

Commercial/Healthcare Exchange PA Criteria

Effective: 6/9/2021

Prior Authorization: VERQUVOTM (vericiguat)

<u>Products Affected</u>: VERQUVOTM (vericiguat) oral tablets

Medication Description:

Vericiguat is a stimulator of soluble guanylate cyclase (sGC), an important enzyme in the nitric oxide (NO) signaling pathway. When NO binds to sGC, the enzyme catalyzes the synthesis of intracellular cyclic guanosine monophosphate (cGMP), a second messenger that plays a role in the regulation of vascular tone, cardiac contractility, and cardiac remodeling. Heart failure is associated with impaired synthesis of NO and decreased activity of sGC, which may contribute to myocardial and vascular dysfunction. By directly stimulating sGC, independently of and synergistically with NO, vericiguat augments levels of intracellular cGMP, leading to smooth muscle relaxation and vasodilation.

Covered Uses: Heart failure (HF)

Exclusion Criteria:

- VERQUVO is contraindicated in patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators
- VERQUVO is contraindicated in pregnancy

Required Medical Information:

- 1. Diagnosis
- 2. Previous medications tried and failed

Age Restrictions: 18 years of age or older.

Prescriber Restrictions: Prescribed by or in consultation with a cardiologist

Coverage Duration: 1 year for initial and continuation of therapy

Other Criteria:

I. Initial Approval Criteria

(must meet all):

- 1. Patient has symptomatic chronic HF (New York Heart Association [NYHA] class II-IV); AND
- 2. Patient has left ventricular ejection fraction (LVEF) less than 45%; AND

Last Rev. June 9, 2021





- 3. The medication is requested following a hospitalization (within 6 months) for heart failure or need for outpatient IV diuretics (within 3 months); AND
- 4. Patient is treated with 3 or more heart failure medications (for example beta blocker, angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), mineralocorticoid receptor antagonist [MRA], angiotensin receptor and neprilysin inhibitor (ARNI), ivabradine, or sodium glucose co-transporter 2 (SGLT2) inhibitor); AND
- 5. There is documentation of an elevated brain natriuretic peptide (BNP) or NT-proBNP level; AND
- 6. If patient is a female of reproductive age, a pregnancy test is obtained prior to initiating treatment, to exclude pregnancy.
- 7. Patient does not have renal impairment (eGFR less than 15 mL/min/1.73 m (2)) or hepatic impairment (severe [eg, Child-Pugh C]); AND
- 8. The dose does not exceed 10 mg orally once daily.

II. Continued Therapy

- 1. Member is responding positively to therapy (there has been a reduction in hospitalizations for heart failure while on therapy compared to baseline, or there is no evidence of disease progression: worsening NYHA functional class or worsening signs and symptoms); AND
- 2. Member has not experienced unacceptable toxicity from the drug AND has not developed any contraindications.

References:

1. VERQUVO™ (vericiguat) tablets [Package Insert]. Whitehouse Station, NJ. MERCK & CO., INC. Updated January 19, 2021. Accessed April 27, 2021. Available at:

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=17056d73-1b1b-4bf2-9c07-b7a9367f0d6d

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New policy	New policy	All	6/9/2021

Last Rev. June 9, 2021

