MEDICAL MUTUAL®

Drug Policy

Policy: SD	Tryvio (aprocitentan)	Annual Review Date: 9/19/2024 Last Revised Date: 9/19/2024

OVERVIEW

Tryvio, an endothelin receptor antagonist, is indicated for the treatment of hypertension in combination with other antihypertensive medications, to lower blood pressure in adults 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.

POLICY STATEMENT

This policy involves the use of Tryvio. Prior authorization is recommended for pharmacy benefit coverage of Tryvio. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tryvio is recommended in those who meet the following criteria:

1. <u>Hypertension</u>

Criteria. *Patient must meet the following criteria*

A. The patient is ≥ 18 years of age; AND

B. Patient has tried, or is currently receiving, at least four other antihypertensive agents for the treatment of hypertension from at least four of the following pharmacological classes (a, b, c, d, e, f, g, h, i, j).
<u>Note:</u> a combination product from two or more different classes would count as an alternative from each class.

- **a.** Angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB)
  <u>Note:</u> Examples of ACE inhibitors include benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, perindopril, ramipril, and trandalopril. Examples of ARBs include azilsartan, candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, and valsartan.
- **b.** Non-dihydropyridine calcium channel blocker
  <u>Note:</u> Examples include diltiazem and verapamil.
- **c.** Dihydropyridine calcium channel blocker
  <u>Note:</u> Examples include amlodipine, felodipine, isradipine, nicardipine, nifedipine, and nisoldipine.

d. Diuretic
Note: Examples of thiazide diuretics include chlorthalidone, chlorothiazide, hydrochlorothiazide, indapamide, and metolazone. Examples of potassium-sparing diuretics are amiloride and triamterene.

e. Mineralocorticoid receptor antagonist
Note: Examples include eplerenone and spironolactone.

f. Beta blocker
Note: Examples of beta blockers include acebutolol, atenolol, betaxolol, bisoprolol, carvedilol, metoprolol, nadolol, nebivolol, pindolol, propranolol, and timolol.

g. Alpha-adrenergic blocker
Note: Examples of alpha-adrenergic blockers are doxazosin, prazosin, and terazosin.

h. Central alpha-adrenergic agonist
Note: Examples of central alpha-adrenergic agonists are clonidine, guanfacine, and methyldopa.

i. Direct vasodilator
Note: Examples of direct vasodilators are hydralazine and minoxidil

j. Direct renin inhibitor
Note: An example of a direct renin inhibitor is aliskiren.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Tryvio has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Tryvio™ tablets [prescribing information]. Radnor, PA: Idorsia; March 2024.
2. The Medical Letter. Drugs for hypertension. *Med Lett Drugs Ther*. 2024;66(1703):81-88.
3. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults. A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2018;138:e484-e594.
4. Carey RM, Calhoun DA, Bakris GL, et al. Resistant hypertension: detection, evaluation, and management: a scientific statement from the American Heart Association. *Hypertension*. 2018;72(5):e53-e90.