

## Tryvio (aprocitentan)

### POLICY

#### I. CRITERIA FOR APPROVAL

##### Resistant Hypertension

An authorization of 3 months may be granted when the requested drug is being prescribed to lower blood pressure (BP) in an adult patient who is NOT adequately controlled on other drugs when ALL of the following criteria are met:

- The patient is  $\geq 18$  years of age.
- The patient is not pregnant.
- Documentation that the patient has an eGFR  $\geq 15$  mL/min.
- Documentation of baseline blood pressure on current therapy.
- The patient has a diagnosis of resistant hypertension [NOTE: The diagnosis of resistant hypertension is made when a patient takes three antihypertensive medications with complementary mechanisms of action (including a diuretic) but does NOT achieve BP control (defined as systolic BP  $\geq 140$  mmHg), OR when BP control is achieved but requires at least four medications.]
- The patient meets ONE of the following:
  - The requested drug will be used in combination with at least THREE other antihypertensive agents at maximally tolerated doses [NOTE: A combination product, containing TWO different blood pressure-lowering agents, would be considered TWO antihypertensive agents.]
  - The patient is unable to take the requested drug in combination with at least THREE other antihypertensive agents at maximally tolerated doses due to intolerance or contraindication [NOTE: A combination product, containing TWO different blood pressure-lowering agents, would be considered TWO antihypertensive agents.]
- The patient meets ONE of the following:
  - The patient is currently taking spironolactone in combination with at least THREE other antihypertensive agents and has not reached BP control after three months of concomitant treatment
  - The patient has experienced an intolerance to spironolactone
  - The patient has a contraindication that would prohibit a trial of spironolactone
- Tryvio is prescribed by, or in consultation with, a specialist (e.g., cardiologist, nephrologist, endocrinologist) with experience in the treatment of resistant hypertension

#### II. CONTINUATION OF THERAPY

##### Resistant Hypertension

An authorization of 12 months may be granted when the requested drug is being prescribed to lower blood pressure (BP) in an adult patient who is not adequately controlled on other drugs when ALL of the following criteria are met:

- Documentation that the patient has achieved or maintained a positive clinical response to treatment as evidenced by a reduction in BP from baseline
- The patient meets ONE of the following:
  - The requested drug will continue to be used in combination with at least THREE other antihypertensive agents at maximally tolerated doses [NOTE: A combination product, containing TWO different blood pressure-lowering agents, would be considered TWO antihypertensive agents.]
  - The patient is unable to take the requested drug in combination with at least THREE other antihypertensive agents at maximally tolerated doses due to intolerance or contraindication [NOTE: A combination product, containing TWO different blood pressure-lowering agents, would be considered TWO antihypertensive agents.]
- Patient does not have any contraindications/risks that would preclude use to Tryvio [i.e., pregnant or planning to become pregnant].

### III. QUANTITY LIMIT

Tryvio 12.5 mg tablets: 1 tablet per day

### IV. REFERENCES

1. Tryvio [package insert]. Radnor, PA: Idorsia Pharmaceuticals US Inc.; March 2024.
2. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed April 16, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 04/16/2024).
4. Schlaich MP, Bellet M, Weber MA, et al. Dual endothelin antagonist aprocitentan for resistant hypertension (PRECISION): a multicentre, blinded, randomized, parallel-group, phase 3 trial. *Lancet*. 2022;400(10367):1927-1937.
5. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PC 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. *Hypertension*. 2018;71(6):e13-e115.
6. Spironolactone [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; January 2023.