Reference number(s)
6451-C

Initial Prior Authorization with Quantity Limit Tryvio

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tryvio	aprocitentan

Indications

FDA-approved Indications

Tryvio, in combination with other antihypertensive drugs, is indicated for the treatment of hypertension, to lower blood pressure (BP) in adult patients who are not adequately controlled on other drugs. Lowering BP reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes. There are no controlled trials demonstrating reduction of risk of these events with Tryvio.

Control of high BP should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve BP goals. For specific advice on goals and management, see published guidelines, such as those of the National High Blood Pressure Education Program's Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC).

Numerous antihypertensive drugs, from a variety of pharmacologic classes and with different mechanisms of action, have been shown in randomized controlled trials to reduce cardiovascular morbidity and mortality, and it can be concluded that it is BP reduction, and not some other pharmacologic property of the drugs, that is largely responsible for those benefits. The largest and most consistent cardiovascular outcome benefit has been a reduction in the risk of stroke, but reductions in myocardial infarction and cardiovascular mortality also have been seen regularly.

Elevated systolic or diastolic pressure causes increased cardiovascular risk, and the absolute risk increase per mmHg is greater at higher BPs, so that even modest reductions of severe hypertension can provide substantial benefit. Relative risk reduction from BP reduction is similar across populations with varying absolute risk, so the absolute benefit is greater in patients who are at higher risk independent of their hypertension (for example, patients with diabetes or hyperlipidemia), and such patients would be expected to benefit from more aggressive treatment to a lower BP goal.

Coverage Criteria

Resistant Hypertension

Authorization 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 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, 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.
    - The patient has experienced an inadequate treatment response to spironolactone.
    - The patient has experienced an intolerance to spironolactone.
    - The patient has a contraindication that would prohibit a trial of spironolactone.

Reference number(s)
6451-C

Continuation of Therapy

Resistant Hypertension

Authorization 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 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.]

Quantity Limits Apply

30 tablets per 25 days or 90 tablets per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 6451-C: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

References

1. Tryvio [package insert]. Radnor, PA: Idorsia Pharmaceuticals US Inc.; April 2025.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed March 25, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 03/25/2025).
4. Schlaich MP, Bellet M, Weber MA, et al. Dual endothelin antagonist aprocitentan for resistant

hypertension (PRECISION): a multicentre, blinded, randomized, parallel-group, phrase 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/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. Hypertension. 2018;71(6):e13-e115.
6. Spironolactone [package insert]. Yardley, PA: Jubilant Cadista Pharmaceuticals Inc.; August 2024.