Clinical Policy Title:	mavacamten
Policy Number:	RxA.770
Drug(s) Applied:	Camzyos™
Original Policy Date:	07/18/2022
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Obstructive Hypertrophic Cardiomyopathy (must meet all)**:**

1. Diagnosis of obstructive hypertrophic cardiomyopathy;
2. Member has New York Heart Association (NYHA) Class II to III symptoms;
3. Member has a left ventricular ejection fraction (LVEF) ≥ 55%;
4. Member has Valsalva left ventricular outflow tract (LVOT) ≥ 50 mmHg at rest or with provocation;
5. Trial and failure of the following, unless contraindicated or clinically significant adverse effects are experienced (a or b):
   a. Beta-blocker (e.g., atenolol, nadolol);
   b. Calcium channel blocker (e.g., verapamil, diltiazem);
6. Member is not currently treated or planning to be treated with disopyramide, ranolazine, or a combination of beta blockers and calcium channel blockers.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Obstructive Hypertrophic Cardiomyopathy (must meet all):

1. Member is currently receiving or has been treated with this medication within the past 120 days, excluding manufacturer samples;
2. Member has a left ventricular ejection fraction (LVEF) ≥ 55%.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. 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(10253):759-769. Available at: https://pubmed.ncbi.nlm.nih.gov/32871100/. Accessed September 4, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	06/20/2022	07/18/2022

Policy was reviewed: 1. Initial approval criteria I.A.6 was updated from "resting oxygen saturation ≥ 90%" to “LVOT ≥ 50 mmHg at rest or with provocation”. 2. Continued approval criteria II.A.2 was updated from “Documents supporting improvement of mixed peakVO_2 by ≥1.5 mL/kg/min plus at least one NYHA class reduction or a ≥3.0 mL/kg/min peakVO_2 increase without NYHA class worsening” to “Member has a left ventricular ejection fraction (LVEF) ≥ 55%”.	06/29/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with the new verbiage containing 120 days lookback period. 5. Updated approval duration verbiage.	8/28/2024	9/13/2024