CVS Caremark®

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| Reference number(s) |
| 5268-A |

# Specialty Guideline Management Camzyos

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
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| Camzyos | mavacamten |

## 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.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

### Initial requests

* Imaging reports, chart notes, or medical record documentation supporting left ventricular wall thickness.
* 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).
* 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.
* 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.

### Continuation requests

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

## Coverage Criteria

### Obstructive Hypertrophic cardiomyopathy

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

* Member has one of the following:
  + Left ventricular wall thickness of greater than or equal to 15 mm anywhere in the left ventricle.
  + 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).
* Member has NYHA functional class II to class III symptoms (see Appendix).
* Member must have a baseline left ventricular ejection fraction (LVEF) ≥ 55% and baseline Valsalva left ventricular outflow tract (LVOT) peak gradient ≥ 50 mmHg.
* Member has experienced an inadequate response to a beta-adrenergic antagonist (e.g., atenolol, metoprolol) or non-dihydropyridine calcium channel blocker (diltiazem, verapamil) at maximally tolerated dose, or has an intolerance or contraindication to both therapies.

## 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:

* The member has achieved or maintained a positive clinical response to therapy (e.g., increase in pVO2, NYHA class reduction).
* Member has a left ventricular ejection fraction (LVEF) ≥ 50%.

## Appendix

New York Heart Association (NYHA) Functional Classification

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| 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. |

## 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.