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Drug Policy

Policy:	Camzyos (mavacamten)	Annual Review Date: 06/20/2024 Last Revised Date: 06/20/2024

OVERVIEW

Camzyos, a cardiac myosin inhibitor, is indicated for the treatment of symptomatic New York Heart Association Class (NYHA) II to III **obstructive hypertrophic cardiomyopathy** in adults to improve functional capacity and symptoms.

POLICY STATEMENT

This policy involves the use of Camzyos. Prior authorization is recommended for pharmacy benefit coverage of Camzyos. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Camzyos as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Camzyos be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Camzyos is recommended in those who meet the following criteria:

1. **Obstructive Hypertrophic Cardiomyopathy.** Approve for the duration noted below if the patient meets ONE of the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 8 months if the patient meets the following criteria (i, ii, iii, iv, v, and vi):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets both of the following (a and b):
       - **a)** Patient has 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.
       - **b)** Patient has New York Heart Association Class II or III symptoms of heart failure; AND

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Note: 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.

iii. Patient with left ventricular hypertrophy meets one of the following (a or b):
- **a)** Patient has maximal left ventricular wall thickness ≥ 15 mm; OR
- **b)** Patient has familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness ≥ 13 mm; AND

iv. Patient has a peak left ventricular outflow tract gradient ≥ 50 mmHg (at rest or after provocation [Valsalva maneuver or post exercise]); AND

v. Patient has a left ventricular ejection fraction of ≥ 55%; AND

vi. Medication is prescribed by a cardiologist; OR

B) Patient is Currently Receiving Camzyos. Approve for 1 year if the patient meets ALL of the following criteria (i, ii, iii, iv, v and vi):

i. Patient has been established on therapy for at least 8 months; AND
Note: A patient who has received < 8 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).

ii. Patient is ≥ 18 years of age; AND

iii. Patient meets both of the following (a and b):
- **a)** 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.
- **b)** Currently or prior to starting therapy, patient is in or was in New York Heart Association Class II or III heart failure; AND
  Note: 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.

iv. Patient has a current left ventricular ejection fraction of ≥ 50%; AND

v. Patient meets at least one of the following (a or b):
- **a)** Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
  Note: 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.
- **b)** Patient experienced stabilization or improvement in at least one symptom related to obstructive hypertrophic cardiomyopathy; AND
  Note: 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.

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vi. Medication is prescribed by a cardiologist.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 8 months
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Camzyos has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Camzyos™ capsules [prescribing information]. Princeton, NJ: MyoKardia/Bristol Myers Squibb; September 2022.
2. Olivotto I, Oreziak A, Barriales-Villa R, et al, for the EXPLORER-HCM study investigators. Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomized, double-blind, placebo-controlled, phase 3 trial. *Lancet.* 2020;396(10253):759-769.
3. Maron BJ. Clinical course and management of hypertrophic cardiomyopathy. *N Engl J Med*. 2018;379(7):655-668.
4. Ommen SR, Semsarian C. Hypertrophic cardiomyopathy: a practical approach to guideline directed management. *Lancet.* 2021;398(10316):2102-2108.
5. Burstein Waldman CY, Owens A. A plain language summary of the EXPLORER-HCM study: mavacamten for obstructive hypertrophic cardiomyopathy. *Future Cardiol*. 2021;17(7):1269-1275.
6. Keam SJ. Mavacamten: first approval. *Drugs.* 82:1127-1135.
7. Ommen SR, Mital S, Burke MA, et al. 2020 AHA/ACC guideline for the diagnosis and treatment of patients with hypertrophic cardiomyopathy. *J Am Coll Cardiol*. 2020;76(25):e159-240.

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