Effective Date: 9/01/2022
Reviewed: 06/2022, 5/2023
Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

CAMZYOS (mavacamten)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Camzyos is 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.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
1. Initial requests: Documentation confirming diagnosis of obstructive hypertrophic cardiomyopathy (oHCM), LVEF, NYHA class, baseline peak oxygen consumption (pVO_2) and previous drug trials with outcomes provided.
2. Continuation requests: chart notes or medical records documenting a benefit from therapy (e.g., improvement in symptoms and exercise tolerance).

III. CRITERIA FOR INITIAL APPROVAL

Symptomatic obstructive hypertrophic cardiomyopathy (oHCM)
Authorization of 6 months may be granted for treatment of oHCM when all of the following criteria are met:
1. This medication must be prescribed by a cardiologist enrolled in the CAMZYOS REMS PROGRAM
2. The member is at least 18 years of age
3. The member's weight is at least 45 kg
4. The member has a confirmed diagnosis of symptomatic oHCM consistent with current ACC/AHA and ESC guidelines (unexplained LV hypertrophy with maximal LV wall thickness of ≥15 mm OR ≥13 mm with family history of HCM; left ventricular outflow tract (LVOT) gradient ≥50 mm Hg)
5. The member's functional status is NYHA Class II or III
6. The member has a documented LVEF ≥55%
7. The member has experienced an inadequate treatment response, intolerance, or contraindication to beta blockers (e.g., metoprolol, propranolol, atenolol)
8. The member has experienced an inadequate treatment response, intolerance, or contraindication to a nondihydropyridine calcium channel blocker (e.g., verapamil, diltiazem)

9. The member has experienced an inadequate treatment response, intolerance, or contraindication to disopyramide
10. The member is not currently treated or planning to be treated with disopyramide, ranolazine, or dual therapy with a beta blocker and calcium channel blocker
11. The member is not currently diagnosed with a disorder that causes cardiac hypertrophy that mimics oHCM, such as Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting continuation of therapy when the member is experiencing benefit from therapy documented by:

1. Improvement of peak oxygen consumption (pVO_2) by ≥1.5 mL/kg/min AND improvement in NYHA class by at least one (e.g., NYHA Class III to Class II) OR
2. Improvement of pVO2 by ≥ 3 mL/kg/min AND no worsening of NYHA class

V. QUANTITY LIMIT

Camzyos 2.5mg, 5mg, 10mg, and 15mg capsules have a quantity limit of 1 capsule per day.

VI. REFERENCES

1. Camzyos [package insert]. Brisbane, CA: Bristol Myers Squibb; September 2022.
2. Ommen, SR, Mital S, Burke MA, et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy. Circulation. 2020; 142:e558–e631.