

aficamten (MyqorzoTM)**Policy # 00971**

Original Effective Date: 06/01/2026

Current Effective Date: 06/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider aficamten (MyqorzoTM)[†] for the treatment of obstructive hypertrophic cardiomyopathy to be **eligible for coverage**.^{**}

Patient Selection Criteria

Coverage eligibility for aficamten (Myqorzo) will be considered when the following criteria are met:

Initial

- Patient is 18 years of age or older; AND
- Patient has a diagnosis of obstructive hypertrophic cardiomyopathy; AND
- Patient is a New York Heart Association (NYHA) Class II or III; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has maximal left ventricular wall thickness greater than or equal to 15 mm, OR patient has familial hypertrophic cardiopathy and maximal left ventricular wall thickness greater than or equal to 13 mm; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has a peak left ventricular outflow tract gradient greater than or equal to 30 mmHg at rest or greater than or equal to 50 mmHg after provocation (Valsalva maneuver or post exercise); AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has a left ventricular ejection fraction (LVEF) greater than or equal to 55%; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) therapy with beta blockers (metoprolol, propranolol, atenolol) and/or calcium channel blockers (diltiazem, verapamil) unless there is clinical evidence or patient history that suggests the use of these agents will be ineffective or cause an adverse reaction to the patient; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

aficamten (Myzorzo™)

Policy # 00971

Original Effective Date: 06/01/2026

Current Effective Date: 06/01/2026

- Requested drug will NOT be used in combination with rifampin; AND
- Requested drug will NOT be used in combination with another cardiac myosin inhibitor (i.e., mavacamten [Camzyos™]).

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

Continuation

- Patient has an initial authorization; AND
- Patient has a left ventricular ejection fraction (LVEF) greater than or equal to 40%; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- If LVEF is less than 50% and greater than or equal to 40%, prescriber attests that appropriate dose adjustment and follow-up echocardiography have been performed; AND

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Patient has experienced a beneficial clinical response with Myzorzo. (Beneficial clinical responses 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; a reduction in maximum left atrial volume index; improvement in symptoms associated with obstructive hypertrophic cardiomyopathy).

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of aficamten (Myzorzo) when the patient is not a New York Heart Association (NYHA) Class II or III to be **not medically necessary.****

Based on review of available data, the Company considers the use of aficamten (Myzorzo) when the patient does not have maximal left ventricular wall thickness greater than or equal to 15 mm OR when the patient does not have familial hypertrophic cardiopathy and maximal left ventricular wall thickness greater than or equal to 13 mm to be **not medically necessary.****

Based on review of available data, the Company considers the use of aficamten (Myzorzo) when the patient does not have a peak left ventricular outflow tract gradient greater than or equal to 30 mmHg at rest or greater than or equal to 50 mmHg after provocation (Valsalva maneuver or post exercise) to be **not medically necessary.****

Based on review of available data, the Company considers the use of aficamten (Myzorzo) when the patient has not tried and failed therapy with beta blockers (metoprolol, propranolol, atenolol) and/or calcium channel blockers (diltiazem, verapamil) to be **not medically necessary.****

Based on review of available data, the Company considers the use of aficamten (Myzorzo) in combination with another cardiac myosin inhibitor to be **not medically necessary.****

aficamten (MyzorzoTM)

Policy # 00971

Original Effective Date: 06/01/2026

Current Effective Date: 06/01/2026

Based on review of available data, the Company considers the continued use of aficamten (Myzorzo) when the patient does not have a left ventricular ejection fraction greater than or equal to 40% to be **not medically necessary**.**

Based on review of available data, the Company considers the continued use of aficamten (Myzorzo) when the prescriber does not prescriber attests that appropriate dose adjustment and follow-up echocardiography have been performed when the patient has a LVEF less than 50% and greater than or equal to 40% to be **not medically necessary**.**

Based on review of available data, the Company considers the continued use of aficamten (Myzorzo) when the patient has not experienced a beneficial clinical response to Myzorzo to be **not medically necessary**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of aficamten (Myzorzo) for any non-FDA approved indication to be **investigational**.*

Based on review of available data, the Company considers the use of aficamten (Myzorzo) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary****) to be **investigational**.*

Background/Overview

Myzorzo (aficamten) is an oral cardiac myosin inhibitor indicated for the treatment of symptomatic obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms in adults. Aficamten is an allosteric and reversible inhibitor of cardiac myosin that reduces excessive myocardial contractility, thereby decreasing left ventricular outflow tract (LVOT) obstruction and improving diastolic filling. Treatment is initiated at 5 mg orally once daily, with dose increases in 5-mg increments at intervals of 2 to 8 weeks, as needed, to a maximum recommended dose of 20 mg once daily, based on left ventricular ejection fraction (LVEF) and LVOT gradient. Initiation of therapy is not recommended in patients with LVEF < 55%, and treatment should be reduced or interrupted if LVEF declines, with interruption recommended when LVEF falls below 40%. Due to the risk of heart failure related to systolic dysfunction, Myzorzo carries a boxed warning, requires routine echocardiographic monitoring, and is available only through a Risk Evaluation and Mitigation Strategy (REMS) program.

Hypertrophic cardiomyopathy (HCM) is the most common inherited cardiovascular disorder and is caused by mutations in sarcomere genes that lead to excessive myocardial contractility and unexplained left ventricular hypertrophy. The condition is inherited in an autosomal-dominant pattern and affects approximately 1 in 200 to 500 adults, although many individuals remain undiagnosed or asymptomatic. HCM is classified as obstructive or non-obstructive, with obstructive disease occurring in approximately 70% of patients due to dynamic left ventricular outflow tract

aficamten (MyzorzoTM)

Policy # 00971

Original Effective Date: 06/01/2026

Current Effective Date: 06/01/2026

(LVOT) obstruction. As disease progresses, patients may experience exertional dyspnea, chest pain, fatigue, palpitations, syncope, or exercise intolerance, and a subset develop serious complications such as heart failure, atrial or ventricular arrhythmias, thromboembolic events, or sudden cardiac death. There is no cure for obstructive or non-obstructive HCM; management focuses on symptom control, improvement in functional capacity, and risk reduction. Initial pharmacologic therapy typically includes beta blockers or nondihydropyridine calcium channel blockers, with additional options for patients who remain symptomatic including cardiac myosin inhibitors, disopyramide (in combination with atrioventricular nodal blockade), or septal reduction therapy (SRT) performed at experienced centers.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Myzorzo was approved in 2025 for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Clinical efficacy of Myzorzo was established in the SEQUOIA-HCM trial, a randomized, double-blind, placebo-controlled, multinational Phase III study that enrolled 282 adults with symptomatic obstructive hypertrophic cardiomyopathy. Eligible patients were 18 to 85 years of age with a confirmed diagnosis of HCM, left ventricular wall thickness ≥ 15 mm (or ≥ 13 mm for familial HCM), left ventricular ejection fraction (LVEF) $\geq 60\%$, and left ventricular outflow tract (LVOT) gradient ≥ 30 mmHg at rest or ≥ 50 mmHg with Valsalva, and were New York Heart Association (NYHA) functional class II or III with reduced exercise capacity. Key exclusion criteria included significant valvular disease, obstructive coronary artery disease or prior myocardial infarction, infiltrative or storage disorders causing cardiac hypertrophy, and severe renal impairment. Patients were randomized to receive Myzorzo starting at 5 mg once daily with protocol-guided titration up to 20 mg once daily or placebo for 24 weeks, with background HCM therapy permitted. The primary endpoint was the change from baseline to Week 24 in peak oxygen uptake measured by cardiopulmonary exercise testing. At Week 24, patients receiving Myzorzo demonstrated a mean increase of 1.8 mL/kg/min in peak oxygen uptake compared with no change in the placebo group, corresponding to a least-squares mean between-group difference of 1.7 mL/kg/min ($P < 0.001$).

References

1. Myzorzo [package insert]. Cytokinetics. San Francisco, California. Updated February 2026.
2. Myzorzo. Drug Evaluation. Express Scripts. Updated December 2025.
3. Myzorzo (aficamten). New Drug Review. IPD Analytics. Updated February 2026.

Policy # 00971

Original Effective Date: 06/01/2026

Current Effective Date: 06/01/2026

Policy History

Original Effective Date: 06/01/2026

Current Effective Date: 06/01/2026

05/07/2026 Medical Policy Committee review

05/13/2026 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 05/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

aficamten (MyzorroTM)

Policy # 00971

Original Effective Date: 06/01/2026

Current Effective Date: 06/01/2026

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.