AETNA BETTER HEALTH® Coverage Policy/Guideline			♥aetna ™	
Name:	Tryvio		Page:	1 of 2
Effective Date: 10/25/2024			Last Review Date:	5/23/2024
Applies to:	⊠Illinois ⊠Maryland	⊠New Jersey ⊠Florida Kids	⊠Virginia ⊠Pennsylvania Kids	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Tryvio under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

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.

Applicable Drug List:

Tryvio

Policy/Guideline:

Criteria for Initial Approval:

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 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 pressurelowering 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:

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- 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
- o The patient has experienced an intolerance to spironolactone
- o The patient has a contraindication that would prohibit a trial of spironolactone

<u>Criteria for Continuation of Therapy</u>

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 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.]

Approval Duration and Quantity Restrictions:

Initial Approval: 3 months

Renewal Approval: 12 months

Quantity Level Limit: 30 tablets per 30 days

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, 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/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.