**Effective Date: 05/30/2026**
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**Policy Number: C30603-A**

# Myqorzo (aficamten)

## PRODUCTS AFFECTED

Myqorzo (aficamten)

## COVERAGE POLICY

*Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.*

***Documentation Requirements:***
*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

**DIAGNOSIS:**
Obstructive hypertrophic cardiomyopathy

**REQUIRED MEDICAL INFORMATION:**
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. This clinical policy will be reviewed along with state and federal requirements, the benefit being administered and formulary preferencing. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available. The Pharmacy and Therapeutics Committee has determined that biosimilars may be preferred.

A. OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY:
   1. Documented diagnosis of New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (oHCM)
      AND

2. Documentation member's left ventricular ejection fraction (LVEF) is ≥ 55% [DOCUMENTATION REQUIRED]
   AND
3. Documentation member has had prior therapy or labeled contraindication or serious side effect to beta blockers (e.g., metoprolol, propranolol, atenolol) and/or non-dihydropyridine calcium channel blockers (e.g., verapamil, diltiazem)
   AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Myqorzo (aficamten) include: concomitant use of rifampin. Avoid concomitant use of fluconazole or voriconazole if receiving Myqorzo 5 mg or 10 mg.]

**CONTINUATION OF THERAPY:**

A. OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms
   AND
4. Documentation member's most recent (within the last 60 days) left ventricular ejection fraction (LVEF) is ≥50% [DOCUMENTATION REQUIRED]

**DURATION OF APPROVAL:**
Initial authorization: 12 months, Continuation of Therapy: 12 months

**PRESCRIBER REQUIREMENTS:**
Prescribed by or in consultation with a board-certified cardiologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

**AGE RESTRICTIONS:**
18 years of age and older

**QUANTITY:**
Starting dose: 5 mg once daily (See Appendix)

**Maximum Quantity Limits –** 20 mg daily

**PLACE OF ADMINISTRATION:**
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

## DRUG INFORMATION

**ROUTE OF ADMINISTRATION:**
Oral

**DRUG CLASS:**
Cardiac Myosin Inhibitors

**FDA-APPROVED USES:**
Indicated for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms.

**COMPENDIAL APPROVED OFF-LABELED USES:**
None

## APPENDIX

**APPENDIX:**
The recommended starting dose of Myqorzo (aficamten) is 5 mg orally once daily. Increase the dose every 2 to 8 weeks by 5 mg until a maintenance dose or the maximum recommended dose of 20 mg once daily is achieved. The maintenance dose of Myqorzo is individualized based on the patient's LVEF and Valsalva left ventricular outflow tract gradient (LVOT-G). Recommendations for dosing based on LVEF and LVOT-G criteria are provided in the table below.

**Dose Adjustment of MYQORZO**

| LVEF | Valsalva LVOT-G | Dose Adjustment |
|---|---|---|
| ≥55% | ≥30 mmHg | Increase dose by 5 mg<br>(up to the maximum dose of 20 mg once daily) |
| ≥55% | <30 mmHg | Maintain Dose |
| <55% and ≥50% | Any | Maintain Dose |
| <50% and ≥40% | Any | Decrease dose by 5 mg[1]<br><br>If already on 5 mg, interrupt treatment for at least 7 days |
| <40% | Any | Interrupt treatment for at least 7 days |

1. Decrease dose as follows: 20 mg to 15 mg; 15 mg to 10 mg; 10 mg to 5 mg

Perform an echocardiographic assessment 2 to 8 weeks after initiation of treatment or any dose adjustment (e.g., due to LVEF and LVOT-G criteria or drug interaction). After a treatment interruption due to low LVEF, resume treatment, no earlier than 7 days, when LVEF ≥55% and re-initiate dose titration at the starting dose of 5 mg (see table).

After the maintenance dose has been established, assess LVEF and Valsalva LVOT-G every 6 months, or every 3 months in patients with LVEF <55% to ≥50%. Consider monitoring LVEF and adjust the dose as needed (see table), in patients with an intercurrent illness (e.g., severe infection or COVID-19), new arrhythmia (e.g., new or uncontrolled atrial fibrillation or other uncontrolled tachyarrhythmia) or any other conditions that may impair systolic function. Do not increase the dose until the intercurrent illness or new arrhythmia has resolved or stabilized.

## BACKGROUND AND OTHER CONSIDERATIONS

**BACKGROUND:**
Hypertrophic cardiomyopathy (HCM) is recognized as the most common inherited cardiovascular disorder. It results from pathogenic variants in sarcomere-related genes responsible for the heart's contractile function. The condition follows an autosomal-dominant pattern of inheritance. Although genetic transmission occurs equally among males and females, women are diagnosed at a lower frequency than men.

HCM is a chronic, progressive disease characterized by unexplained left ventricular (LV) hypertrophy that results from excessive myocardial contractility. HCM is classified into two subtypes: obstructive HCM (oHCM), which is defined by left ventricular outflow tract (LVOT) obstruction, and nonobstructive HCM (nHCM), in which myocardial hypertrophy is present without LVOT obstruction. Over the course of disease progression, approximately 5–10% of patients with HCM develop serious complications, including heart failure (HF), thromboembolic events (such as stroke), and sudden cardiac death (SCD) due to arrhythmia.

While many individuals remain asymptomatic, others may experience chest pain, dyspnea, palpitations, syncope, or lightheadedness, particularly with exertion. Clinical evaluation is typically prompted by the onset of symptoms, a cardiac event, the detection of a heart murmur, an abnormal 12-lead electrocardiogram on routine examination, or cardiac imaging findings during family screening.

Diagnosis of HCM is largely based on symptom manifestation, imaging of the heart (primarily through echocardiography), and genetic testing. Advances in diagnostic imaging and disease management have improved the detection and treatment of HCM, with contemporary data suggesting that overall HCM-related mortality is approximately 0.5% per year.

There is currently no cure for oHCM or nHCM. Management focuses on symptom relief, functional capacity improvement, and SCD prevention, with treatment guided by symptom severity and disease progression. Foundational pharmacologic therapy includes the use of β-blockers (e.g. metoprolol, propranolol, atenolol) or non-dihydropyridine calcium channel blockers (CCBs) (e.g. verapamil, diltiazem). For patients with atrial fibrillation, additional therapies could also include antiarrhythmics (e.g. amiodarone, disopyramide) or anticoagulants, which both reduce thromboembolic risk. For patients with persistent or severe symptoms, procedural intervention (such as septal reduction therapy [SRT]), implantable cardioverter-defibrillator (ICD) placement (for SCD risk mitigation), or heart transplantation (in advanced disease) may also be considered. SRT reduces LVOT obstruction and can improve symptoms in patients who do not respond adequately to medical therapy.

Cardiac myosin inhibitors (CMIs) are the first disease-specific pharmacologic drug class for symptomatic oHCM. CMIs target the underlying hypercontractility of the LV, which drives the obstruction of the LVOT. Camzyos (mavacamten) was the first CMI approved for adults with symptomatic, New York Heart Association (NYHA) class II–III oHCM indicated to improve functional capacity and symptoms. The 2024 American Heart Association (AHA)/American College of Cardiology Foundation (ACC) guidelines recommend CMIs for patients with symptomatic oHCM who remain symptomatic despite having received first-line therapy with β-blockers or non-dihydropyridine CCBs. Accordingly, CMIs are positioned as a second-line therapy alongside the antiarrhythmic agent disopyramide (in combination with an atrioventricular nodal blocking agent) or SRT (when performed at an experienced, comprehensive HCM center).

Currently, there are no FDA-approved pharmacologic therapies specifically indicated for the treatment of nHCM, with treatment typically limited to symptom management.

Myqorzo (aficamten) is an allosteric and reversible inhibitor of cardiac myosin motor activity. Aficamten reduces the force generated by myosin at the cardiac sarcomere, which contributes to the pathophysiology of HCM. In patients with HCM, myosin inhibition with aficamten reduces cardiac contractility and LVOT obstruction.

The efficacy of Myqorzo was evaluated in SEQUOIA-HCM (NCT05186818), a phase 3, multicenter, randomized, double-blind, placebo-controlled study in 282 adults (142 aficamten, 140 placebo) with symptomatic New York Heart Association (NYHA) class II and III oHCM, LVEF ≥60%, and resting and post-Valsalva peak LVOT-G ≥30 and ≥50 mmHg at screening, respectively. Patients who completed SEQUOIA-HCM were eligible to participate in an ongoing, open-label, single-arm extension study (FOREST-HCM). Patients with a known infiltrative or storage disorder causing cardiac hypertrophy such as Noonan syndrome, Fabry disease or amyloidosis were excluded.

Patients were randomized in a 1:1 ratio to receive either Myqorzo or placebo once daily for 24 weeks. Randomization was stratified by use of beta-blockers (yes or no) and cardiopulmonary exercise testing (CPET) exercise modality (treadmill or bicycle).

At baseline, 76% of the randomized patients were NYHA class II and 24% were NYHA class III. The mean peak oxygen uptake (pVO2) by CPET at baseline was 18.5 mL/kg/min with 55% using treadmill and 45% using bicycle, respectively. At baseline, the median LVEF was 76%, the mean resting LVOT-G was 55 mmHg, the mean Valsalva LVOTG was 83 mmHg, and mean Kansas City Cardiomyopathy Questionnaire – Clinical Summary Score (KCCQ-CSS) was 74. At baseline, 61% of patients were on beta-blockers, 29% were on non-dihydropyridine calcium channel blockers, 13% were on disopyramide, and 15% were not taking any background medication for oHCM.

Patients were initiated on Myqorzo at a dose of 5 mg once daily. Doses were individually titrated (or sham-titrated if on placebo) at Week 2, 4 and 6 if Valsalva LVOT-G was ≥30 mmHg and LVEF was ≥55% in 5 mg dose increments up to a maximum dose of 20 mg once daily. At Week 24, in the Myqorzo group, 46% of patients were on the 20 mg dose, 35% were on the 15 mg dose, 15% were on the 10 mg dose and 4% were on the 5 mg dose.

In SEQUOIA-HCM, the primary endpoint of change from baseline in pVO2 to Week 24 was greater with Myqorzo compared to placebo.

Secondary endpoints (treatment effects of Myqorzo on health status, functional capacity, and LVOT obstruction) were assessed by change in the KCCQ-CSS, proportion of patients with ≥1 class improvement in NYHA functional class, change from baseline in Valsalva LVOT-G, proportion of patients with Valsalva LVOT-G ≤30 mmHg, duration of eligibility for septal reduction therapy (SRT), and change in total workload during CPET. At Week 24, patients receiving Myqorzo had greater improvement compared to the placebo group across all secondary points.

Myqorzo's label includes a Boxed Warning noting that Myqorzo reduces LVEF and can cause HF due to systolic dysfunction. The Boxed Warning states dosage should be decreased if LVEF is <50% and ≥40% and interrupted if LVEF <40% or if the patient experiences HF symptoms or worsening clinical status due to systolic dysfunction. Due to HF risk, Myqorzo is available only through a Risk Evaluation and Mitigation Strategy (REMS) program.

Importantly, the SEQUOIA-HCM Phase 3 trial reported there were no instances of clinical worsening of HF or treatment interruptions due to LVEF on Myqorzo. However, core lab echocardiography showed that five patients receiving Myqorzo experienced reversible reductions in LVEF to <50%, compared with one patient on placebo; these decreases were not associated with clinical HF and did not require treatment discontinuation. Myqorzo reduces cardiac contractility as part of its mechanism of action, which can lower LVEF and carries an inherent risk of systolic dysfunction, therefore necessitating regular echocardiographic monitoring per the REMS requirements.

Hypertension was the only adverse reaction occurring in >5% of patients, occurring in 8% of Myqorzo-treated patients versus 2% in placebo-treated patients. Eligible patients with oHCM could participate in an ongoing, open-label, single-arm, long-term safety study (FOREST-HCM [NCT04848506]). Based on available data, the safety profile of Myqorzo in FOREST-HCM was similar to that observed in SEQUOIA-HCM.

**MYQORZO REMS Program**

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure the benefits of a drug outweigh its risks.

Myqorzo (aficamten) is available only through a restricted program called the MYQORZO REMS Program, because of the risk of heart failure due to systolic dysfunction.

Notable requirements of the MYQORZO REMS Program include the following:

- Prescribers must be certified by enrolling in the MYQORZO REMS Program.
- Patients must enroll in the MYQORZO REMS Program and comply with ongoing monitoring requirements.
- Pharmacies must be certified by enrolling in the MYQORZO REMS Program and must only dispense to patients who are authorized to receive Myqorzo.
- Wholesalers and distributors must only distribute to certified pharmacies.

Further information is available at www.MYQORZOREMS.com or by telephone at 1-844-285-7367.

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**
All other uses of Myqorzo (aficamten) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Myqorzo (aficamten) include: concomitant use of rifampin. Avoid concomitant use of fluconazole or voriconazole if currently receiving Myqorzo 5 mg or 10 mg.

**Exclusions/Discontinuation:**
Initiation or up-titration of Myqorzo (aficamten) in patients with LVEF <55% is not recommended.

Interrupt the dose of Myqorzo if LVEF <40% or if the patient experiences heart failure symptoms or worsening clinical status due to systolic dysfunction.

**OTHER SPECIAL CONSIDERATIONS:**
Myqorzo (aficamten) has a Black Box Warning for risk of heart failure Myqorzo reduces LVEF and can cause heart failure due to systolic dysfunction. Echocardiogram assessments are required prior to and during treatment with Myqorzo to monitor for systolic dysfunction. Myqorzo is available only through a restricted program called the MYQORZO REMS Program, because of the risk of heart failure due to systolic dysfunction.

The recommended starting dose of Myqorzo is 5 mg once daily. Increase the dose every 2 to 8 weeks by 5 mg until a maintenance dose or the maximum recommended dose of 20 mg once daily is achieved. Maintenance dose is based on individual clinical status and echocardiographic assessment.

Initiate Myqorzo at the recommended starting dose (5 mg once daily) in patients who are on stable therapy with fluconazole, voriconazole, fluvoxamine, strong CYP2C9 inhibitors, or in patients discontinuing a moderate to strong CYP3A inducer.

Concomitant Administration with Fluconazole or Voriconazole -
In patients who initiate fluconazole (if used for more than 3 days) or voriconazole, reduce the dose of Myqorzo to 5 mg if they are currently receiving 15 mg or 20 mg. Assess LVEF and LVOT-G 2 to 8 weeks after initiation of fluconazole or voriconazole and titrate the dose of Myqorzo. (See Appendix)

Concomitant Administration with Fluvoxamine or Strong CYP2C9 Inhibitors -
In patients who initiate fluvoxamine or a strong CYP2C9 inhibitor, reduce the dose of Myqorzo (20 mg to 10 mg; 15 mg to 5 mg; 10 mg to 5 mg). For patients currently receiving Myqorzo 5 mg, maintain the 5 mg dose. Assess LVEF and LVOT-G 2 to 8 weeks after inhibitor initiation and titrate the dose of Myqorzo. (See Appendix)

Concomitant Administration with Moderate to Strong CYP3A Inducers -
In patients who are on stable therapy with moderate to strong CYP3A inducers (e.g., carbamazepine), when discontinuing these medications, reduce the dose of Myqorzo (20 mg to 10 mg; 15 mg to 5 mg; 10 mg to 5 mg). For patients currently receiving Myqorzo 5 mg, maintain the 5 mg dose. Assess LVEF and LVOT-G 2 to 8 weeks after inducer discontinuation and titrate the dose of Myqorzo. (See Appendix)

## CODING/BILLING INFORMATION

***CODING DISCLAIMER.*** *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

| HCPCS CODE | DESCRIPTION |
|---|---|
| NA | |

**AVAILABLE DOSAGE FORMS**:
Myqorzo TABS 5MG
Myqorzo TABS 10MG
Myqorzo TABS 15MG
Myqorzo TABS 20MG

## REFERENCES


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3. Masri A, Choudhury L, Barriales-Villa R, Elliott P, et al: FOREST-HCM Investigators. Open-label extension study to evaluate the long-term safety and tolerability of aficamten in adults with HCM. https://clinicaltrials.gov/study/NCT04950118
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7. Butzner, M., Sharma, A., Amin, A., Miller, J., Lemor, A., Basir, M. B., & Alkhouli, M. (2026). Epidemiology of hypertrophic cardiomyopathy in the United States from 2016 to 2023. JACC: Advances, 5(2), 102552. https://doi.org/10.1016/j.jacadv.2025.102552


| SUMMARY OF REVIEW/REVISIONS | DATE |
|---|---|
| NEW CRITERIA CREATION | Q1 2026 |