Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Camzyos™ (mavacamten)

Effective: August 8, 2023

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Camzyos (mavacamten) is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertonic cardiomyopathy (oHCM) to improve functional capacity and symptoms.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Camzyos for Members when all of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of obstructive hypertonic cardiomyopathy

AND

2. Documentation the Member exhibits New York Heart Association class II-III symptoms (e.g., effort-related dyspnea, effort-related chest pain, syncope, near syncope)

AND

3. The patient is at least 18 years of age

AND

4. The prescribing physician is a cardiologist

AND

5. Documentation the patient remains symptomatic despite treatment with all of the following, or documented clinical inappropriateness with all of the following:
    a. Nonvasodilating beta blockers (e.g. atenolol, bisoprolol, metoprolol, propranolol)
    b. Non-dihydropyridine calcium channel blockers (e.g., diltiazem, verapamil)
    c. Disopyramide

AND

6. Documentation the patient has not received septal reduction therapy in the previous year

Reauthorization Criteria

1. Documented diagnosis of obstructive hypertonic cardiomyopathy

AND

2. The patient is at least 18 years of age

AND

3. The prescribing physician is a cardiologist

AND

4. Documentation the patient has achieved a therapeutic response as evidenced by one of the following:
    a. Improvements or stabilization of baseline post-exercise left ventricular outflow tract (LVOT) peak gradient
    b. Improvement or stabilization of baseline peak oxygen consumption (pVO_2)
    c. Improvement or stabilization of symptoms

AND

5. Documentation the patient has not received septal reduction therapy in the previous year

Limitations

1. Initial coverage of Camzyos will be authorized for six (6) months. Reauthorization of Camzyos will be provided in 12-month intervals.
2. Members new to the plan stable on Camzyos should be reviewed against Reauthorization Criteria.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Camzyos (mavacamten). Prescribing information. MyoKardia, Inc.; June 2023.
2. Ho CY, Olivotto I, Jacoby D, et al. Study design and rationale of EXPLORER-HCM: evaluation of mavacamten in adults with symptomatic obstructive hypertrophic cardiomyopathy. Circ Heart Fail. 2020;13:e006853.
3. Olivotto I, Oreziak A, Barriales-Villa R, et al. Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2020;396.
4. 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. Circulation. 2020;142:e558-e631.
5. Spertus JA, Fine JT, Elliott P, et al. Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): health status analysis of a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2021;397:2467-2475.
6. Wasfy JH, Walton SM, Beinfeld M, et al. Mavacamten for hypertrophic cardiomyopathy: effectiveness and value; final evidence report and meeting summary. Institute for Clinical and Economic Review. Published November 16, 2021. Accessed May 5, 2022

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- August 8, 2023: Administrative update to add the Limitation “Members new to the plan stable on Camzyos should be reviewed against Reauthorization Criteria (effective 8/8/23)

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.