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Coverage Policy Number IP0125

Vericiguat

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for vericiguat (**Verquvo**TM).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Vericiguat (Verquvo) is considered medically necessary when the following are met:

Heart failure. Individual meets **ALL** of the following criteria:

- A. 18 years of age or older
- B. **EITHER** of the following:
 - i. Hospitalization for heart failure was required within the last 6 months
 - ii. Outpatient intravenous diuretics were given within the last 3 months
- C. Left ventricular ejection fraction less than 45% prior to the initiation of Verquvo
- D. Medication is prescribed by, or in consultation with, a cardiologist

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of vericiguat (Verquvo) is considered medically necessary for the treatment of heart failure when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial and reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW

Verquvo, a soluble guanylate cyclase stimulator, is indicated for the management of symptomatic chronic heart failure (HF) in adults with an ejection fraction < 45 % to reduce the risk of cardiovascular (CV) death and HF hospitalization following a hospitalization for HF or need for outpatient intravenous diuretics.^{1,2}

Disease Overview

HF is a complex clinical syndrome hallmarked by dyspnea or exertional limitation caused by impaired ventricular filling or ejection of blood, or a combination of both.³ The condition impacts approximately 6.5 million US adults and accounts for an estimated 1 million hospitalizations annually. Approximately one-half of patients have heart failure with reduced ejection fraction. HF leads to significant morbidity and mortality, with a 1-year mortality rate of 7% and a 1-year hospitalization rate of approximately 32% of patients with chronic HF. HF has traditionally been broadly sub-classified according to the left ventricular ejection fraction (LVEF) into three categories: HF with preserved ejection fraction (LVEF ≥ 50%), HF with midrange ejection fraction (LVEF 41% to 49%), and HF with reduced ejection fraction (LVEF ≤ 40%).

References

1. Verquvo™ tablets [prescribing information]. Whitehouse Station, NJ: Merck; January 2021.
2. Armstrong PW, Pieske B, Anstrom KJ, et al, for the VICTORIA Study Group. Verquvo in patients with heart failure and reduced ejection fraction. *N Engl J Med*. 2020; 382(20):1883-1893.
3. Murphy SP, Ibrahim NE, Januzzi JL. Heart failure with reduced ejection fraction. A review. *JAMA*. 2020; 324(5):488-504.

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