Verquvo (vericiguat)
Policy Number: C21141-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
05/01/2021	04/2021	04/26/2022
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
	RxPA	Q2 2021 20210428C21141-A

PRODUCTS AFFECTED:
Verquvo (vericiguat)

DRUG CLASS:
Vasoactive Soluble Guanylate Cyclase Stimulator (sGC)

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Retail Pharmacy
The recommendation is that medications in this policy will be for pharmacy benefit coverage and patient self-administered

AVAILABLE DOSAGE FORMS:
Verquvo (vericiguat) Tab 2.5 MG (14,30, 100 ct), Verquvo (vericiguat) Tab 5 MG (14,30, 100 ct), Verquvo (vericiguat) Tab 10 MG(30, 90, 100ct)

FDA-APPROVED USES:
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%.

COMPENDIAL APPROVED OFF-LABELED USES:
None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
chronic heart failure

REQUIRED MEDICAL INFORMATION:
A. CHRONIC HEART FAILURE:
1. Documented diagnosis of chronic heart failure (New York Heart Association [NYHA] class II-IV)
   AND

2. Documentation of left ventricular ejection fraction (LVEF) less than 45% following a worsening heart failure event [previous hospitalization within 6 months OR outpatient IV diuretic treatment for heart failure within previous 3 months]
   AND
3. Prescriber attestation that member is currently taking concomitant or has had prior treatment with ACEI/ARB/Entresto and beta-blocker
   AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Verquvo (vericiguat) include: Patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators and pregnancy.]
   AND
5. Prescriber attests member is not concurrently using a PDE-5 inhibitor [(sildenafil (Viagra), tadalafil (Cialis), vardenafil (Levitra), and avanafil (Stendra)- Concomitant use is not recommended.]

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months

QUANTITY:
Maximum quantity: target maintenance dose of 10 mg once daily

PRESCRIBER REQUIREMENTS: Prescribed by or in consultation with a cardiologist (consultation notes should be provided as documentation at a minimum of annually)

AGE RESTRICTIONS: 18 years of age and older

CONTINUATION OF THERAPY:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history (Note: Review Rx history for compliance)
   AND
2. Documentation of no intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: All other uses of Verquvo (vericiguat) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindication to Verquvo (vericiguat) include patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators and pregnancy

OTHER SPECIAL CONSIDERATIONS:

BACKGROUND:
DISEASE INFORMATION:
Heart failure (HF), which is characterized by the reduced ability of the heart to pump and/or fill with blood, is widely considered a global pandemic. Despite significant advances in therapies and prevention, mortality and morbidity rates are still high. In the United States, about 5.7 million people have HF. HF is classified into three subtypes: HF with reduced ejection fraction (HFrEF); HF with preserved ejection fraction (HFpEF), and HF with mid-range ejection fraction (HFmrEF).

Approximately 50% of people with HF have HFrEF, and those with HFrEF have a high prevalence of coronary artery disease, particularly in males and older patients. 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.

The following are key points from the 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment[5]:

1. For patients with newly diagnosed Stage C heart failure with reduced ejection fraction (HFrEF), a beta-blocker and an angiotensin-converting enzyme inhibitor (ACEI)/angiotensin receptor blocker (ARB)/angiotensin receptor-neprilysin inhibitor (ARNI) should be started in any order. Each agent should be up-titrated to maximally tolerated or target dose. Initiation of a beta-blocker is better tolerated when patients are dry and an ACEI/ARB/ARNI when patients are wet.
2. Only guideline-recommended beta-blockers (i.e., carvedilol, metoprolol succinate, or bisoprolol) should be used in patients with HFrEF. Among angiotensin antagonists, ARNIs are preferred agents. Renal function and potassium should be checked within 1-2 weeks of initiation or dose up-titration of ACEI/ARB/ARNI.
3. Diuretics should be added as needed and dose should be titrated to achieve decongestion. If doses in excess of furosemide 80 mg twice daily are needed, either a different loop diuretic should be considered, or a thiazide should be added.
4. After initiation of beta-blocker and angiotensin antagonist, addition of an aldosterone antagonist should be considered with close monitoring of electrolytes. Sodium-glucose cotransporter-2 (SGLT-2) inhibitors should also be considered for HFrEF with New York Heart Association (NYHA) class II-IV patients.
5. For persistently symptomatic Black patients despite above therapies, hydralazine and isosorbide dinitrate should be considered. In addition, if despite maximally tolerated beta-blocker, resting HR is ≥70 bpm in sinus rhythm, ivabradine may be considered.
6. An ideal time to consider therapy optimization is during hospitalization for HFrEF. As an outpatient, adjustment of therapies should be considered every 2 weeks to achieve guideline-directed medical therapy (GDMT) within 3-6 months of initial diagnosis. An echocardiogram should be repeated 3-6 months after achieving target doses of therapy for consideration of an implantable cardioverter-defibrillator (ICD)/cardiac resynchronization therapy (CRT).
7. Socioeconomic barriers pose a major barrier to use of ARNI, SGLT-2 inhibitors, and ivabradine. In these cases, financially feasible options should be considered. This may include virtual care and visiting home nursing services particularly during the coronavirus disease 2019 (COVID-19) pandemic.
8. For patients with recovery of left ventricular ejection fraction (LVEF) to >40%, GDMT should be resumed in the absence of a defined, reversible cause.
9. Medication adherence should be assessed regularly. Interventions helping with adherence include patient education, medication management, pharmacist co-management, cognitive behavioral therapies, medication taking reminders, and incentives to improve adherence.

DRUG INFORMATION:

The approval was based on data from the double-blind, placebo-controlled phase 3 VICTORIA trial that evaluated the efficacy and safety of vericiguat, a soluble guanylate cyclase stimulator, in 5050

adult patients with symptomatic chronic HF (New York Heart Association class II-IV) and left ventricular ejection fraction (LVEF) less than 45% following a worsening HF event. Patients were randomized to receive vericiguat 10mg once daily (n=2526) or placebo (n=2524) in combination with HF standard of care therapy.
Results showed that vericiguat was superior to placebo in reducing the risk of CV death or HF hospitalization at a median follow-up of 11 months based on a time-to-event analysis (hazard ratio [HR] 0.90; 95% CI, 0.82-0.98; P =.019). Treatment with vericiguat was associated with a 4.2% annualized absolute risk reduction compared with placebo. Additionally, vericiguat reduced the incidence of HF hospitalizations (27.4% vs 29.6% for placebo; HR 0.90; 95% CI, 0.81-1.00) and CV death (16.4% vs 17.5% for placebo; HR 0.93; 95% CI, 0.81-1.06).

As for safety, the most common adverse reactions (incidence of greater than or equal to 5%) observed with vericiguat were hypotension and anemia. Verquvo is contraindicated in patients with concomitant use of other soluble guanylate cyclase stimulators and in pregnancy due to embryo-fetal toxicity.

The recommended starting dose of Verquvo is 2.5 mg orally once daily with food. Double the dose ofVerquvo approximately every 2 weeks to reach the target maintenance dose of 10 mg once daily, astolerated by the patient. Tablets may be crushed and mixed with water for patients who have difficulty swallowing.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available aspart of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member,and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate orexcessive.

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