PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 12/30/2025; selected revision 01/14/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 vs. 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 CCBs (e.g., verapamil, diltiazem) is recommended. If patients continue to have severe symptoms despite beta blockers and 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.

Myqorzo™ (aficamten tablets – Cytokinetics) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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, and vi):
     - **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. 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, v, and vi):

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
Note: Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest.

iv. Patient has a left ventricular ejection fraction of ≥ 50%; AND

v. 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.

vi. The medication is prescribed by a cardiologist.

CONDITIONS NOT COVERED

Myqorzo™ (aficamten tablets – Cytokinetics) is(are) considered not medically necessary for ANY other use(s). Criteria will be updated as new published data are available.

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

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