Original Effective Date: 05/01/2021
Current Effective Date: 03/28/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C21141-C

Verquvo (vericiguat)

PRODUCTS AFFECTED

Verquvo (vericiguat)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part 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 or excessive.

DIAGNOSIS:
Chronic heart failure

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

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) [DOCUMENTATION REQUIRED]
AND

3. Prescriber attestation that member is currently taking appropriate guideline-directed medical therapy (GDMT) for heart failure (Heidenreich et al., 2022 AHA/ACC/HFSA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines)
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 or clinical review has found member is not concurrently using a PDE-5 inhibitor [(sildenafil (Viagra), tadalafil (Cialis), vardenafil (Levitra), and avanafil (Stendra)- Concomitant use is not recommended.]

CONTINUATION OF THERAPY:

A. CHRONIC HEART FAILURE:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of 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.

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a cardiologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Maximum quantity: Target maintenance dose of 10 mg once daily

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral

DRUG CLASS:

Vasoactive Soluble Guanylate Cyclase Stimulator (sGC)

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

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER 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 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure [6]

1. Guideline-directed medical therapy (GDMT) for heart failure (HF) with reduced ejection fraction (HfrEF) now includes 4 medication classes that include sodium-glucose cotransporter-2 inhibitors (SGLT2i).
2. SGLT2i have a Class of Recommendation 2a in heart failure with mildly reduced ejection fraction (HfmrEF). Weaker recommendations (Class of Recommendation 2b) are made for ARNi, ACEi, ARB, MRA, and beta blockers in this population.
3. New recommendations for HfpEF are made for SGLT2i (Class of Recommendation 2a), MRAs (Class of Recommendation 2b), and ARNi (Class of Recommendation 2b). Several prior recommendations have been renewed including treatment of hypertension (Class of Recommendation 1), treatment of atrial fibrillation (Class of Recommendation 2a), use of ARBs (Class of Recommendation 2b), and avoidance of routine use of nitrates or phosphodiesterase-5 inhibitors (Class of Recommendation 3: No Benefit).
4. Improved LVEF is used to refer to those patients with a previous HfrEF who now have an LVEF >40%. These patients should continue their HfrEF treatment.
5. Value statements were created for select recommendations where high-quality, cost- effectiveness studies of the intervention have been published.
6. Amyloid heart disease has new recommendations for treatment including screening for serum and urine monoclonal light chains, bone scintigraphy, genetic sequencing, tetramer stabilizer therapy, and anticoagulation.
7. Evidence supporting increased filling pressures is important for the diagnosis of HF if the LVEF is >40%. Evidence for increased filling pressures can be obtained from noninvasive (eg, natriuretic peptide, diastolic function on imaging) or invasive testing (eg, hemodynamic measurement).

8. Patients with advanced HF who wish to prolong survival should be referred to a team specializing in HF. A HF specialty team reviews HF management, assesses suitability for advanced HF therapies and uses palliative care including palliative inotropes where consistent with the patient's goals of care.
9. Primary prevention is important for those at risk for HF (stage A) or pre-HF (stage B). Stages of HF were revised to emphasize the new terminologies of "at risk" for HF for stage A and pre-HF for stage B.
10. Recommendations are provided for select patients with HF and iron deficiency, anemia, hypertension, sleep disorders, type 2 diabetes, atrial fibrillation, coronary artery disease, and malignancy.

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 of Verquvo approximately every 2 weeks to reach the target maintenance dose of 10 mg once daily, as tolerated by the patient. Tablets may be crushed and mixed with water for patients who have difficulty swallowing.

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

OTHER SPECIAL CONSIDERATIONS:
Verquvo (vericiguat) has a Black Box Warning for embryo-fetal toxicity.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-*

standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Verquvo TABS 2.5MG
Verquvo TABS 5MG
Verquvo TABS 10MG

REFERENCES

1. Verquvo (vericiguat) [prescribing information]. Rahway, NJ: Merck Sharp and Dohme LLC; July 2023.
2. Aimo A, et al. Relative efficacy of sacubitril-valsartan, vericiguat, and SGLT2 inhibitors in heart failure with reduced ejection fraction: a systematic review and network meta-analysis. Cardiovasc Drugs Ther. 2020;10.1007/s10557-020-07099-2. Doi:10.1007/s10557-020- 07099-2
3. Armstrong PW, et al. Effect of vericiguat vs placebo on quality of life in patients with heart failure and preserved ejection fraction: The VITALITY-HfpEF randomized clinical trial. JAMA. 2020;324(15):1512-1521. Doi:10.1001/jama.2020.15922
4. Armstrong PW, et al. Vericiguat in patients with heart failure and reduced ejection fraction. N Engl J Med. 2020;382(20):1883-1893. Doi:10.1056/NEJMoa1915928
5. Maddox TM, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 pivotal issues about heart failure with reduced ejection fraction: A report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2021;S0735- 1097(20)37867-0. Doi:10.1016/j.jacc.2020.11.022
6. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines Paul A. Heidenreich, MD, MS, FACC, FAHA, FHFSA, Chair, Biykem Bozkurt, MD, PhD, FACC, FAHA, FHFSA, Vice Chair, David Aguilar, MD, MSc, FAHA, Larry A. Allen, MD, MHS, FACC, FAHA, FHFSA, Joni J. Byun, Monica M. Colvin, MD, MS, FAHA, Anita Deswal, MD, MPH, FACC, FAHA, FHFSA, Mark H. Drazner, MD, MSc, FACC, FAHA, FHFSA, Shannon M. Dunlay, MD, MS, FAHA, FHFSA, Linda R. Evers, JD, James C. Fang, MD, FACC, FAHA, FHFSA, Savitri E. Fedson, MD, MA, Gregg C. Fonarow, MD, FACC, FAHA, FHFSA, Salim S. Hayek, MD, FACC, Adrian F. Hernandez, MD, MHS, Prateeti Khazanie, MD, MPH, FHFSA, Michelle M. Kittleson, MD, PhD, Christopher S. Lee, PhD, RN, FAHA, FHFSA, Mark S. Link, MD, Carmelo A. Milano, MD, Lorraine C. Nnacheta, DrPH, MPH, Alexander T. Sandhu, MD, MS, Lynne Warner Stevenson, MD, FACC, FAHA, FHFSA, Orly Vardeny, PharmD, MS, FAHA, FHFSA, Amanda R. Vest, MBBS, MPH, FHFSA, Clyde W. Yancy, MD, MSc, MACC, FAHA, FHFSA
7. McMurray JJ, et al. Angiotensin-neprilysin inhibition versus enalapril in heart failure. N Engl J Med. 2014;371(11):993-1004. Doi:10.1056/NEJMoa1409077
8. McMurray JJV, et al. Dapagliflozin in patients with heart failure and reduced ejection fraction. N Engl J Med. 2019;381(21):1995-2008. Doi:10.1056/NEJMoa1911303
9. Murphy SP, et al. Heart failure with reduced ejection fraction: A review. JAMA 2020;324(5):488-504. doi:10.1001/jama.2020.10262
10. Pitt B, et al. Randomized 38ldactone evaluation study investigators. The effect of spironolactone on morbidity and mortality in patients with severe heart failure. N Engl J Med.1999;341(10):709- 717. doi:10.1056/NEJM199909023411001
11. Savarese G, et al. Global public health burden of heart failure. Card Fail Rev. 2017;3(1):7-11.

doi:10.15420/cfr.2016:25:2
12. Yancy CW, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. 2017;136(6):e137-e161. doi:10.1161/CIR.0000000000000509
13. Heidenreich, P. A., Bozkurt, B., Aguilar, D., Allen, L. A., Byun, J. J., Colvin, M. M., … Milano, C. A. (2022). 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. Journal of the American College of Cardiology, 79(17). https://doi.org/10.1016/j.jacc.2021.12.012

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy	Q1 2025
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Background Other Special Considerations References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file