UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2025 P 2342-2 |
| Program | Prior Authorization/Medical Necessity |
| Medication | Tryvio™ (aprocitentan) |
| P&T Approval Date | 6/2024, 2/2025 |
| Effective Date | 5/1/2025 |

## 1. Background:

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. Resistant hypertension (RH) is defined as above-goal elevated blood pressure (BP) in a patient despite the concurrent use of 3 antihypertensive drug classes, commonly including a long-acting calcium channel blocker, a blocker of the renin-angiotensin system (angiotensin-converting enzyme inhibitor or angiotensin receptor blocker), and a diuretic. The antihypertensive drugs should be administered at maximum or maximally tolerated daily doses.[1]

Tryvio is only available through a restricted distribution program called the Tryvio REMS.

## 2. Coverage Criteria[a]:

**A. Initial Authorization**

1. Tryvio will be approved based on **all** of the following criteria:

   a. Diagnosis of resistant hypertension

   **-AND-**

   b. One of the following:

      1) Systolic blood pressure ≥ 130 mm Hg on two consecutive measurements despite maximally tolerated antihypertensive treatment

      **-OR-**

      2) Diastolic blood pressure ≥ 80 mm Hg on two consecutive measurements despite maximally tolerated antihypertensive treatment

   **-AND-**

   c. Patient has been previously treated with all of the following antihypertensive classes for an adequate duration (minimum 4 weeks each) at a maximally tolerated dose:

      1) Maximally tolerated blocker of the renin-angiotensin system [angiotensin-converting enzyme (ACE) inhibitor (e.g., enalapril, lisinopril) or angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)]

2) Maximally tolerated calcium channel blocker (e.g., amlodipine, diltiazem, verapamil)
3) Maximally tolerated diuretics (e.g., hydrochlorothiazide)
4) Maximally tolerated mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)]

**-AND-**

d. Provider attests other causes of hypertension have been excluded (e.g., secondary causes [e.g., primary hyperaldosteronism], white coat effect, medication nonadherence)

**-AND-**

e. Used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

**-AND-**

f. Tryvio will be used in combination with at least 3 antihypertensive medications from different classes at maximally tolerated doses

**-AND-**

g. Prescribed by or in consultation with a specialist experienced in the treatment of resistant hypertension (e.g., cardiologist, nephrologist)

**Authorization will be issued for 12 months**

**B. Reauthorization**

1. **Tryvio** will be approved based on **both** of the following criteria:

   a. Documentation the patient is receiving clinical benefit to Tryvio therapy

   **-AND-**

   b. Tryvio will be used in combination with at least 3 antihypertensive medications from different classes at maximally tolerated doses

**Authorization will be issued for 12 months**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

**4. References:**

1. Tryvio [package insert]. Radnor, PA: Idorsia Pharmaceuticals US Inc; April 2024.
2. 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.

| Program | Prior Authorization/Medical Necessity - Tryvio |
|---|---|
| **Change Control** | |
| Date | Change |
| 6/2024 | New program. |
| 2/2025 | Added lifestyle modification and other causes have been ruled out. Modified prescriber requirement and concomitant medication requirements. Updated reference. |