<<Date>> Name: <<Patient’s Name>>

<<Health Plan Name>> DOB: <<XX/XX/XXXX>>

ATTN: <<Department>> Patient Policy ID Number: <<Policy ID #>>

<<Medical/Pharmacy Director Name>> Reference Number: <<Reference #>>

<<Health plan address>> Date(s) of Service: <<XX/XX/XXXX>>

<<City, State Zip>>

Re: Letter of Medical Necessity for CAMZYOS® Patient Echocardiograms

Dear <<Medical/Pharmacy Director Name>>,

I am writing on behalf of <<patient’s name>> to document the medical necessity of periodic echocardiograms (<<CPT Code>>) that are required for treatment with CAMZYOS® (mavacamten). The patient is <<a/an age>>-year-old <<male/female/other gender identification>> who was diagnosed with <<diagnosis>> on <<date>>. The *International Classification of Diseases, 10th Revision, Clinical Modification* diagnosis code is <<diagnosis code>>.

CAMZYOS is a cardiac myosin inhibitor that was approved by the US Food and Drug Administration in April 2022 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.

CAMZYOS is only available through a restricted program called the CAMZYOS Risk Evaluation and Mitigation Strategy (REMS) Program.1 The goal of the REMS Program is to mitigate the risk of heart failure due to systolic dysfunction.

The CAMZYOS REMS Program has the following objectives:

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

According to the CAMZYOS prescribing information and REMS, prescribers must regularly assess the patient’s response to CAMZYOS, including Valsalva LVOT gradient and LVEF, through echocardiogram assessments.2 Additionally, prescribers must monitor clinical status throughout treatment, including monitoring for systolic dysfunction and other intercurrent illness. Echocardiographic data are essential for dose titration and assessment of patient response to treatment and safety.

Specifically, the CAMZYOS prescribing information and REMS require echocardiograms prior to and during treatment (at Weeks 4, 8, 12, and every 12 weeks thereafter) with CAMZYOS.3 Pursuant to the CAMZYOS prescribing information and REMS, additional echocardiograms may be required throughout therapy, including upon treatment interruption and subsequent restart, dosing changes, initiation of certain drugs that may affect CAMZYOS exposures, and changes in clinical status of the patient.4

* Based on the dosing recommendations within the prescribing information, a patient may undergo 7+ echocardiograms in year 1 and 4+ echocardiograms in years 2+.

Considering the patient’s condition, the prescribing information and REMS requirements of their treatment for <<diagnosis>> with CAMZYOS, [insert conclusion regarding medical necessity of <<type of echocardiogram>>

(<<CPT Code>>) for the patient.] Please contact me at <<physician’s phone number>> or via email at <<physician’s email>> should you have questions or need additional information.

Thank you for your time and immediate attention to this request. Sincerely,

<<Provider name, contact information, and signature>>

Enclosures: <<List and attach additional documents to support your treatment rationale>>

References:

1. https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=413
2. CAMZYOS [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; 2022.
3. CAMZYOS [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; 2022.
4. CAMZYOS [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; 2022.

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