MEDICAL MUTUAL®

Drug Policy

Policy:	Verquvo (vericiguat)	Annual Review Date: 03/20/2024 Last Revised Date: 03/20/2024

OVERVIEW

Verquvo is a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%. Verquvo is contraindicated in combination with other sGC stimulators and in pregnancy and is not recommended for use in lactating women and in combination with PDE-5 inhibitors.

POLICY STATEMENT

This policy involves the use of Verquvo. Prior authorization is recommended for pharmacy benefit coverage of Verquvo. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Verquvo as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Verquvo be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Verquvo is recommended in those who meet the following criteria:

1. <u>Cardiovascular Death and Heart Failure (HF) Hospitalization Risk Reduction, initial therapy</u>
Criteria. *Patient must meet the following criteria*

- **A.** The patient is 18 years of age or older; AND
- **B.** The patient has a diagnosis of symptomatic chronic HF, NYHA class II-IV; AND
- **C.** The patient has ejection fraction (LVEF) less than 45%; AND
- **D.** The patient is not pregnant; AND
- **E.** The patient meets one of the following:
  - **a.** Recent hospitalization for HF (within 6 months of therapy initiation); OR
  - **b.** Recent need for outpatient IV diuretics (within 3 months of therapy initiation); AND

F. Verquvo is prescribed by or in consultation with a cardiologist; AND
G. The dose of Verquvo will not exceed 10 mg/day; AND
H. The patient had prior therapy trials with an ACEI/ARB and/or beta-blocker and/or mineralocorticoid receptor antagonist (MRA, also called aldosterone antagonist); AND
I. The patient will continue to receive concomitant therapy with at least THREE (3) other agents for HF, each from a separate pharmacotherapeutic class as follows:
  a. An ACEI (e.g. lisinopril, enalapril, etc.) or ARB (e.g. valsartan, candesartan, etc.); AND/OR
  b. A beta-blocker (e.g. metoprolol succinate, carvedilol, etc.); AND/OR
  c. An MRA (also called aldosterone antagonist, e.g. spironolactone, etc.); AND/OR
  d. A diuretic (e.g. furosemide, metolazone, etc.); AND/OR
  e. A sodium glucose co-transporter 2 (SGLT-2) inhibitor (e.g. Farxiga, Jardiance, etc.); AND/OR
  f. Entresto; AND/OR
  g. Corlanor; AND/OR
  h. Hydralazine and isosorbide dinitrate

2. <u>Cardiovascular Death and Heart Failure (HF) Hospitalization Risk Reduction, continuation of therapy</u>
Criteria. *Patient must meet the following criteria*

A. The patient is 18 years of age or older; AND
B. The patient has a diagnosis of chronic HF NYHA class II-IV with ejection fraction less than 45%; AND
C. Verquvo is prescribed by or in consultation with a cardiologist; AND
D. The dose of Verquvo will not exceed 10 mg/day; AND
E. The patient is not pregnant; AND
F. The prescriber determines that the patient has experienced clinical benefit while taking Verquvo (e.g. decreased hospitalizations, improved heart failure symptoms, improved quality of life, reduction in need of IV diuretics, etc.); AND
J. The patient will continue to receive concomitant therapy with at least THREE (3) other agents for HF, each from a separate pharmacotherapeutic class as follows:
  a. An ACEI (e.g. lisinopril, enalapril, etc.) or ARB (e.g. valsartan, candesartan, etc.); AND/OR
  b. A beta-blocker (e.g. metoprolol succinate, carvedilol, etc.); AND/OR
  c. An MRA (also called aldosterone antagonist, e.g. spironolactone, etc.); AND/OR
  d. A diuretic (e.g. furosemide, metolazone, etc.); AND/OR
  e. A sodium glucose co-transporter 2 (SGLT-2) inhibitor (e.g. Farxiga, Jardiance, etc.); AND/OR
  f. Entresto; AND/OR
  g. Corlanor; AND/OR
  a. Hydralazine and isosorbide dinitrate

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Verquvo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concomitant Use of Other Soluble Guanylate Cyclase (sGC) Stimulators.** Verquvo is contraindicated in patients with concomitant use of other sGC stimulators.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Verquvo [prescribing information]. Whitehouse Station, NJ: Merck; June 2021.
2. Vericiguat. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 6 January 2022. Accessed on 17 March 2022.