

Cynthia A. Persily, Ph.D. Cabinet Secretary Cynthia Beane Commissioner

Office of Pharmacy Services Prior Authorization Criteria Tryvio[®] (aprocitentan) *Effective 5/22/2024*

Prior Authorization Request Form

TRYVIO (aprocitentan) *is* an endothelin receptor antagonist indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions.

CRITERIA FOR APPROVAL:

- 1. Patient has a diagnosis of hypertension; AND
- 2. Patient is within the age range as recommended by the FDA label; **AND**
- 3. Prescribed by, or in consultation with, a cardiologist or nephrologist; AND
- 4. The prescriber and pharmacy must be enrolled in the TRYVIO REMS program; AND
- Patient must have uncontrolled blood pressure (systolic blood pressure [SBP] ≥140 mmHg) despite the compliant concurrent use of agents at <u>maximally</u> tolerated doses from <u>each</u> of the following classes:
 - a. angiotensin-converting enzyme [ACE] inhibitors or angiotensin receptor blockers [ARB],
 - b. long-acting dihydropyridine calcium channel-blockers,
 - c. long-acting thiazide like diuretics and/or loop diuretics,
 - d. mineralocorticoid receptor antagonist (spironolactone or eplerenone), AND
- 6. Causes of secondary hypertension (such as obstructive sleep apnea [OSA], primary aldosteronism, and renal artery stenosis) have been ruled out; **AND**
- 7. Patients who are taking a medication that can exacerbate hypertension should discontinue the medication (or have been evaluated for a dose reduction); **AND**
- Patient does not have moderate to severe hepatic impairment or elevated aminotransferases (>3 × ULN); AND
- 9. Tryvio is not prescribed concurrently with other endothelin receptor antagonists; AND

DUR Board Approval: 5/22/2024



10. **FOR FEMALE PATIENTS:** Documentation has been submitted that the patient is not pregnant and has been counseled that they must not become pregnant while taking this medication and for at least 1 month after treatment has been stopped.

Initial approvals will be for 90 days. Further approvals may be granted for 1 year after all the continuation of therapy criteria has been met.

CONTINUATION OF THERAPY CRITERIA:

- 1) Patient in not pregnant; AND
- 2) Demonstrate continued documented compliance; AND
- 3) Documentation of positive clinical response to therapy must be provided (such as achieving and maintaining goal blood pressure for patient.

Approved 5/22/2024 DUR Board Meeting

