Verquvo Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

POLICY REVIEW CYCLE

Effective Date
9/1/2023

Date of Origin
6/1/0202

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Verquvo® (vericiguat) Tablets	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

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

HEART FAILURE

Heart failure (HF) is a complex clinical syndrome with symptoms and signs that result from any structural or functional impairment of ventricular filling or ejection of blood. The American Heart Association/American College of Cardiology (AHA/ACC) stages of heart failure emphasize the development and progression of disease. The New York Heart Association (NYHA) classification is used to characterize symptoms and functional capacity of patients with symptomatic or advanced heart failure. It is a subjective assessment by a clinician and can change over time. It is widely used in clinical practice to determine the eligibility of patients for treatment strategies. (2)

ACC/AHA Stages of HF	ACC/AHA Stage Description	NYHA Functional Classification	NYHA Functional Classification Description
A	At high risk for HF but without structural heart disease or symptoms of HF	None	None
B	Structural heart disease but without signs or symptoms of HF	I	No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF
C	Structural heart disease with	I	No limitation of physical activity. Ordinary physical

		prior or current symptoms of HF		activity does not cause symptoms of HF
			II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of HF
			III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes symptoms of HF
			IV	Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest
	D	Refractory HF requiring specialized interventions	IV	Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest

Efficacy	Vericiguat is a stimulator of soluble guanylate cyclase (sGC), an enzyme in the nitric oxide (NO) signaling pathway. When NO binds to sGC, the enzyme catalyzes the synthesis of intracellular cyclic guanosine monophosphate (cGMP). cGMP is a 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. Since vericiguat directly stimulates sGC, both independently and synergistically with NO, vericiguat increases levels of intracellular cGMP, leading to smooth muscle relaxation and vasodilation. Vericiguat also demonstrated a dose-dependent reduction in N-terminal-prohormone B natriuretic peptide (NT-proBNP), a biomarker in heart failure.(1) Verquvo gained FDA approval through the VICTORIA trial. This was a randomized, parallel-group, placebo-controlled, double-blind, multicenter trial that enrolled 5,050 adult patients with symptomatic chronic heart failure (New York Heart Association class II-IV) that also had a left ventricular ejection fraction of less than 45%. Patients also had a worsening heart failure event, defined as a 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 patients were on a beta blocker, 73% of patients were on an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), 70% of patients were on a mineralocorticoid receptor antagonist (MRA), 15% of patients were on a combination of an angiotensin receptor and neprilysin inhibitor (ARNI), 28% of patients had an implantable cardiac defibrillator, and 15% had a biventricular pacemaker. Ninety-one percent of patients were treated with 2 or more heart failure medications (beta blocker, any renin-angiotensin system [RAS] inhibitor or MRA) and 60% of patients were treated with all 3. At baseline, 6% of patients were on ivabradine and 3% of patients were on a sodium glucose co-transporter 2 (SGLT2) inhibitor. Patients in both the study drug and the placebo group had their doses titrated up as tolerated. The primary endpoint was a composite of time to first event of cardiovascular (CV) death or hospitalization for heart failure. The median follow-up for the primary endpoint was 11 months. Verquvo was found to be superior to placebo in reducing the risk of CV death or heart failure hospitalization. Over the course of the study, there was a 4.2% annualized absolute risk reduction in CV death or heart failure hospitalization compared with placebo.(1)
Safety	Verquvo is contraindicated in patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators and in patients that are pregnant.(1) Verquvo carries a black box warning for embryo-fetal toxicity. • Do not administer VERQUVO to a pregnant female because it may cause fetal harm. • Females of reproductive potential: Exclude pregnancy before the start of treatment. To prevent pregnancy, females of reproductive potential must use

	effective forms of contraception during treatment and for one month after stopping treatment.(1)

REFERENCES

Number	Reference
1	Verquvo Prescribing Information. Merck & Co., Inc. February 2023.
2	2022 ACCF/AHA Guideline for the Management of Heart Failure". Circulation. 145, (18) e895-e1032. May 2022. Available at: https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000001063

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Verquvo	vericiguat tab	10 MG ; 2.5 MG ; 5 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Verquvo	Vericiguat Tab	2.5 MG	30	Tablets	30	DAYS			
Verquvo	Vericiguat Tab	5 MG	30	Tablets	30	DAYS			
Verquvo	Vericiguat Tab	10 MG	30	Tablets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Verquvo	vericiguat tab	10 MG ; 2.5 MG ; 5 MG	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Verquvo	Vericiguat Tab	10 MG	Medicaid
Verquvo	Vericiguat Tab	5 MG	Medicaid
Verquvo	Vericiguat Tab	2.5 MG	Medicaid

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agent(s) Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**

Module	Clinical Criteria for Approval
	2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of symptomatic chronic heart failure (NYHA class II-IV) and ALL of the following: 1. The patient has a baseline prior to therapy with the requested agent OR current left ventricular ejection fraction of 45% or less **AND** 2. The patient has had a worsening heart failure event, defined as a heart failure hospitalization within 6 months of agent request, or use of outpatient intravenous diuretics for heart failure within 3 months of agent request **AND** 3. ONE of the following: A. The patient will be using standard CHF therapy (e.g., beta blockers, ACE inhibitors) in combination with the requested agent **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL standard CHF therapy (e.g., beta blockers, ACE inhibitors) that is not expected to occur with the requested agent **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. BOTH of the following: 1. The patient's medication history includes standard CHF therapy (e.g., beta blockers, ACE inhibitors) as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried using standard CHF therapy (e.g., beta blockers, ACE inhibitors) **AND** 2. ONE of the following: A. Standard CHF therapy was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over standard CHF therapy **OR** E. The prescriber has provided documentation ALL standard CHF therapy (e.g., beta blockers, ACE inhibitors) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Compendia Allowed: CMS approved compendia NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. If the requested agent is being used for heart failure, ONE of the following: A. The patient will be using standard CHF therapy (e.g., beta blockers, ACE inhibitors) in combination with the requested agent **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL standard CHF therapy (e.g., beta blockers, ACE inhibitors) that is not expected to occur with the requested agent **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. BOTH of the following: 1. The patient's medication history includes standard CHF therapy (e.g., beta blockers, ACE inhibitors) as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried using standard CHF therapy (e.g., beta blockers, ACE inhibitors) **AND** 2. ONE of the following: A. Standard CHF therapy was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over standard CHF therapy **OR** E. The prescriber has provided documentation ALL standard CHF therapy (e.g., beta blockers, ACE inhibitors) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Length of Approval:** 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met:

Module	Clinical Criteria for Approval
	1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 12 months