
When enrolling a patient, can I select	You can select "Yes" and enter the patient's name on the enrollment form if the patient is not in the office to sign when:
"Yes" and enter a patient's name on the enrollment form if the patient is not in the office to sign?	 The patient enrollment form is being completed via telemedicine/telephone A patient is unable to physically travel to an office due to distance, COVID, or other illness The patient has been counseled on all sections of the patient agreement within the CAMZYOS REMS Patient Enrollment Form and agrees to the REMS Program requirements

CAMZYOS REMS Patient Enrollment (cont'd)



CAMZYOS REMS Patient Enrollment (cont'd)

Question	Response
How do I reactivate a patient after a dose interruption? What are the next steps?	If the dose interruption was due to LVEF <50%, refer to Figure 3 of the Prescribing Information. The steps to reactivating a patient after a dose interruption depend on how long the patient's dose has been interrupted.
	 If treatment has been interrupted for >1 year, an HCP or Designee must submit a new Patient Enrollment Form indicating an echocardiogram was performed within 12 weeks of reinitiation. The patient will need to restart their echocardiogram monitoring. The Patient Status Form submission schedule will be at Week 4, Week 8, and Week 12, and at minimum every 12 weeks thereafter (please see Figures 1 and 2 in the US Prescribing Information)
	 If treatment has been interrupted for >8 weeks and ≤1 year, either a Patient Status Form or Patient Enrollment Form must be submitted indicating an echocardiogram was performed within 12 weeks of reinitiation. Echocardiograms (and Patient Status Form submissions) are required 4, 8, and 12 weeks after treatment restart, then a minimum every 12 weeks thereafter
	 If treatment has been interrupted for ≤8 weeks, treatment may be restarted with submission of a Patient Status Form, with required follow-up echocardiograms (and Patient Status Form submissions) 4 and 12 weeks after treatment restart, then a minimum every 12 weeks thereafter
	For more information, please refer to the echocardiogram assessments and Patient Status Form submission scenarios within the <u>REMS Education Program for Healthcare Providers and Pharmacies</u> .

Patient Status Form

Question	Response
Does the next echocardiogram get scheduled based on when the last one was completed?	The patient's echocardiogram schedule should be based on the treatment start date (ie, the patient's first dose of CAMZYOS). Please refer to Figures 1, 2, and 3 in the US Prescribing Information for the full echocardiogram schedule. If the patient's treatment start date needs to be updated, please see the question, "How do I update a patient's treatment start date?
I made a mistake when entering the Patient Status Form responses and accidentally submitted it. How can I go back to fix it?	The Patient Status Form responses can be edited by contacting the REMS Call Center at 1-833-628-7367 from 8 AM–8 PM ET Monday through Friday.
My patient will not start CAMZYOS within a 90-day period. Can my practice still update the start date?	Treatment initiation may be delayed for up to 90 calendar days from Patient Enrollment Form submission. If treatment initiation is delayed for more than 90 days from the submission of the Patient Enrollment Form, a new Patient Enrollment Form must be submitted to update the start date beyond the 90 days.
My patient took a break in treatment, and now the Patient Status Form submission schedule is not aligned with their treatment. What can I do to fix it?	Contact the REMS Call Center at 1-833-628-7367 from 8 AM—8 PM ET Monday through Friday for further assistance with adjusting the Patient Status Form schedule.

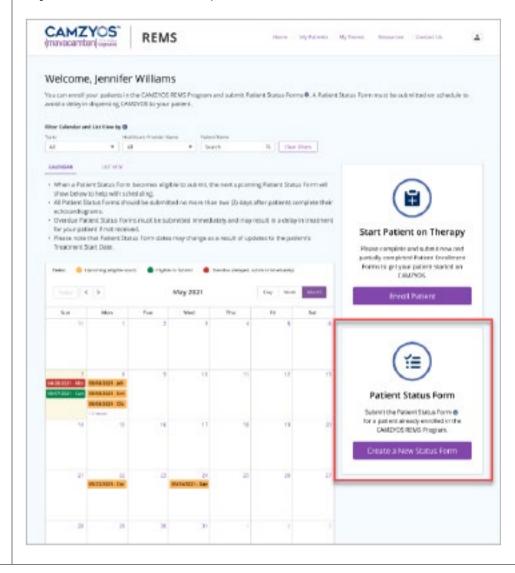
Question	Response		
When a patient begins treatment with CAMZYOS, what is their initial Patient Status Form submission schedule?	Patient Status Form submissions should accompany all required echocardiograms for CAMZYOS while on treatment. After initiating CAMZYOS, the Patient Status Form submission schedule will be at Week 4, Week 8, and Week 12, then a minimum of every 12 weeks thereafter. After the Week 12 echocardiogram, the echocardiogram and Patient Status Form submission schedule is determined by individual patient dosing. Please see the echocardiogram assessments and Patient Status Form submission schedule in the REMS Education Program for Healthcare Providers and Pharmacies, also included below.		
Can you complete an echocardiogram earlier than the Patient Status Form eligible- to-submit date?	The patient's echocardiogram schedule should be based on the treatment start date (ie, the patient's first dose of CAMZYOS). Please refer to Figures 1, 2, and 3 in the US Prescribing Information for the full echocardiogram schedule to understand when echocardiograms should be completed. Submit the Patient Status Form as soon as possible after the echocardiogram has been performed.		

Question

How do you submit an ad-hoc or unscheduled Patient Status Form, and what is it used for?

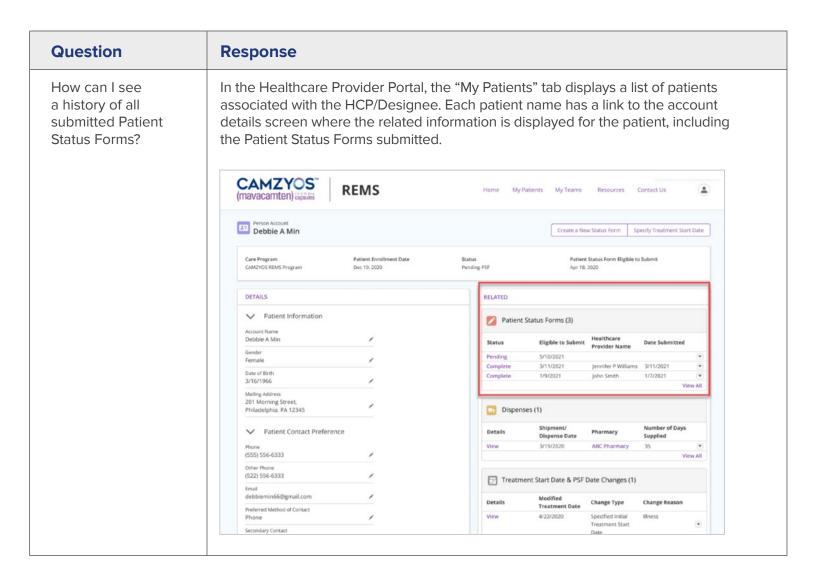
Response

In the Healthcare Provider Portal, an ad-hoc Patient Status Form is submitted by clicking on the "Create a New Status Form" option. Ad-hoc Patient Status Forms are used to deactivate a patient (ie, unauthorize a patient from receiving CAMZYOS), enable dose adjustments OR to reactivate patients who have been deactivated for less than 90 days.



Question	Response
Is a prescription required for CAMZYOS, or will the Patient Status Form submission automatically trigger the pharmacy to dispense?	A Patient Status Form cannot be used as a prescription. HCPs must ensure that pharmacies have a valid and accurate prescription for CAMZYOS to be dispensed. Pharmacies will require new prescriptions if the CAMZYOS dose is changed.
How long will a Patient Status Form remain overdue when not completed on time?	A Patient Status Form will remain overdue until the next scheduled Patient Status Form becomes eligible to submit.
What responses on the submitted Patient Status Form would cause my patient to become deactivated?	There are 2 questions on the Patient Status Form with answers that will result in patient deactivation—when "Yes" is selected for question number 3 or if "No" is selected for question number 7. Question number 3: Did the patient experience a decrease in LVEF to <50%? Question number 7: Is the patient authorized to continue treatment?

Question Response How can I see In the Healthcare Provider Portal, when a Patient Status Form becomes eligible to submit, future Patient Status the next scheduled Patient Status Form will be displayed to help with scheduling Form submission echocardiograms. The Calendar/List View will display the date the next Patient Status due dates so that Form will become eligible to submit. echocardiograms can be scheduled? CAMZYOS REMS My Pacients - My Teams. 1 (mavacamten):... Welcome, Jennifer Williams You can enroll your patients in the CAMZYOS REMS Program and submit Patient Status Forms 8. A Patient Status Form must be submitted on schedule to asold a delay in dispensing CAMENOS to your patient. When a Patient Status Form becomes eligible to submit, the next upcoming Patient Status Form will show below to help with scheduling All Patient Status Forms should be submitted no more than two (2) days after patients complete their ediocardiograms. Overdue Patient Status Forms must be submitted Immediately and may result in a delay in treatment for your patient if not received. Start Patient on Therapy · Please note that Patient Status Form dates may change as a result of updates to the patient's Treatment Start Date. Please complete and submit new and partially completed Patient Enrollment Forms to get your patient started on CAMZYOS. May 2021 Patient Status Form In the Healthcare Provider Portal, you can also find the future Patient Status Form eligible to submit date on the Person Account page. Debbie A Min Create a New Status Form Specify Treatment Start Date Care Program Patient Enrollment Date Status Patient Status Form Eligible to Submit Dec 19, 2020 Apr 18, 2020



Question Response How do I update In the Healthcare Provider Portal, the patient's treatment start date may be updated by a patient's treatment clicking on "Specify Treatment Start Date" within the patient account screen. Treatment initiation may be delayed for up to 90 calendar days from Patient Enrollment Form start date? submission. If treatment initiation is delayed for more than 90 days from the submission of the Patient Enrollment Form, a new Patient Enrollment Form must be completed. CAMZYOS REMS (mavacamten) Debbie A Min. Gare Program DOSEPHOL BEHILD Program. Parlant Status Form Eligible to Salenti DETRACT RELATED Patient Information Patient Status Forms (3) le code 1/1/2/01 Dispenses (1) Philadelphia, FA 12345 Potient Contact Preference 0550 554-6300 022) 914-6333 Treatment Start Date & PSF Date Changes (1) Treatment Date Change Type In the Pharmacy Portal, a pharmacy may update the patient's treatment start date when associated to a shipping delay by clicking on "Modify Treatment Date" within the patient account screen. CAMZYOS REMS 0 Plora Fawna Dark Program Cold/DS NEWS Program DETAILS w Patient Information Drug Interaction & Counseling Checklets (1) Date Drested Flora Famma

Disperses (f)

Question	Response
My patient's treatment is going to be interrupted. When should echos be scheduled and how do I reinitiate treatment?	If a patient's treatment is interrupted due to LVEF below 50%, follow-up echocardiograms must be scheduled every 4 weeks following treatment interruption until LVEF ≥50%.
	If the echocardiogram confirms LVEF ≥50% (please refer to the CAMZYOS Prescribing Information for complete dosing schedule):
	 For patients whose treatment was interrupted for ≤8 weeks, treatment may be restarted with submission of a Patient Status Form, with required follow-up echocardiograms (and Patient Status Form submissions) 4 and 12 weeks after treatment restart, then a minimum of every 12 weeks thereafter
	 For patients whose treatment was interrupted for >8 weeks, treatment may be restarted with submission of a Patient Status Form, with required follow-up echocardiograms (and Patient Status Form submissions) 4, 8, and 12 weeks after treatment restart, then a minimum of every 12 weeks thereafter

Question Response My patient's dose is If a patient's dose is changing, a Patient Status Form must be submitted that indicates changing. How will the dose change for the new dose to be dispensed. Echocardiogram and submission of a Patient Status Form are then required 4 and 12 weeks following the dose change. this impact their current Patient Status See Scenarios 1 and 5 within the REMS Education Program for Healthcare Providers Form submission and Pharmacies, also included below. schedule? Echo Assessments and Patient Status Form Submissions: Case Scenarios (I) Scenario 1: Dose increase after Initiation Phase monitoring* Week 12 Week 16 We sk 16 fallow-up scho indicates LVEF 160% and Because the Week 16 follow -up echo indicated that the patient is statile, results the 12 -week Clinical Week 12 e che indicates Patient with echo LVOT XXX mmHz necel work Waterier CO'CT 400 myster or he schedule (in reed eche is at Week 3d) higher doce (3) 15 weeks 12 meste B Linked to edie Submission of Patient Patient Status Fore submission indicates Patient Status Fores submission indicates Status Forms aptitration of dose continuation on same dose "The dasing signifithm described in the CANIZYOS" Prescribing information does not include does increases until the Maintenance Phase [see Side 8]. Eshe-rechecardiogram; LVEF-tettive stilisalar ejection fraction; LVOF-left ventrioular suffort tect. Echo Assessments and Patient Status Form Submissions: Case Scenarios (V) Scenario 5: Dose decrease after Initiation Phase monitoring (including initiation of a weak CYF2C19 inhibitor or a moderate CYF3A4 inhibitor) Week 36 Wools 94 Work 28 All Work 31, patient initiative a week CYP2C19 inhibitor Patient Patient Assessment LYEF263N and LYDE 265% and receives higher show or moderate CYPSALIMIDIDE Pet out Status Form Patient Status Form submission indicates Potent Status Form Status Foress down-titration of dose' continuation on some dose 1 up-titration Potents who are on CAMEYOF through and intention their awards CHPOFS inhibitor or a moderate CHPOFA inhibitor should reduce dose of CAMEYOR by one level lie. 15 mg 3 18 mg, 10 mg 3 5 mg, or 5 mg 3 2.5 mg. Avoid inhibitor of concern bank week CMPOFS and moderate CHPOFA inhibitors in patients who are on stable through at 8.5 mg at CAMEYOR because a lower date is not available. The potent connot be up through and 12 we do a district the inhibitors. The potent connot be up through an inhibitor with the inhibitors. The potent connot be up through an area of the inhibitors as produced and inhibitor above the inhibitor of the inhibitors are not as the inhibitor of the inhibitors and inhibitors are not as the inhibitor of the inhibitors of the inhibitors are not as the inhibitor of the inhibitor of the inhibitors are not as the inhibitor of the inhibitor o

Medication Dispensing

Question	Response
When can a pharmacy complete an override for more CAMZYOS?	An override is an exemption made to complete a dispense in the CAMZYOS REMS system when a patient has more than 7 days' supply remaining from the previous dispense. The approved override reasons are as follows: • Dose adjustment
	Inpatient to Outpatient Outpatient to Inpatient Lost/Missing/Damaged product Travel requiring an early dispense
Where can the list of dispensing pharmacies be found?	A list of the certified dispensing pharmacies can be found <u>here</u> .
How can I view the dispensing pharmacy for my patient?	The CAMZYOS REMS HCP Online Portal has a My Patients section that allows you to click on each patient's name for additional details. The Related section contains a list with all Dispenses for the patient and the associated pharmacy details.
How much time do I have to submit a Patient Status Form before it is considered overdue?	The status of a Patient Status Form changes to "Overdue" if it is not submitted within 9 calendar days after the Eligible to Submit Date shown on the Patient Details screen (see screenshot below).
	Failure to complete and submit Patient Status Forms may lead to interruptions in dosing.
If the pharmacy identifies a DDI, will they contact me directly?	If a pharmacy identifies a DDI, they are instructed to contact the CAMZYOS prescribing HCP to resolve the interaction. Please refer to the Drug Interaction and Counseling Checklist for Pharmacies for more information.
How do I know how many days' supply my patient has for every dispense?	The Healthcare Provider Portal has a My Patients section that allows you to click on each patient's name for additional details. The Related section contains the Shipment/Dispense Date and Number of Days Supplied.

Product Information

Response
For more information on the CAMZYOS REMS, please visit our website at www.CAMZYOSREMS.com or contact the REMS Call Center at (833) 628-7367 or by email at REMSSupport@bms.com
For more information on CAMZYOS, please refer to the US Prescribing Information. You may also contact the BMS Medical Information Contact Center at (800) 321-1335.
To report any suspected adverse reactions to CAMZYOS, please contact (800) 721-5072 or email worldwide.safety@bms.com.

Glossary

DDI=drug-drug interaction; DO=doctor of osteopathic medicine; echo=echocardiogram; HCP=healthcare provider; LPN=licensed practical nurse; LVEF=left ventricular ejection fraction; LVN=licensed vocational nurse; LVOT=left ventricular outflow tract; MA=medical assistant; MD=medical doctor; NP=nurse practitioner; PA=physician assistant; REMS=Risk Evaluation and Mitigation Strategy; RN=registered nurse; RPh=registered pharmacist.