VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Cardiology – Myqorzo Prior Authorization with Step Therapy Policy
- Myqorzo™ (aficamten tablets – Cytokinetics)

REVIEW DATE: 04/01/2026

OVERVIEW

Myqorzo, a cardiac myosin inhibitor, is indicated for the **treatment of symptomatic obstructive hypertrophic cardiomyopathy (HCM)** to improve functional capacity and symptoms in adults.[1]

Disease Overview

HCM is a complex, heterogeneous myocardial disorder characterized by thickening (hypertrophy) of the left ventricular wall without dilation and in the absence of another identifiable cardiac, systemic, or metabolic cause.[2] The condition is typically inherited in an autosomal dominant pattern and affects approximately 1 in 200 to 500 adults across all ethnic backgrounds, equally in men and women. Patients of any age can be impacted, though many remain undiagnosed or asymptomatic. Diagnosis is usually established by echocardiography or cardiac magnetic resonance imaging, which reveals a hypertrophied, nondilated left ventricle. The hypertrophied ventricle becomes stiff, impairing diastolic filling and reducing stroke volume. In addition, the heart muscle may contract with excessive force, further compromising cardiac efficiency.[3] Approximately 70% of patients have obstructive HCM, in which left ventricular outflow tract obstruction occurs due to systolic contact between the mitral valve and the ventricular septum.[2] This obstruction forces the heart to generate higher pressures to maintain cardiac output. Cardiac hypercontractility, driven by excessive actin-myosin crossbridge formation within the sarcomere, further promotes obstruction and increases myocardial workload.[3] Patients may experience exertional dyspnea, fatigue, chest pain, palpitations, lightheadedness, syncope, or exercise intolerance.[2] Many develop atrial fibrillation, ventricular arrhythmias, or heart failure, and sudden cardiac death can occur.

Clinical Efficacy

The efficacy of Myqorzo was evaluated in SEQUOIA-HCM (n = 282), a Phase III, double-blind, placebo-controlled pivotal study.[1,3] Adults with a confirmed diagnosis of symptomatic obstructive HCM, New York Heart Association (NYHA) functional class II or III heart failure, and left ventricular ejection fraction (LVEF) ≥ 60% were randomized to receive Myqorzo or placebo. The starting dose of Myqorzo was 5 mg, with subsequent opportunities to increase to a maximum dose of 20 mg. The primary efficacy endpoint was the change from baseline to Week 24 in the peak oxygen uptake as assessed by cardiopulmonary exercise testing. At 24 weeks, the mean change in peak oxygen uptake was 1.8 mL/kg/min (95% confidence interval [CI]: 1.2, 2.3) in the Myqorzo group vs. 0.0 mL/kg/min (95% CI: -0.5, 0.5) in the placebo group. The least squares mean between-group difference was 1.7 mL/kg/min (95% CI: 1.0, 2.4; $P < 0.001$). The results of all ten secondary endpoints were significantly improved with Myqorzo vs. placebo.

Guidelines

Myqorzo is not yet addressed in guidelines. The American Heart Association and American College of Cardiology, alongside other organizations, published updated guidelines for the diagnosis and treatment of patients with HCM in 2024.[4] For symptomatic patients with obstructive HCM attributable to left ventricular outflow tract obstruction, non-vasodilating beta-blockers are recommended to be titrated to effectiveness or maximally tolerated doses. In patients for whom beta-blockers are not effective or not tolerated, substitution with nondihydropyridine calcium channel blockers (CCBs) [e.g., verapamil, diltiazem] is recommended. If patients continue to have severe symptoms despite treatment with beta-blockers and/or nondihydropyridine CCBs, adding a myosin inhibitor (i.e., Camzyos) or disopyramide (in combination with

an atrioventricular nodal blocking agent), or septal reduction performed at experienced centers is recommended. The guidelines note that Camzyos is only for use in adults. Camzyos is also contraindicated in pregnant patients due to potential teratogenic effects.

Safety

Myqorzo has a Boxed Warning regarding the risk of heart failure.[1] The agent may cause heart failure due to systolic dysfunction. Echocardiogram assessment of LVEF is required before and during Myqorzo use. Initiation in patients with LVEF < 55% is not recommended. Therapy should be interrupted if LVEF < 50% or if worsening clinical status occurs. Certain cytochrome P450 inhibitors and inducers are contraindicated in patients receiving Myqorzo due to an increased risk of heart failure. Myqorzo is available only through a restricted program called the Myqorzo Risk Evaluation and Mitigation Strategy (REMS) program. Notable requirements 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 the medication to certified pharmacies.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Myqorzo. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Myqorzo as well as the monitoring required for adverse events and long-term efficacy, approval requires Myqorzo to be prescribed by a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Myqorzo is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Obstructive Hypertrophic Cardiomyopathy.** Approve for the duration noted below if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets BOTH of the following (a and b):
       - **a)** Patient has at least one symptom associated with obstructive hypertrophic cardiomyopathy; AND
         Note: Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise.
       - **b)** Patient has New York Heart Association Class II or III symptoms of heart failure; AND
     - **iii.** Patient with left ventricular hypertrophy meets ONE of the following (a or b):
       - **a)** Patient has maximal left ventricular wall thickness ≥ 15 mm; OR
       - **b)** Patient has familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness ≥ 13 mm; AND

iv. Patient has a peak left ventricular outflow tract gradient ≥ 30 mmHg at rest or ≥ 50 mmHg after provocation (Valsalva maneuver or post exercise); AND
v. Patient has a left ventricular ejection fraction of ≥ 55%; AND
vi. Patient meets ONE of the following (a or b):
a) Patient has tried or is currently receiving at least one beta-blocker or nondihydropyridine calcium channel blocker for at least 3 months; OR
Note: Examples of beta-blockers include metoprolol, atenolol, and bisoprolol. Examples of nondihydropyridine calcium channel blockers include verapamil and diltiazem.
b) According to the prescriber, the patient has a contraindication or intolerance to a beta-blocker or nondihydropyridine calcium channel blocker; AND
Note: Examples of contraindications to beta-blockers include bradycardia, severe hypotension, severe reactive airway disease or active bronchospasms. Examples of intolerances to beta-blockers include symptomatic fatigue or exercise intolerance, symptomatic bradycardia, and hypotension. Examples of contraindications to calcium channel blockers include bradycardia and hypotension. Examples of intolerances to calcium channel blockers include peripheral edema and dizziness or orthostasis.
vii. The medication is prescribed by a cardiologist; OR

B) Patient Currently Receiving Myqorzo. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, and v):
i. Patient has been established on therapy for at least 1 year; AND
Note: A patient who has received < 1 year of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
ii. Patient is ≥ 18 years of age; AND
iii. Patient meets BOTH of the following (a and b):
a) Currently or prior to starting therapy, patient has or has experienced at least one symptom associated with obstructive hypertrophic cardiomyopathy; AND
Note: Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise.
b) Currently or prior to starting therapy, patient is in or was in New York Heart Association Class II or III heart failure; AND
iv. Patient meets ONE of the following (a or b):
a) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
Note: Examples include improved peak oxygen consumption/mixed venous oxygen tension; decreases in left ventricular outflow tract gradient; reductions in N-terminal pro-B-type natriuretic peptide levels; decreased high-sensitivity cardiac troponin I levels; reduced ventricular mass index; and/or a reduction in maximum left atrial volume index.
b) Patient experienced stabilization or improvement in at least one symptom related to obstructive hypertrophic cardiomyopathy; AND
Note: Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, ability to perform physical exercise, and/or favorable changes in the Kansas City Cardiomyopathy Questionnaire-23 (KCCQ-23) Clinical Summary Score (CSS) or Hypertrophic Cardiomyopathy Symptom Questionnaire (HCMSQ) Shortness of Breath domain scores.
v. The medication is prescribed by a cardiologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Myqorzo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Myqorzo™ tablets [prescribing information]. South San Francisco, CA: Cytokinetics; December 2025.
2. Braundwald E. Hypertrophic cardiomyopathy. *N Engl J Med.* 2025;393(10):1004-1015.
3. Maron MS, Masri A, Nassif ME, et al. Aficamten for symptomatic obstructive hypertrophic cardiomyopathy. *NEJM*. 2024;390(20):1849-1861.
4. Ommen SR, Ho CY, Asif IM, et al. 2024 ACC/AHA/AMSSM/HRS/PACES/SCMR guideline for the management of hypertrophic cardiomyopathy: a report of the American Heart Association/American College of Cardiology joint committee on clinical practice guidelines. *Circulation.* 2024;149(23):1524-4539.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/30/2025
Selected Revision	**Obstructive Hypertrophic Cardiomyopathy**. The approval duration for initial therapy was changed to 1 year. Previously, it was 8 months. The Note defining Class II and Class III heart failure was removed. For patients currently receiving Myqorzo, the requirement regarding patients being established on therapy for at least 8 months was changed to 1 year. The specialist requirement was updated to only allow a cardiologist to prescribe the medication; previously, consultation with a cardiologist was allowed.	01/14/2026
Selected Revision	**Obstructive Hypertrophic Cardiomyopathy**. The requirement for ejection fraction to be ≥ 50% for patients currently receiving Myqorzo was removed. The Note defining Class II and Class III heart failure symptoms was also removed.	03/11/2026
Early Annual Revision	The policy name was changed to as listed. Previously, it was Cardiology – Myqorzo Prior Authorization Policy. **Obstructive Hypertrophic Cardiomyopathy**. For the initial treatment, a requirement was added that a patient has tried or is currently receiving at least one beta-blocker or nondihydropyridine calcium channel blocker for at least 3 months, or, according to the prescriber, the patient has a contraindication or intolerance to a beta-blocker or nondihydropyridine calcium channel blocker. A Note of Examples of beta-blockers and nondihydropyridine calcium channel blockers was added. Another Note of Examples of contraindications and intolerances was added.	04/01/2026