Camzyos (mavacamten)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial requests: 6 months Continuation requests: 1 year

Medications	Quantity Limit
Camzyos (mavacamten)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Camzyos (mavacamten) may be approved if the following criteria are met:

I. Individual has a diagnosis of obstructive hypertrophic cardiomyopathy (HCM); **AND**
II. Imaging shows (2020 AHA/ACC):
   A. Maximal end-diastolic left ventricular wall thickness of greater than or equal to 15 mm; **OR**
   B. Maximal end-diastolic left ventricular wall thickness of 13-14 mm in individual with family history of HCM or positive genetic test; **AND**
III. Individual is using to treat New York Heart Association (NYHA) class II-III symptoms; **AND**
IV. Individual has had a trial and inadequate response or intolerance to (2020 AHA/ACC):
   A. Beta-blocker therapy; **OR**
   B. Non-dihydropyridine calcium channel blocker therapy (diltiazem, verapamil); **OR**
   C. Contraindication to both beta blockers and non-dihydropyridine calcium channel blockers; **AND**
V. Individual has a left ventricular ejection fraction (LVEF) of greater than or equal to 55%.

Continuation requests for Camzyos (mavacamten) may be approved if the following criteria are met:

I. There is clinically significant improvement in clinical signs and symptoms of disease (including but not limited to improvement in NYHA class, improvement in mixed venous oxygen tension [pVO_2], improvement in post exercise left ventricular outflow tract [LVOT] gradient); **AND**
II. Individual has maintained a left ventricular ejection fraction (LVEF) of greater than or equal to 50% on therapy.

Requests for Camzyos (mavacamten) may not be approved for the following:

I. Use in combination with any of the following:

A. Moderate to strong CYP2C19 inhibitors (including but not limited to fluconazole, fluoxetine, fluvoxamine, felbamate); **OR**
B. Moderate to strong CYP2C19 inducers (including but not limited to rifampin, efavirenz, phenytoin); **OR**
C. Strong CYP3A4 inhibitors (including but not limited to clarithromycin, ketoconazole, itraconazole, ritonavir, nelfinavir, nefazodone); **OR**
D. Moderate to strong CYP3A4 inducers (including but not limited to carbamazepine, phenytoin, rifampin, St. John's wort, bosentan, efavirenz, phenobarbital); **OR**
E. Disopyramide; **OR**
F. Ranolazine; **OR**
G. Verapamil or diltiazem in combination with a beta blocker.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: May 5, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
4. 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;396:759–69.
5. 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.
6. US Food and Drug Administration. Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Last updated: March 10, 2020. Available at https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm093664.htm. Accessed: May 5, 2022.