Verquvo® (vericiguat)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Verquvo (vericiguat) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Verquvo (vericiguat) is the first soluble guanylate cyclase stimulator approved for a heart failure (HF) indication

FDA-Approved Indications

Verquvo is 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%.

POLICY

Criteria for Approval

I. Verquvo (vericiguat) may be considered **medically necessary** when the following criteria is met:
   - The requested drug is being prescribed to reduce the risk of cardiovascular death and heart failure hospitalization in an adult patient with symptomatic chronic heart failure
   - The patient has a left ventricular ejection fraction (LVEF) less than 45 percent. Documentation is required for approval.
   - The patient is currently receiving optimal therapy for heart failure management (e.g., angiotensin-converting enzyme inhibitor [ACEI], angiotensin II receptor blocker [ARB], angiotensin receptor-neprilysin inhibitor [ARNI], beta-blocker)

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- If the request is not for continuation of therapy, the patient has had any of the following: A) Hospitalization for heart failure within the past 6 months, B) Use of outpatient intravenous (IV) diuretics for heart failure within the past 3 months

Approval will be for **12 months**

Verquvo (vericiguat) is considered **not medically necessary** for patients who do not meet the criteria set forth above.

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limit
Verquvo 30 tablets/30days

CLINICAL RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Verquvo is indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

VICTORIA was a randomized, parallel-group, placebo-controlled, double-blind, event-driven, multi-center trial that compared Verquvo to placebo in 5,050 adult patients with symptomatic chronic heart failure (New York Heart Association [NYHA] class II-IV) and left ventricular ejection fraction (LVEF) less than 45% following a worsening heart failure event. A worsening heart failure event was defined as heart failure hospitalization within 6 months before randomization or use of outpatient IV diuretics for heart failure within 3 months before randomization. Using the time parameters indicated in the study, the patient must have had a heart failure hospitalization within the past 6 months or use of outpatient IV diuretics for heart failure within the past 3 months if they are new to Verquvo treatment.

The 2021 update to the 2017 American College of Cardiology (ACC) expert consensus decision pathway for optimization of heart failure treatment incorporates streamlined information from the 2013 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) heart failure guideline and the 2017 ACC/AHA/Heart Failure Society of America (HFSA) focused update, in addition to new therapies for heart failure with reduced ejection fraction (HFrEF) that have emerged. The 2021 update can serve as interim guidance to clinicians during the comprehensive heart failure guideline update under development by the ACC. The 2021 update treatment algorithm for guideline-directed medical therapy including novel therapies recommends an angiotensin receptor-neprilysin inhibitor (ARNI)/angiotensin-converting enzyme inhibitor (ACEI)/angiotensin receptor blocker (ARB) (ARNI preferred), and an evidence-based beta blocker (carvedilol, metoprolol succinate, or bisoprolol) with a diuretic agent, as needed, as the mainstay of therapy. For patients with an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73m^2 or creatinine ≤ 2.5 mg/dL in males or ≤ 2.0 mg/dL in females or potassium ≤ 5.0 mEq/L, NYHA class II-IV, an aldosterone antagonist can be added. For patients meeting eGFR criteria, NYHA class II-IV, a sodium-glucose cotransporter-2 (SGLT2) inhibitor can be added. For patients with persistent volume overload, NYHA class II-IV, a diuretic agent can be titrated. For persistently symptomatic Black patients despite ARNI/beta-blocker/aldosterone antagonist/SGLT2 inhibitor, NYHA class III-IV, hydralazine and isosorbide dinitrate can be added. For patients with resting heart rate ≥ 70, on a maximally tolerated beta-blocker dose in sinus rhythm, NYHA class II-III, ivabradine can be added. Due to the various pharmacologic recommendations

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needed to create a patient-driven heart failure regimen, the patient must currently be receiving optimal therapy for heart failure management to receive approval.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD Diagnostic Codes.

- No applicable codes

REFERENCES

- Verquvo prescribing information. Whitehouse Station, NJ: Merck & Co., Inc.; 2021 January.
- Armstrong P, Pieske B, Anstrom K et al. Vericiguat in patients with heart failure and reduced ejection fraction. N Engl J Med. 2020; 382(20):1883-93.
- Maddox T, Januzzi Jr JL, Allen LA et al. 2021 update to the 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: answers to 10 pivotal issues about heart failure with reduced ejection fraction: a report of the American College of Cardiology solution set oversight committee. J Am Coll Cardiol. In press.

POLICY HISTORY

Policy #: 05.01.87
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Current Effective Date: June 4, 2021

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