Clinical Policy: Aficamten (Myqorzo)

Reference Number: CP.PHAR.766
Effective Date: 03.01.26
Last Review Date: 02.26
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Aficamten (Myqorzo™) is a cardiac myosin inhibitor.

FDA Approved Indication(s)

Myqorzo is indicated for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results, or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Myqorzo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Obstructive Hypertrophic Cardiomyopathy (must meet all)**:**

1. Diagnosis of oHCM;
2. Member exhibits NYHA Class II to III symptoms, including but not limited to: effort-related dyspnea or chest pain, or syncope or near syncope attributed to left ventricular outflow tract obstruction;
3. Prescribed by or in consultation with a cardiologist;
4. Age ≥ 18 years;
5. Member has left ventricular hypertrophy with maximal left ventricular wall thickness of one of the following (a or b):
   a. ≥ 15 mm;
   b. ≥ 13 mm if member has familial HCM or in conjunction with a positive genetic test (*see Appendix D*);
6. Member has a left ventricular ejection fraction (LVEF) ≥ 55%;
7. Member has peak left ventricular outflow tract (LVOT) gradients of both of the following (a and b):
   a. ≥ 30 mmHg at rest;
   b. ≥ 50 mmHg with provocation;
8. Failure of TWO of the following at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated:*
   **For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   a. Non-vasodilating beta-blocker (e.g., atenolol, metoprolol, bisoprolol, propranolol);

b. Non-dihydropyridine calcium channel blocker (e.g., verapamil, diltiazem);
c. Add-on disopyramide therapy after failure of beta-blocker or calcium channel blocker monotherapy;

9. Myqorzo is not prescribed concurrently with Camzyos®;
10. Dose does not exceed 20 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Obstructive Hypertrophic Cardiomyopathy (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy as evidenced by improvement in obstructive HCM symptoms;
3. Myqorzo is not prescribed concurrently with Camzyos;
4. If request is for a dose increase, new dose does not exceed 20 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ER: extended release
FDA: Food and Drug Administration
IR: immediate release
LVEF: left ventricular ejection fraction
LVOT: left ventricular outflow tract
NYHA: New York Heart Association
oHCM: obstructive hypertrophic cardiomyopathy
REMS: Risk Evaluation and Mitigation Strategy

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
atenolol	50-100 mg PO QD	200 mg/day
metoprolol	50-100 mg PO QD	400 mg/day
bisoprolol	5-20 mg PO QD	20 mg/day
propranolol	80-320 mg PO QD or divided into 2-4 doses/day	320 mg/day
nadolol	40-80 mg PO QD	240 mg/day
verapamil	80-120 mg PO TID	480 mg/day
diltiazem	Immediate-release (IR): 30 mg PO QID Extended-release (ER): 120-180 mg PO QD	IR: 360 mg/day ER: 360-540 mg/day
disopyramide	200-250 mg PO BID	600 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): concomitant use of rifampin

- Boxed warning(s): risk of heart failure due to systolic dysfunction
  - Echocardiogram assessments of LVEF are required before and during Myqorzo use. Initiation in patients with LVEF < 55% is not recommended. Decrease dose if LVEF < 50% and ≥ 40%. Interrupt dosing if LVEF < 40% or if worsening clinical status. Myqorzo is available only through a restricted program called the Myqorzo REMS Program because of the risk of heart failure due to systolic dysfunction.

Appendix D: General Information

- The 2 most common genes associated with familial HCM are beta myosin heavy chain 7 (MYH7) and myosin-binding protein C3 (MYBPC3). Other genes include TNNI3, TNNT2, TPM1, MYL2, MYL3, and ACTC1.

V. Dosage and Administration

<table>
<tr><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td>oHCM</td><td>Initiation: 5 mg PO QD.

Maintenance: Increase the dose every 2 to 8 weeks by 5 mg until a maintenance dose or the maximum recommended dose of 20 mg PO QD is achieved. The maintenance dose is individualized based on the patient's LVEF and LVOT gradient. See table below for dose adjustments:
<table>
<tr><th>LVEF</th><th>Valsalva LVOT gradient</th><th>Dose adjustment</th></tr>
<tr><td>≥ 55%</td><td>≥ 30 mmHg</td><td>Increase dose by 5 mg (up to the maximum dose of 20 mg PO QD)</td></tr>
<tr><td>≥ 55%</td><td>< 30 mmHg</td><td>Maintain dose</td></tr>
<tr><td>< 55% and ≥ 50%</td><td>Any</td><td>Maintain dose</td></tr>
<tr><td>< 50% and ≥ 40%</td><td>Any</td><td>Decrease dose by 5 mg; if already on 5 mg, interrupt treatment for at least 7 days</td></tr>
<tr><td>< 40%</td><td>Any</td><td>Interrupt treatment for at least 7 days</td></tr>
</table>
Perform an echocardiographic assessment 2 to 8 weeks after initiation of treatment or any dose adjustment (e.g., due to LVEF and LVOT gradient 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. After the maintenance dose has been established, assess LVEF and Valsalva LVOT gradient every 6 months, or every 3 months in patients with LVEF < 55% to ≥ 50%.</td><td>20 mg/day</td></tr>
</table>

VI. Product Availability

Film-coated tablets: 5 mg, 10 mg, 15 mg, 20 mg

VII. References

1. Myqorzo Prescribing Information. South San Francisco, CA: Cytokinetcs, Inc.; December 2025. Available at: https://cytokinetics.com/wp-content/uploads/2025/12/MYQORZO_US_Prescribing_Information_and_Med_Guide.pdf. Accessed January 5, 2026.
2. Maron MS, Masri A, Nassif ME, et al. Aficamten for symptomatic obstructive hypertrophic cardiomyopathy. *N Engl J Med*. 2024;390(20):1849-1861.
3. Ommen SR, Ho CY, Asif IM, et al. 2024 AHA/ACC/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. J Am Coll Cardiol. 2024;83(23):2324-2405.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.06.26	02.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or

regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.