

PRIOR AUTHORIZATION POLICY

POLICY: Cardiology – Tryvio Prior Authorization Policy

- Tryvio™ (aprocitentan tablets – Idorsia)

REVIEW DATE: 08/14/2024; selected revision 12/04/2024

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.¹ Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions.

Guidelines

Guidelines have not addressed Tryvio. Guidelines are available for the management of hypertension in adults. There are many medications available for the management of hypertension.² These include thiazide-like diuretics (e.g., chlorthalidone, hydrochlorothiazide, metolazone), potassium-sparing diuretics (e.g., amiloride, triamterene), mineralocorticoid receptor antagonists (e.g., spironolactone, eplerenone), angiotensin converting enzyme (ACE) inhibitors (e.g., enalapril, lisinopril, ramipril, trandolapril), angiotensin receptor blockers (ARBs) [e.g., candesartan, irbesartan, valsartan], a direct renin inhibitor (i.e., aliskiren), dihydropyridine calcium channel blockers (CCBs) [e.g., felodipine, amlodipine], non-dihydropyridine CCBs (e.g., diltiazem, verapamil), beta blockers (e.g., atenolol, bisoprolol, metoprolol, acebutolol), alpha-adrenergic blockers (e.g., doxazosin, prazosin, terazosin), central alpha-adrenergic agonists (e.g., clonidine, guanfacine, methyl dopa), and direct vasodilators (e.g., hydralazine, minoxidil).

- **American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines for High Blood Pressure:** The ACC/AHA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults (2017) cites normal blood pressure (systolic blood pressure [SBP]/diastolic blood pressure [DBP]) as < 120/80 mmHg; a SBP of 120 to 129 mmHg and a DBP > 80 mmHg is considered elevated.³ Stage 1 hypertension is denoted at SBPs of 130 to 139 mmHg and DBPs as 80 to 89 mmHg; Stage 2 hypertension is defined as a SBP/DBP ≥ 140/90 mmHg.³ The guidelines are extensive. In general, for initiation of antihypertensive drug therapy (SBP/DBP ≥ 130/80 mmHg), first-line medications are thiazide diuretics, CCBs, and ACE inhibitors or ARBs. Beta blockers are also recommended in certain clinical scenarios in patients with hypertension (e.g., patients with stable ischemic heart disease or heart failure). For resistant hypertension, consider spironolactone, if appropriate. The addition of other agents with different mechanisms of action may also be useful (e.g., hydralazine, minoxidil, doxazosin, clonidine).
- **AHA Statement on Resistant Hypertension:** In 2018, the AHA published a Scientific Statement on resistant hypertension.⁴ Resistant hypertension is defined as above goal elevated blood pressure in a patient despite the concurrent use of three antihypertensive drug classes, commonly including a long-acting CCB, a blocker of the renin-angiotensin system (ACE inhibitor or an ARB), and a diuretic. The antihypertensive drugs should be given at maximum or maximally tolerated daily doses. Resistant hypertension also includes patients whose blood pressure achieves target values with use of four or more antihypertensive medications. Management of resistant hypertension includes use of long-acting thiazide-like diuretics (chlorthalidone or indapamide), the addition of a mineralocorticoid receptor antagonist (spironolactone or eplerenone), and, if blood pressure remains elevated, the addition in a stepwise manner of antihypertensive medications with complementary mechanisms of action to lower blood pressure.

POLICY STATEMENT

08/14/2024

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Prior Authorization is recommended for prescription benefit coverage of Tryvio. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. Hypertension. Approve for 1 year if the patient meets BOTH of the following (A and B):

A) Patient is ≥ 18 years of age; AND

B) Patient has tried, or is currently receiving, at least three other antihypertensive agents for the treatment of hypertension from at least three of the following pharmacological classes (i, ii, iii, iv, v, vi, vii, viii, ix, x).

Note: A combination product from two or more different classes would count as an alternative from each class.

i. Angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB);

Note: Examples of ACE inhibitors include benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, perindopril, ramipril, and trandolapril. Examples of ARBs include azilsartan, candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, and valsartan;

ii. Non-dihydropyridine calcium channel blocker;

Note: Examples include diltiazem and verapamil.

iii. Dihydropyridine calcium channel blocker;

Note: Examples include amlodipine, felodipine, isradipine, nicardipine, nifedipine, and nisoldipine.

iv. Diuretic;

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

v. Mineralocorticoid receptor antagonist;

Note: Examples include eplerenone and spironolactone.

vi. Beta blocker;

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

vii. Alpha-adrenergic blocker;

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

viii. Central alpha-adrenergic agonist;

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

ix. Direct vasodilator;

Note: Examples of direct vasodilators are hydralazine and minoxidil.

x. Direct renin inhibitor;

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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

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

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.