Pharmacy Policy Bulletin: J-1071 Verquvo (vericiguat) – Commercial and Healthcare Reform	
Number: J-1071	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial (1.)**: **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1071-006	**Original Date:** 04/07/2021
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Verquvo (vericiguat)
FDA-Approved Indication(s):	• 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 heart failure and ejection fraction less than 45%.

Background:

- Verquvo is a stimulator of soluble guanylate cyclase (sGC), an important enzyme in the nitric oxide (NO) and cyclic guanosine monophosphate (cGMP) pathways. When NO binds to sGC, the enzyme catalyzes the synthesis of intracellular cGMP. cGMP contributes to vascular tone, cardiac contractility, and cardiac remodeling. Heart failure (HF) is associated with impaired synthesis of NO and decreased activity of sGC, which may contribute to myocardial and vascular dysfunction. By directly stimulating sGC, Verquvo increases intracellular levels of cGMP, leading to smooth muscle relaxation and vasodilation.
- HF is a clinical syndrome resulting from any structural or functional impairment of ventricular filling or ejection of blood. The manifestations of HF are dyspnea and fatigue, which may limit exercise tolerance and cause fluid retention. Fluid retention can progress to pulmonary congestion, splanchnic congestion, and peripheral edema.
- Heart failure with reduced ejection fraction (HFrEF) occurs when the left ventricular ejection fraction (LVEF) is 40% or less and is accompanied by progressive left ventricular dilatation and adverse cardiac remodeling.
- Heart failure affects an estimated 6.5 million United States adults; it accounts for an estimated 1 million hospitalizations per year. Approximately 50% of these hospitalizations are caused by HFrEF.
- The New York Heart Association (NYHA) Functional Classification for heart failure is commonly used to evaluate severity of disease.

Class	Patient Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).

II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

- The table below describes the ACC/AHA stage classification system for heart failure.

Stage	**Patient symptoms**
A- At risk for Heart Failure	At risk for HF but without symptoms, structural heart disease, or cardiac biomarkers of stretch or injury (examples: diagnosed with hypertension, ASCVD, diabetes, metabolic syndrome and obesity, exposure to cardiotoxic agents, genetic variant for cardiomyopathy, or family history of cardiomyopathy)
B- Pre Heart Failure	No symptoms or signs of HF and evidence of 1 of the following: Structural Heart disease, increased filling pressures with evidence, and patients with risk factors + increased B-type Natriuretic Peptide (BNP) or constant elevated cardiac troponin levels
C-Symptomatic Heart Failure	Structural heart disease with current or previous symptoms of HF
D-Advanced Heart Failure	Heart failure symptoms that interfere with everyday life and with recurrent hospitalizations despite attempts to use Guideline Directed Medical Therapy (GDMT)

- A worsening HF event is defined as either hospitalization for HF or outpatient IV diuretic use. After the first worsening HF event, patients are at risk of additional worsening HF events. Subsequent worsening HF events tend to be longer in duration and occur more frequently as the heart muscle is unable to completely recover.
- The 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure states that vericiguat may be considered in select high-risk patients with HFrEF and recent worsening of heart failure despite taking guideline directed medical therapy (GDMT). GDMT includes: an angiotensin-converting enzyme inhibitor (ACEi), or an angiotensin receptor blocker (ARB), or an angiotensin receptor & neprilysin inhibitor (ARNi); a beta-blocker proven to reduce mortality (bisoprolol, carvedilol, or extended-release metoprolol succinate); a mineralocorticoid receptor antagonist (MRA) (spironolactone or eplerenone); and a sodium-glucose cotransporter-2 (SGLT2) inhibitor.
- Prescribing Considerations:
    - Verquvo has a boxed warning for embryo-fetal toxicity. Do not administer to a pregnant female because it may cause fetal harm. Females of reproductive potential should exclude pregnancy before the start of treatment. To prevent pregnancy, use an effective form of contraception during treatment and for one month after stopping treatment.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Verquvo may be approved when all of the following criteria are met **(A. through E.)**:

A. The member has a diagnosis of heart failure (ICD-10: I50).
B. The member's heart failure is classified as NYHA class II, III, or IV.
C. The member has a left ventricular ejection fraction (LVEF) less than 45%.
D. The member is taking Verquvo in combination with both of the following guideline directed medical therapies **(1. and 2.)**:
  1. The member is taking Verquvo in combination with one (1) of the following antihypertensives, or all are contraindicated **(a., b., or c.)**:
    a. Angiotensin-Converting Enzyme Inhibitor (ACEI)
    b. Angiotensin II Receptor Blocker (ARB)
    c. Entresto (sacubitril/valsartan)
  2. The member is taking Verquvo in combination with one (1) of the following beta-blockers, or all are contraindicated **(a., b., or c.):**
    a. bisoprolol
    b. carvedilol immediate-release or extended-release
    c. metoprolol succinate extended-release
E. The member meets one (1) of the following criteria **(1. or 2.)**:
  1. The member has been hospitalized for heart failure in the past 6 months.
  2. The member has received outpatient IV diuretics for heart failure in the past 3 months.

I. Reauthorization
When a benefit, reauthorization of Verquvo may be approved when the following criterion is met **(A.)**:
A. The prescriber attests that the member has experienced positive clinical response to therapy.

II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Verquvo [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.; May 2023.
2. Murphy SP, Ibrahim NE, Januzzi JL Jr. Heart Failure With Reduced Ejection Fraction: A Review. *JAMA.* 2020;324(5):488-504.
3. Desai AS, Stevenson LW. Rehospitalization for Heart Failure: Predict or Prevent? *Circulation*. 2012;126(4):501-506.
4. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2022. Accessed February 17, 2025.

5. Clinical Pharmacology powered by ClinicalKey Online; Tampa, FL: Elsevier 2021. Accessed February 17, 2025.
6. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Published April 1, 2022. Accessed February 17, 2025.