

MYQORZO (aficamten)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Symptomatic obstructive hypertrophic cardiomyopathy (oHCM)

Authorization of 6 months may be granted for treatment of oHCM when all of the following criteria are met:

1. This medication must be prescribed by a cardiologist enrolled in the MYQORZO REMS PROGRAM
2. The member is at least 18 years of age
3. Documentation that the member has one of the following:
 - i. Left ventricular wall thickness greater than or equal to 15 mm anywhere in the left ventricle
 - ii. Left ventricular wall thickness greater than or equal to 13mm anywhere in the left ventricle in members with familial hypertrophic cardiomyopathy or a positive genetic test (e.g., MYH7, MYBPC3, TNNI3, TNNT2, TPM1, MYL2, MYL3, ACTC1 gene variants)
4. Documentation that the member's functional status is New York Heart Association (NYHA) Class II or III
5. Documentation that the member has a left ventricular ejection fraction (LVEF) $\geq$ 55%, a baseline Valsalva left ventricular outflow tract (LVOT) peak gradient $\geq$ 50mmHg and a baseline resting LVOT gradient $\geq$ 30 mmHg
6. Documentation that the member has experienced an inadequate treatment response, intolerance, or contraindication to all of the following, or documentation specifying if a drug and/or class of drugs are not appropriate:
 - i. Beta blockers (e.g. metoprolol, propranolol, atenolol)
 - ii. Nondihydropyridine calcium channel blocker (e.g. verapamil, diltiazem)
 - iii. Disopyramide
7. Documentation that the member will not use the requested medication concomitantly with rifampin
8. Documentation that the member is not currently diagnosed with a disorder that causes cardiac hypertrophy that mimics oHCM, such as Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting continuation of therapy when all the following criteria are met:

1. Documentation that the member has achieved or maintained a positive clinical response to therapy (increase in peak oxygen consumption [pVO₂], NYHA class reduction).
2. Documentation that member has a LVEF $\geq$ 50%
3. Member will not use the requested medication concomitantly with rifampin

IV. QUANTITY LIMIT

Myqorzo 5mg, 10mg, and 15mg and 20mg tablets have a quantity limit of 1 tablet per day.

V. REFERENCES

1. Myqorzo [package insert]. South San Francisco, CA: Cytokinetics Incorporated; December 2025.
2. Ommen SR, Ho CY, Balaji S, 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. *Circulation*. 2024;149(23):e1239- e1311.
3. Maron MS, Masri A, Nassif ME, et al. Aficamten for symptomatic obstructive hypertrophic cardiomyopathy. *N Engl J Med*. 2024;390(20):1849-1861.
4. Maron B, Desai M, Nishimura R, et al. Management of Hypertrophic cardiomyopathy. *J Am Coll Cardiol*. 2022;79(4):390-414.