Clinical Policy: Vericiguat (Verquvo®)
Reference Number: MDN.CP.PMN.301
Effective Date: 04.01.22
Last Review Date: 04.22
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Verquvo® is a soluble guanylate cyclase (sGC) stimulator.

FDA Approved Indication
Verquvo® indicated to reduction of cardiovascular mortality and heart failure hospitalization in adults with chronic, symptomatic heart failure and ejection fraction less than 45% following a hospitalization for heart failure or outpatient treatment with IV diuretics.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Verquvo ® is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Symptomatic chronic heart failure (must meet all)**:**

1. Diagnosis of symptomatic chronic heart failure and meets both of the following (a and b):
   a. Ejection fraction less than 45%;
   b. Member meets one of the following (i or ii):
      i. Hospitalization for heart failure in previous 6 months;
      ii. Use of IV diuretic for heart failure in previous 3 months;
2. Age ≥ 18 years;
3. Member meets both of the following (a and b):
   a. Currently taking ARNI (angiotensin receptor-neprilysin inhibitor), ACE-I (angiotensin-converting enzyme inhibitor), ARB (angiotensin receptor blockers), or Aldosterone antagonist, unless contraindicated or clinically significant adverse effects are experienced;
   b. Currently taking Beta blocker, unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section I (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy

Approval Duration: 12 months

A. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section I (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information *Appendix A:*
Abbreviation/Acronym Key ARNI:
ACE-I:
ARB
IV:

Appendix B: Contraindications/Boxed Warnings

Contraindication(s):

1) Patient with concomitant use of other soluble guanylate cyclase (sGC) stimulators. 2) Pregnancy

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose

Symptomatic chronic heart failure and ejection fraction less than 45%	**Adults**: Starting dose 2.5 mg once daily with food. Double the dose approximately every 2 weeks as tolerated to reach maintenance dose of 10 mg once daily.	10 mg/day

VI. Product Availability

2.5 mg tablet, 5 mg tablet, and 10 mg tablet **References**:

1. Verquvo [package insert]. Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ. June 2021. <https://www.merck.com/product/usa/pi_circulars/v/verquvo/verquvo_pi.pdf > Accessed December 14, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created based on HFS PDL requirements	03.15.22	04.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace (HIM) members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.