Clinical Policy: Aficamten (Myqorzo)

Reference Number: PA.CP.PHAR.766
Effective Date: 02/2026
Last Review Date: 01/2026

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 PA Health & Wellness® 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:
   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
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Obstructive Hypertrophic Cardiomyopathy (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
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. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

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 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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>
</table></td><td>20 mg/day</td></tr>
</table>

Indication	Dosing Regimen			Maximum Dose
	< 50% and ≥ 40%	Any	Decrease dose by 5 mg; if already on 5 mg, interrupt treatment for at least 7 days	
	< 40%	Any	Interrupt treatment for at least 7 days	
	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%.			

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
Policy created	01/2026