Oscar Clinical Guideline: Verquvo (vericiguat) (PG091, Ver. 6)

Verquvo (vericiguat)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Verquvo (vericiguat) is FDA-approved 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%. The requirement of hospitalization for heart failure indicates the progression of the disease and is associated with a substantially worsened prognosis compared with outpatients who were not hospitalized for heart failure. Likewise, heart failure decompensation requiring intravenous (IV) diuretics to treat congestion predicts unfavorable outcomes.

Verquvo (vericiguat) may lower the chance of dying from heart disease, or the need to be treated in the hospital for heart failure. Depending on the cause of heart failure, the type of heart failure, and associated symptoms - one or more of the following drugs may be needed to:

- Help to dilate arteries and veins - such as Angiotensin-converting enzyme (ACE) inhibitors (e.g., lisinopril, ramipril) , angiotensin receptor blockers (ARBs) (e.g., losartan, valsartan), and angiotensin receptor neprilysin inhibitor (ARNIs) (e.g., sacubitril with valsartan).

- Slow the heart rate - such as Beta-blockers (e.g., bisoprolol, carvedilol, long-acting metoprolol (extended-release)).
- Help the body get rid of excess sodium and water by increasing the need to urinate more often - such as diuretics (e.g., furosemide, bumetanide, hydrochlorothiazide) , or Aldosterone antagonists (e.g., spironolactone, eplerenone).
- Help the heart pump blood better - such as digoxin.
- Relax the blood vessels and lower blood pressure - such as vasodilators (e.g., hydralazine, nitrates).
- Lower the heart rate and decrease the heart's workload - such as I_f channel blocker (e.g., ivabradine).
- That has been shown to improve symptoms and quality of life in people with heart failure - such as Sodium-glucose cotransporter-2 inhibitors (SGLT-2 inhibitors) (e.g., canagliflozin, dapagliflozin).

Definitions

"**Decompensation**" refers to the inability to maintain adequate functionality or the loss of physiological balance.

"**Diuretic**" refers to a drug or chemical that increases the elimination of extra volume through the urine.

"**Heart failure**" refers to the condition when a person's heart muscle does not pump blood as well as it should. Contributing factors of heart failure include damage, weakening, stiffness, or insufficient filling of the ventricles.

"**Left ventricular ejection fraction**" or "**LVEF**" refers to the measurement of how well the heart is pumping and is used to help classify heart failure and guide treatment. In a normal healthy heart, the ejection fraction is above 50%, meaning that more than half of the blood that fills the ventricle is pumped out with each beat.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Verquvo (vericiguat)** medically necessary when **ALL** of the following criteria are met:

1. Prescribed by or in consultation with cardiologist***; AND***
2. The member is at least 18 years of age or older***; AND***

3. The member has diagnosis of symptomatic chronic heart failure (New York Heart Association [NYHA] class II-IV)***; AND***
4. The member has documentation (e.g., echocardiogram, multigated radionuclide angiography (MUGA), or magnetic resonance imagery (MRI)) of left ventricular ejection fraction (LVEF) less than 45% following a worsening heart failure event, defined as:
    a. heart failure hospitalization within 6 months***; or***
    b. use of outpatient IV diuretics for heart failure within 3 months***; AND***
5. The member has documented evidence of **ALL** of the following background therapies (unless contraindicated or there is a clinical reason why the member cannot take these medications):
    a. An ACE inhibitor (e.g., captopril, enalapril, lisinopril), angiotensin receptor blocker (e.g., candesartan, losartan, valsartan), or angiotensin receptor–neprilysin inhibitor (e.g., sacubitril-valsartan); ***and***
    b. An evidence-based **β**-blockers (e.g., bisoprolol, carvedilol, or metoprolol succinate extended-release); ***and***
    c. A sodium-glucose cotransporter 2 [SGLT2] inhibitor (e.g., dapagliflozin, empagliflozin); ***and***
    d. An aldosterone receptor antagonists (e.g., spironolactone, eplerenone)***; AND***
6. The member does **NOT** meet any of the following:
    a. Has concurrent or anticipated use of ANY of the following:
        i. a sGC stimulator such as Adempas (riociguat)***; or***
        ii. phosphodiesterase type 5 (PDE5) inhibitors such as vardenafil, tadalafil, or sildenafil***; or***
    b. Has an estimated glomerular filtration rate (eGFR) <15 mL/min/1.73 m^2 or chronic dialysis***; or***
    c. Has severe hepatic impairment (e.g., Child-Pugh C)***; or***
    d. Is a female and meets **ONE** of the following:
        i. is not of reproductive potential, defined as **ONE** of the following:
            1. is postmenopausal (defined as at least 12 months with no menses in women ≥45 years of age)***; or***
            2. has had a hysterectomy and/or bilateral oophorectomy, bilateral salpingectomy, or bilateral tubal ligation/occlusion***; or***
            3. has a congenital or acquired condition that prevents childbearing***; or***
        ii. is of reproductive potential and has documentation of a recent negative pregnancy test result (within 30 days)***; AND***
7. Is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature***; AND***

8. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Verquvo (vericiguat) will be approved for 6-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12-months will be granted if **BOTH** of the following are met:

1. The member still meets all applicable initial criteria***; AND***
2. Recent chart documentation (within the last 6 months) shows the member has experienced a positive clinical response to therapy as evidenced by **ANY** of the following:
    a. an improvement in ejection fraction and/or heart failure symptoms (exercise tolerance etc)***; or***
    b. fewer hospitalizations and/or decreased need for IV diuretics***; or***
    c. low disease activity and/or improvements in the condition's signs and symptoms.

Experimental or Investigational / Not Medically Necessary

Verquvo (vericiguat) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

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Clinical Guideline Revision / History Information

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