Reference number(s)
5268-A

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 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:

A. Initial requests:
   1. Imaging reports, chart notes, or medical record documentation supporting left ventricular wall thickness.
   2. Laboratory results, chart notes, or medical record documentation of familial hypertrophic cardiomyopathy or a positive genetic test (e.g., MYH7, MYBPC3, TNNI3, TNNT2, TPM1, MYL2, MYL3, ACTC1 gene variants) (if applicable).
   3. Chart notes or medical record documentation supporting baseline left ventricular ejection fraction (LVEF) ≥ 55% and baseline Valsalva left ventricular outflow tract (LVOT) peak gradient ≥ 50 mmHg.
   4. Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

B. Continuation requests:
   1. Chart notes or medical record documentation supporting a positive clinical response to therapy (e.g., increase in peak oxygen consumption [pVO2], NYHA class reduction).
   2. Chart notes or medical record documentation supporting left ventricular ejection fraction (LVEF) ≥ 50%.

III. CRITERIA FOR INITIAL APPROVAL

Obstructive Hypertrophic cardiomyopathy

Authorization of 3 months may be granted for treatment of obstructive hypertrophic cardiomyopathy when all of the following criteria are met:

A. Member has either of the following:
   1. Left ventricular wall thickness of greater than or equal to 15 mm anywhere in the left ventricle.
   2. Left ventricular wall thickness of greater than or equal to 13 mm anywhere in the left ventricle in members with familial hypertrophic cardiomyopathy or a positive genetic test (e.g., MYH7, MYBPC3, TNNI3, TNNT2, TPM1, MYL2, MYL3, ACTC1 gene variants).

B. Member has NYHA functional class II to class III symptoms (see Appendix).
C. Member must have a baseline left ventricular ejection fraction (LVEF) ≥ 55% and baseline Valsalva left ventricular outflow tract (LVOT) peak gradient ≥ 50 mmHg.
D. Member has experienced an inadequate response to a beta-adrenergic antagonist (e.g., atenolol, metoprolol) or non-dihydropyridine calcium channel blocker (e.g., diltiazem, verapamil) at maximally tolerated dose, or has an intolerance or contraindication to both therapies.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for obstructive hypertrophic cardiomyopathy when both of the following criteria are met:
A. The member has achieved or maintained a positive clinical response to therapy (e.g., increase in pVO2, NYHA class reduction).
B. Member has a left ventricular ejection fraction (LVEF) ≥ 50%.

V. APPENDIX

New York Heart Association (NYHA) Functional Classification

NYHA Grading	
Class I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or shortness of breath.
Class II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, shortness of breath or chest pain.
Class III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, shortness of breath or chest pain.
Class IV	Symptoms of heart failure at rest. Any physical activity causes further discomfort.

VI. REFERENCES

1. Camzyos [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; June 2023.
2. Ommen SR, Mital S, Burke MA, et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2020;76(25):3022-3055.
3. "Classes and Stages of Heart Failure." *American Heart Association.* 7 June 2023. https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure. Accessed April 2, 2024.
4. Spertus JA, Fine JT, Elliott P, et al. Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): health status analysis of a randomized, double-blind placebo-controlled, phase 3 trial. *Lancet.* 2021;397(10293):2467-2475.
5. Maron B, Desai M, Nishimura R, et al. Management of Hypertrophic cardiomyopathy. *J Am Coll Cardiol.* 2022;79(4):390-414.