SmartPA Criteria Proposal

Drug/Drug Class:	Verquvo Clinical Edit
First Implementation Date:	October 21, 2021
Revised Date:	N/A
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒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**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **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:	X	Progress Notes:	
MedWatch Form:		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, June 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 (ECDP) 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;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