

Vericiguat (Verquvo®)

Goal(s):

- Restrict use of vericiguat in populations and at doses in which the drug has demonstrated efficacy.
- Encourage use of beta-blockers and inhibitors of the renin-angiotensin-aldosterone system with demonstrated evidence of mortality reduction in heart failure with reduced ejection fraction.

Length of Authorization:

- 6 to 12 months

Requires PA:

- Vericiguat (Verquvo®)

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. Is this a request for continuation of therapy previously approved by the FFS program?	Yes: Go to Renewal Criteria	No: Go to #2
2. What diagnosis is being treated?	Record ICD10 code. Go to #3.	
3. Does the patient have symptomatic New York Heart Association (NYHA) Class II to IV chronic heart failure?	Yes: Go to #4	No: Pass to RPh. Deny; medical appropriateness
4. Does the patient have reduced ejection fraction (< 45%) assessed within the previous 12 months?	Yes: Go to #5	No: Pass to RPh. Deny; medical appropriateness
5. Does the patient have worsening heart failure defined as one of the following? a. History of previous heart failure hospitalization within the last 6 months b. Intravenous diuretic use within previous 3 months	Yes: Go to #6	No: Pass to RPh. Deny; medical appropriateness
6. Is the patient currently being seen by a cardiologist or heart failure specialist for management of advanced disease?	Yes: Go to #7	No: Pass to RPh. Deny; medical appropriateness

Approval Criteria

<p>7. Is the patient on an angiotensin system inhibitor at maximally tolerated dose, such as:</p> <ol style="list-style-type: none"> Angiotensin converting enzyme inhibitor (ACE-I) Angiotensin receptor blocker (ARB) Angiotensin receptor-neprilysin inhibitor (ARNI) 	<p>Yes: Go to #8</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>8. Is the patient currently on a maximally tolerated dose of carvedilol, sustained-release metoprolol succinate, or bisoprolol; and if not, is there a documented intolerance or contraindication to each of these beta-blockers?</p> <p><i>Note: the above listed beta-blockers have evidence for mortality reduction in chronic heart failure at target doses and are recommended by national and international heart failure guidelines.^{1,2} Carvedilol and metoprolol succinate are preferred agents on the PDL.</i></p>	<p>Yes: Go to #9</p>	<p>No: Pass to RPh. Deny, medical appropriateness</p>
<p>9. Is there evidence of adherence and tolerance to goal directed heart failure therapy (beta-blocker and angiotensin inhibitor) through pharmacy claims/refill history and provider assessment?</p>	<p>Yes: Go to #10</p>	<p>No: Pass to RPh. Deny, medical appropriateness</p>
<p>10. Is the patient on long-acting nitrates such as isosorbide dinitrate, isosorbide 5-mononitrate, transdermal nitroglycerin, or other similar agents or phosphodiesterase-5 (PDE5) inhibitors (e.g. sildenafil, tadalafil)?</p>	<p>Yes: Pass to RPh. Deny; medical appropriateness</p>	<p>No: Go to #11</p>
<p>11. Does the patient have stage 5 chronic kidney disease (eGFR < 15 ml/min or on hemodialysis/peritoneal dialysis)?</p>	<p>Yes: Pass to RPh. Deny; medical appropriateness</p>	<p>No: Go to #12</p>
<p>12. Is the patient of childbearing potential?</p>	<p>Yes: Go to #13</p>	<p>No: Approve for 6 months</p>
<p>13. Is the patient pregnant or actively trying to conceive?</p>	<p>Yes: Pass to RPh. Deny; medical appropriateness</p>	<p>No: Go to #14</p>

Approval Criteria

14. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant?

Yes: Approve for 6 months

No: Pass to RPh. Deny, medical appropriateness

Renewal Criteria

1. Has the patient developed symptomatic hypotension or syncope while on vericiguat?

Yes: Pass to RPh. Deny; medical appropriateness

No: Go to #2

2. Has the patient experienced disease progression, defined as either worsening NYHA functional class or worsening signs and symptoms of heart failure requiring intensification of therapy?

Yes: Go to #3

No: Approve for 12 months

3. Is the patient currently being seen by a cardiologist or heart failure specialist for management of advanced disease?

Yes: Approve for 12 months

No: Pass to RPh. Deny; medical appropriateness

References:

1. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2013;62(16):e147-239. doi: 10.1016/j.jacc.2013.05.019.
2. McMurray J, Adamopoulos S, Anker S, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. *European Journal of Heart Failure.* 2012;14:803-869. doi:10.1093/eurjhf/hfs105.

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