SmartPA Criteria Proposal

Drug/Drug Class:	Camzyos™ Clinical Edit
First Implementation Date:	April 27, 2023
Revised Date:	TBD
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Camzyos™ (mavacamten)

Why Issue Selected: Camzyos™ (mavacamten) is the first FDA-approved medication for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM). HCM prevalence is age-dependent, with cases in both pediatric and adult populations. The prevalence of unexplained asymptomatic hypertrophy in young adults in the United States is reported to range from 1:200 to 1:500. In the 2020 AHA/ACC/HFSA Guideline for the Management of Heart Failure, non-vasodilating beta-blockers are considered first line therapy management of HCM. Non-dihydropyridine calcium channel blockers (non-DHP CCB) are recommended in patients for whom beta blockers are ineffective or not tolerated, and third line disopyramide are recommended only to reduce symptoms. However, these are not disease modifying treatments. Septal reduction therapy, although effective, has its own inherent risks, including death. Camzyos, likely be used as add-on therapy especially in patients that are poor candidates for surgical intervention, does not have long-term evidence that supports therapy. Camzyos is available only through REMS program because of its risk of heart failure due to systolic dysfunction.

Due to the possible adverse events and specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Camzyos.

Program-Specific Information:

Date Range FFS 10-1-2021 to 9-30-2022			
Drug	**Claims**	**Cost per tablet (WAC)**	**Cost per year (WAC)**
CAMZYOS 2.5MG CAPSULE	0	$245.21	$89,499.93
CAMZYOS 5MG CAPSULE			
CAMZYOS 10MG CAPSULE			
CAMZYOS 15MG CAPSULE			

Type of Criteria:
☒ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Camzyos™ (mavacamten)
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

- Prescribed by or in consultation with cardiologist or other specialist in the treated disease state **AND**
- Documented compliance with current therapy regimen (90/120 days) **OR**
- Participant is aged ≥ 18 years old **AND**
- Documented diagnosis of obstructive hypertrophic cardiomyopathy **AND**
- Documentation of at least 6 months therapy with a beta blocker or non-DHP CCB

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Claim exceeds 1 capsule per day

Required Documentation

Laboratory Results:		Progress Notes:	X
MedWatch Form:	X	Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

6 months

References

- CAMZYOS™ (mavacamten) [package insert]. Brisbane, CA: MyoKardia, Inc; May 2022
- Sensarian C, Ingles J, Maron MS, et al. New perspectives on the prevalence of hypertrophic cardiomyopathy. J AM Coll Cardiol. 2015;65:1249-54.
- Ommen SR, Mital S, Burke MA, et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy: Executive Summary. Circulation.2020;142(25):e533-e557.
- IPD Analytics: New Drug Review: Camzyos (mavacamten). Accessed June 2022.
- Institute for Clinical and Economic Review. Mavacamten for Hypertrophic Cardiomyopathy: Effectiveness and Value: Evidence Report, 2021, https://icer.org/wp-content/uploads/2021/04/ICER_HCM_Revised_Report_100721.pdf . Accessed June 2022.
- Bristol Myers Squibb. CAMZYOS™ (mavacamten) REMS Education Program for Healthcare Providers and Pharmacies. https://www.camzyosrems.com/assets/commercial/us/camzyosrems/en/pdf/Camzyos-Prescriber-Education-Program.pdf. June 2022.