Camzyos (mavacamten)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Camzyos (mavacamten) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits 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.

POLICY

Documentation

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

A. Initial requests:
   1. Chart notes or medical record documentation confirming left ventricular wall thickness of greater than or equal to 15 mm, OR left ventricular wall thickness of greater than or equal to 13 mm in members with familial hypertrophic cardiomyopathy or in conjunction with a positive genetic test (e.g., MYH7, MYBPC3, TNNI3, TNNT2, TPM1, MYL2, MYL3, ACTC1 gene variants).
   2. Chart notes or medical record documentation confirming baseline LVEF is ≥ 55% and baseline Valsalva left ventricular outflow tract (LVOT) peak gradient ≥ 50 mmHg.

B. Continuation requests:
   1. Documentation (e.g., chart notes) that the member has achieved or maintained a positive clinical response to therapy (increase in pVO2, NYHA class reduction, symptom improvement).

2. Documentation (e.g., chart notes) that left ventricular ejection fraction (LVEF) is at or above the 50% threshold.

Prescriber Specialties

Camzyos must be prescribed by or in consultation with a cardiologist

Criteria for Initial Approval

Obstructive Hypertrophic Cardiomyopathy

Authorization of 6 months may be granted for treatment of obstructive hypertrophic cardiomyopathy when all of the following criteria are met:

A. Member is 18 years of age or older
B. Member has one of the following:
    1. Left ventricular wall thickness of greater than or equal to 15 mm, OR
    2. Left ventricular wall thickness of greater than or equal to 13 mm in members with familial hypertrophic cardiomyopathy or in conjunction with a positive genetic test (e.g., MYH7, MYBPC3, TNNI3, TNNT2, TPM1, MYL2, MYL3, ACTC1 gene variants)
C. Member has NYHA class II-III symptoms
D. Member must have a baseline left ventricular ejection fraction (LVEF) ≥ 55% and baseline Valsalva left ventricular outflow tract (LVOT) peak gradient ≥ 50 mmHg
E. Member is not currently diagnosed with a disorder that causes cardiac hypertrophy that mimics obstructive hypertrophic cardiomyopathy, such as Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy
F. The medication is prescribed by or in consultation with a cardiologist

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for obstructive hypertrophic cardiomyopathy when all the of the following criteria are met:

A. The member achieves or maintains a positive clinical response to therapy as defined by:
    1. Increase in pVO2 by ≥1.5 mL/kg/min plus at least one NYHA class reduction OR a ≥3.0 mL/kg/min pVO2 increase without NYHA class worsening
    2. Improvement or continued improvement in symptoms
B. LVEF is at or above the 50% threshold.

Camzyos (mavacamten) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

30 capsules per 30 days

APPENDIX

NYHA Grading	
Class I	No limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath)
Class II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
Class III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
Class IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

New York Heart Association (NYHA) Functional Classification[3]

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

1. Camzyos [package insert]. Brisbane, CA: Bristol Myers Squibb; April 2022.
2. Ommen, Steve R, 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.” Circulation, vol. 142, no. 25, 2020, pp. e558–e631., https://doi.org/10.1161/cir.0000000000000945. Accessed May 2, 2022.
3. “Classes of Heart Failure.” *American Heart Association.* 31 May 2017. https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure. Accessed May 2, 2022.
4. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Cardiology Agents. May 2022.

*Some content reprinted from CVS Health

POLICY HISTORY

Policy #: 05.04.66
Original Effective Date: September 29, 2022
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