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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Cardiovascular Agent	**Original Policy Date:**	February 26, 2021
Subject:	Verquvo	**Page:**	1 of 5

Last Review Date: June 16, 2022

Verquvo

Description

Verquvo (vericiguat)

Background
Verquvo (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, Verquvo augments levels of intracellular cGMP, leading to smooth muscle relaxation and vasodilation (1).

Regulatory Status
FDA-approved indication: Verquvo is a soluble guanylate cyclase (sGC) stimulator, 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% (1).

Verquvo has a boxed warning that fetal harm can occur when administered to a pregnant woman. Females of reproductive potential should have a pregnancy test prior to initiation treatment with Verquvo. Females of reproductive potential should be advised to use effective contraception during treatment with Verquvo and for at least one month after the final dose (1).

Verquvo is contraindicated in patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators (1).

The safety and effectiveness of Verquvo in patients less than 18 year of age have not been established (1).

Related policies
Corlanor, Entresto

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Verquvo may be considered **medically necessary** in patients 18 years of age or older with heart failure and if the conditions indicated below are met.

Verquvo may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic heart failure

AND ALL of the following:

1. NYHA activity class II – IV
2. Systolic dysfunction with left ventricular ejection fraction < 45%
3. Heart failure hospitalization within the last 6 months **OR** use of outpatient IV diuretics for heart failure within the last 3 months
4. Prescribed by or recommended by a cardiologist
5. Patient is currently receiving optimal therapy for heart failure management (e.g., beta blocker, angiotensin-converting enzyme (ACE) inhibitor, angiotensin II receptor blocker (ARB), angiotensin receptor and neprilysin inhibitor (ARNI)
6. Used in combination with other heart failure therapies as tolerated (e.g., beta blocker, angiotensin-converting enzyme (ACE) inhibitor, angiotensin II

receptor blocker (ARB), angiotensin receptor and neprilysin inhibitor (ARNI) and diuretics)
7. Patient has had an inadequate response, intolerance, or contraindication to a sodium-glucose cotransporter-2 (SGLT2) inhibitor
8. **NO** concurrent therapy with other soluble guanylate cyclase (sGC) stimulators (such as riociguat)
9. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Verquvo and for 1 month after the final dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic heart failure

AND ALL of the following:
1. Symptoms have improved or stabilized
2. Patient is currently receiving optimal therapy for heart failure management (e.g., beta blocker, angiotensin-converting enzyme (ACE) inhibitor, angiotensin II receptor blocker (ARB), angiotensin receptor and neprilysin inhibitor (ARNI)
3. Used in combination with other heart failure therapies as tolerated (e.g., beta blocker, angiotensin-converting enzyme (ACE) inhibitor, angiotensin II receptor blocker (ARB), angiotensin receptor and neprilysin inhibitor (ARNI) and diuretics)
4. **NO** concurrent therapy with other soluble guanylate cyclase (sGC) stimulators (such as riociguat)
5. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Verquvo and for 1 month after the final dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 100 tablets per 100 days

Duration 2 years

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Verquvo (vericiguat) is a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics. Verquvo has a boxed warning that fetal harm can occur when administered to a pregnant woman. The safety and effectiveness of Verquvo in patients less than 18 year of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Verquvo while maintaining optimal therapeutic outcomes.

References

1. Verquvo [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; June 2021.

Policy History

Date	Action
February 2021	Addition to PA
June 2021	Annual review. Added requirements: “Patient is currently receiving optimal therapy for heart failure management” and “Patient has had an inadequate response, intolerance, or contraindication to a SGLT2 inhibitor per SME
June 2022	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.