

Commercial/Healthcare Exchange PA Criteria Effective: August 11th, 2022

Prior Authorization: Camzyos

Products Affected: Camzyos[™] (mavacamten) oral capsules

<u>Medication Description</u>: Camzyos is an allosteric and reversible inhibitor selective for cardiac myosin. It modulates the number of myosin heads that cross-bridge to actin during systole or diastole. Excess myosin actin cross-bridge formation and dysregulation of the super-relaxed state are mechanistic hallmarks of hypertrophic cardiomyopathy (HCM). Mavacamten promotes an energy-sparing, recruitable, super-relaxed state. In HCM patients, this reduces dynamic left ventricular outflow tract obstruction and improves cardiac filling pressures.

<u>Covered Uses</u>: Treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis

Prescriber Restriction: Prescribed by a cardiologist

Age Restriction: 18 years of age or older

Coverage Duration: Initial: 8 months Renewal: 12 months

Other Criteria:

Initial Approval Criteria

- 1. Obstructive Hypertrophic Cardiomyopathy. Approve for 8 months if patient meets the following criteria:
 - A. Patient meets both of the following (i **and** ii):
 - i. Patient has at least one symptom associated with obstructive hypertrophic cardiomyopathy; AND <u>Note</u>: Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise
 - ii. Patient has New York Heart Association Class II or III symptoms of heart failure; AND
 <u>Note</u>: Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest.
 - B. Patient with left ventricular hypertrophy meets one of the following (i or ii):
 - i. Patient has maximal left ventricular wall thickness ≥ 15 mm; **OR**

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- ii. Patient has familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness ≥ 13 mm;
 AND
- C. Patient has a peak left ventricular outflow tract gradient ≥ 50 mmHg (at rest or after provocation [Valsalva maneuver or post exercise]); **AND**
- D. Patient has a left ventricular ejection fraction of ≥ 55%

Renewal Criteria

- 1. Obstructive Hypertrophic Cardiomyopathy Approve for 1 year if the patient meets ALL of the following criteria
 - A. Patient has been established on therapy for at least 8 months; **AND**<u>Note</u>: A patient who has received < 8 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy)
 - B. Patient meets both of the following (i and ii):
 - i. Currently or prior to starting therapy, patient has or has experienced at least one symptom associated with obstructive hypertrophic cardiomyopathy AND
 - Note: Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise.
 - ii. Currently or prior to starting therapy, patient is in or was in New York Heart Association Class II or III heart failure; **AND**
 - <u>Note</u>: Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest.
 - C. Patient has a current left ventricular ejection fraction of ≥ 50%; AND
 - D. Patient meets at least one of the following (i or ii):
 - i. Patient experienced a beneficial clinical response when assessed by at least one objective measure; **OR**
 - <u>Note</u>: Examples include improved peak oxygen consumption/mixed venous oxygen tension; decreases in left ventricular outflow tract gradient; reductions in N-terminal pro-B-type natriuretic peptide levels; decreased high-sensitivity cardiac troponin I levels; reduced ventricular mass index; and/or a reduction in maximum left atrial volume index.
 - ii. Patient experienced stabilization or improvement in at least one symptom related to obstructive hypertrophic cardiomyopathy
 - <u>Note</u>: Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, ability to perform physical exercise, and/or favorable changes in the Kansas City Cardiomyopathy Questionnaire-23 (KCCQ-23) Clinical Summary Score (CSS) or Hypertrophic Cardiomyopathy Symptom Questionnaire (HCMSQ) Shortness of Breath domain scores.

References:

1. Camzyos[™] capsules [prescribing information]. Brisbane, CA; MyoKardia/Bristol Myers Squibb; April 2022.

Policy Revision history

August 2022





Rev	# Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	8/11/2022