

Cardiovascular Agents – Vasoactive Soluble Guanylate Cyclase Stimulators

Medical policy no. 40.90.00-1

Effective Date: Month, 1, Year

Related medical policies:

Policy Name
<Policy Title>
<Policy Title>
N/A

Note: New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: <https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx>

Medical necessity

Drug	Medical Necessity
Vericiguat (Verquvo) Click or tap here to enter text.	<p>Cardiovascular Agents – Vasoactive Soluble Guanylate Cyclase Stimulators may be considered medically necessary in patients who meet the criteria described in the clinical policy below.</p> <ul style="list-style-type: none"> Non-Preferred brand name products on the Apple Health Drug List with an A-rated generic, biosimilar or interchangeable biosimilar must also meet criteria in Non-Clinical Policy No 0001 (NC-001). <p>If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.</p>

Clinical policy:

Policy: Cardiovascular Agents – Vasoactive Soluble Guanylate Cyclase Stimulators

Medical Policy No.40.90.00-1

Clinical Criteria	
Chronic Heart Failure with Reduced Ejection Fraction Vericiguat (Verquvo)	<p>Vericiguat (Verquvo) may be approved when all of the following documented criteria are met:</p> <ol style="list-style-type: none"> 1. Patient is 18 years of age or older, AND 2. Prescribed by, or in consultation with, a cardiologist; AND 3. Diagnosis of chronic heart failure with reduced ejection fraction; AND 4. Patient has an ejection fraction less than 45%; AND 5. Patient has a New York Heart Association (NYHA) Classification II-IV; AND 6. Patient is prescribed vericiguat following either: <ol style="list-style-type: none"> a. A hospitalization due to heart failure; OR b. Outpatient use of intravenous diuretics; AND 7. Provider attests or there is documentation that the patient is being managed with all of the following at optimized doses unless contraindicated or not tolerated: <ol style="list-style-type: none"> a. Beta-blocker b. Inhibitor of the renin-angiotensin system (e.g. angiotensin receptor-neprilysin inhibitor, angiotensin-converting enzyme inhibitor, angiotensin receptor blocker) c. Mineralocorticoid receptor antagonist <p>If ALL criteria are met, the request will be authorized for 12 months.</p>
	Criteria (Reauthorization) <p>Vericiguat (Verquvo) may be approved when all the following documented criteria are met:</p> <ol style="list-style-type: none"> 1. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., patient has a documented improvement or stability of disease since starting vericiguat]. <p>If ALL criteria are met, the request will be authorized for 12 months.</p>

Dosage and quantity limits

Drug	Indication	Approved Dose	Dosage Form and Quantity Limit
Verquvo (vericiguat)	Heart failure	2.5 mg once daily. Double the daily dose every 2 weeks as tolerated up to 10 mg once daily.	<ul style="list-style-type: none"> • 2.5 mg tablets: 30 tablets per days • 5 mg tablets: 30 tablets per days • 10 mg tablets: 30 tablets per days

Background:

The safety and efficacy of vericiguat was established in a randomized, parallel-group, placebo-controlled, double-blind event-driven trial. The trial consisted of 5,050 adults with symptomatic chronic heart failure with a New York Heart Association (NYHA) class II-IV and a left ventricular ejection fraction (LVEF) less than 45% following a worsening heart failure event. A worsening heart failure event was defined as heart failure hospitalization within 6 months before randomization or use of outpatient intravenous diuretics for heart failure within 3 months before randomization. At baseline, 93% of trial participants were using a beta-blocker, 73% were using an angiotensin-converting enzyme inhibitor or angiotensin II receptor blocker, 70% of patients were using a mineralocorticoid receptor antagonist, and 15% of patients were using a combination of an angiotensin receptor and neprilysin inhibitor. 91% of participants were treated with 2 or more heart failure medications and 60% were treated with all 3. The primary endpoint was a composite of time to first event of cardiovascular death or hospitalization for heart failure. Median follow-up for the primary endpoint was 11 months. Over the course of the study, there was a 4.2% annualized absolute risk reduction with vericiguat compared with placebo (33.6% event rate for vericiguat and 37.8% event rate for placebo). The cardiovascular event rate for vericiguat and placebo was 12.9% and 13.9%, respectively. The heart failure hospitalization rate for vericiguat and placebo was 25.9% and 29.1%, respectively.¹

References

1. Verquvo [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLE. May 2023.

History

Approved Date	Effective Date	Version	Action and Summary of Changes
MM/DD/YYYY	MM/DD/YYYY	XX.XX.XX-X	New policy created

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Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible. **Without this information, we may deny the request in seven (7) working days.**

Apple Health Preferred Drug list: <https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx>

For policy criteria, see: <https://www.hca.wa.gov/billers-providers-partners/program-information-providers/apple-health-medicare-drug-coverage-criteria>

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength		Directions for use	Qty/Days supply

1. Is this request for a continuation of therapy? ☐ Yes ☐ No
 If yes, does patient have clinical documentation demonstrating disease stability or a positive clinical response since starting vericiguat? ☐ Yes ☐ No
2. Is this prescribed by, or in consultation with, a cardiologist? ☐ Yes ☐ No
3. Indicate patient's diagnosis:
☐ Chronic heart failure with reduced ejection fraction
☐ Other. Specify: _____
4. Does patient have an ejection fraction less than 45%? ☐ Yes ☐ No
5. Does patient have a New York Heart Association (NYHA) Classification II-IV? ☐ Yes ☐ No
6. Has patient been prescribed vericiguat following any of the following? Check all that apply:
☐ A hospitalization due to heart failure
☐ Outpatient use of intravenous diuretics
7. Is patient being managed with any of the following at optimized doses unless contraindicated or not tolerated? Check all that apply:
☐ Beta-blocker
☐ Inhibitor of the renin-angiotensin system (e.g. angiotensin receptor-neprilysin inhibitor, angiotensin-converting enzyme inhibitor, angiotensin receptor blocker)
☐ Mineralocorticoid receptor antagonist

CHART NOTES ARE REQUIRED WITH THIS REQUEST		
Prescriber signature	Prescriber specialty	Date