

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Verquvo Clinical Edit
<b>First Implementation Date:</b>	TBD
<b>Proposed Date:</b>	June 17, 2021
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input checked="" type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of Verquvo® (vericiguat)

**Why Issue Selected:** Verquvo®, FDA approved in January 2021, is a stimulator of soluble guanylate cyclase (sGC), an enzyme in the nitric oxide (NO) signaling pathway. It is indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for HF or need for outpatient IV diuretics in adults with symptomatic chronic HF and an ejection fraction less than 45%. 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. HF is associated with impaired synthesis of NO and decreased activity of sGC, which may contribute to myocardial and vascular dysfunction. By directly stimulating sGC, independently of and synergistically with NO, Verquvo augments the levels of intracellular cGMP, leading to smooth muscle relaxation and vasodilation. Current guideline-directed first line therapy for patients with HF with reduced ejection fraction consists of beta-blockers in combination with either an angiotensin-converting enzyme inhibitor (ACEI), an angiotensin receptor blocker (ARB), or Entresto® (sacubitril/valsartan). Due to the specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Verquvo.

### Program-Specific Information:

Date Range FFS 4-01-2020 to 3-31-2021				
Drug	Claims	Cost per tablet	Cost per month	Cost per year
VERQUVO 2.5 MG TABLET	0	\$19.43 WAC	\$582.90 WAC	\$7,091.95 WAC
VERQUVO 5 MG TABLET	0			
VERQUVO 10 MG TABLET	0			

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Verquvo® (vericiguat)
- Age range: All appropriate MO HealthNet participants aged 18 years or older

## Approval Criteria

- Documented history of previous therapy with Verquvo in the past 60 days **OR**
- Prescribed by or in consultation with a cardiologist or other appropriate specialist in the treated disease state **AND**
- Participant is aged 18 years or older **AND**
- Documented diagnosis of heart failure, NYHA class II – IV **AND**
- Documented ejection fraction < 45% **AND**
- Documentation of worsening heart failure, defined as one of the following:
  - History of previous hospitalization for heart failure in the past 6 months **OR**
  - History of outpatient intravenous diuretic therapy for treatment of heart failure (without hospitalization) in the past 3 months **AND**
- Documented therapy with Entresto for 60 of the past 90 days

## Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is currently pregnant
- Claim exceeds 1 tablet per day

## Required Documentation

Laboratory Results:  
MedWatch Form:

X

Progress Notes:  
Other:

X

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

1 year

## References

- VERQUVO (vericiguat) [Package Insert]. White House Station, NJ Merck & Co, January 2021.
- IPD Analytics. New Drug Review: Verquvo (vericiguat). February 2021.
- Aimo A, Pateras K, Stamatelopoulos K, 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. doi:10.1007/s10557-020-07099-2
- Maddox TM, Januzzi JL, Allen LA, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway (ECPD) for Optimization of Heart Failure Treatment: Answers to 10 pivotal issues about

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heart failure with reduced ejection fraction: A report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol.* 2021;77(6):772-810. doi.org/10.1016/j.jacc.2020.11.022

- Murphy SP, Ibrahim NE, Januzzi JL. Heart failure with reduced ejection fraction: A review. *JAMA* 2020;324(5):488-504. doi:10.1001/jama.2020.10262

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