Generic Name: Mavacamten

Applicable Drugs: Camzyos®

Applicable Drugs (if Therapeutic Class): Cardiovascular Agents

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/29/2022

Date Last Reviewed / Revised: 11/3/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of the following condition AND must meet criteria listed under applicable diagnosis:

   A. Symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy AND criteria 1 through 3 are met:

      1. Documentation of a left ventricular ejection fraction (LVEF) ≥ 55%.
      2. Documentation of a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation.
      3. Documented treatment failure, intolerance to, or contraindication to therapies including:
         1. Beta blocker
         2. Non-dihydropyridine calcium channel blocker
         3. Disopyramide

II. Minimum age requirement: 18 years old.

III. Prescribed by or in consultation with a cardiologist.

EXCLUSION CRITERIA

- Concomitant use of moderate to strong CYP2C19 inhibitors or inducers.
- Concomitant use of strong CYP3A4 inhibitors or inducers.
- Concomitant use of disopyramide or ranolazine
- Concomitant use with both beta blocker and non-dihydropyridine calcium channel blocker
- Persistent LVEF < 50% despite maintenance with 2.5 mg daily

OTHER CRITERIA

- Camzyos® is only available through a restricted program called the Camzyos® REMS Program because of the risk of heart failure due to systolic dysfunction.

- Interrupt treatment with Camzyos® if LVEF goes below 50% at any time.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 2.5 mg, 5 mg, 10 mg, and 15 mg capsules.
- Quantity limit of 30 capsules per 30 days.

APPROVAL LENGTH

- **Authorization:** 8 months.
- **Re-Authorization:** 1 year: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met, that the medication is effective, and LVEF remains > 50%.

APPENDIX

N/A

REFERENCES

1. Camzyos [package insert]. Brisbane, CA; MyoKardia, Inc.; 2023. https://packageinserts.bms.com/pi/pi_camzyos.pdf
2. Spertus JA. 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(10293):2467-2475. doi:10.1016/S0140-6736(21)00763-7
3. Ommen SR. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy: Executive Summary: 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. doi:10.1016/j.jacc.2020.08.044
4. Maron BJ, Desai MY, Nishimura RA, et al. Management of Hypertrophic Cardiomyopathy: JACC State-of-the-Art Review. *J Am Coll Cardiol*. 2022;79(4):390-414. doi:10.1016/j.jacc.2021.11.021