



AmeriHealth.

Policy Title Oral Antihypertensive Agents

Policy Number FS.CLIN.8

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This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Angiotensin II receptor blockers (ARBs) are indicated to treat primary hypertension and nephropathy in individuals who have Type 2 diabetes. These agents are also indicated for the treatment of individuals with heart failure and hypertension with left ventricular hypertrophy.

Aliskiren (Tekturna®) and aliskiren HCT (Tekturna HCT®) and Aliskiren, amlodipine and Hydrochlorothiazide (Amturnide) are indicated for the treatment of hypertension.

Aliskiren/Valsartan (Valturna®) is indicated for the treatment of hypertension.

Amlodipine/valsartan (Exforge®) is indicated for individuals whose blood pressure is not controlled on monotherapy with a calcium channel blocker or an angiotensin receptor blocker.

Amlodipine/valsartan/hydrochlorothiazide (Exforge HCT®) is indicated for individuals whose blood pressure is not controlled on any two of the antihypertensive classes: calcium channel blockers, angiotensin receptor blockers, and diuretics.

Telmisartan/amlodipine besylate (Twynta®) is an angiotensin II receptor blocker (ARB) and a dihydropyridine calcium channel blocker (DHP-CCB) combination product indicated for the treatment of hypertension alone or with other antihypertensive agents.

Aliskiren/amlodipine (Tekamlo) is a renin inhibitor and calcium channel blocker combination indicated for the treatment of hypertension.

The use of non preferred agents require prior authorization (i.e., clinical pharmacy and/or Medical Director review).

Policy description

Angiotensin II receptor blockers (ARBs) inhibit the vasoconstricting and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in many types of tissues (eg, vascular smooth

muscle, adrenal gland). Angiotensin II (formed from angiotensin I) is a potent vasoconstrictor, the primary vasoactive hormone of the renin-angiotensin system, and an important component in the pathophysiology of hypertension. Its effects include: vasoconstriction; stimulation of synthesis and release of aldosterone; cardiac stimulation; and renal re-absorption of sodium.

Aliskiren (Tekturna®) and aliskiren HCT (Tekturna HCT®) are the first drugs in a new class of antihypertensive medications called renin inhibitors. Renin is the enzyme responsible for converting angiotensinogen into angiotensin I. Angiotensin I is then converted into the potent vasoconstrictor angiotensin II by the angiotensin converting enzyme (ACE). The inhibition of renin results in decreased formation of angiotensin I and, ultimately, angiotensin II.

Aliskiren/amlodipine (Tekamlo) is a combination of the renin inhibitor aliskiren and the calcium channel blocker amlodipine.

Aliskiren, amlodipine and Hydrochlorothiazide (Amturnide) is a combination of the renin inhibitor aliskiren and the calcium channel blocker amlodipine and the diuretic hydrochlorothiazide.

Aliskiren/Valsartan (Valturna®) is a combination of aliskiren, a direct renin inhibitor, and valsartan, an angiotensin II receptor blocker (ARB). Angiotensin II is the principal pressor agent of the renin angiotensin aldosterone system. Valsartan blocks the effects of angiotensin II at the angiotensin receptor. Renin is secreted by the kidney and cleaves angiotensinogen to form angiotensin I. Angiotensin I is converted to angiotensin II which causes vasoconstriction. Aliskiren is a direct renin inhibitor that decreases plasma renin activity and inhibits conversion of angiotensinogen to angiotensin I.

Amlodipine/valsartan (Exforge®), and amlodipine/telmisartan (Twynsta®) are combination products of amlodipine and angiotensin II receptor blockers (ARBs). Amlodipine is a dihydropyridine calcium channel blocker that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. The decrease in calcium influx leads to reduced contraction of the vascular smooth muscle and vasodilation, which leads to a decrease in blood pressure. Valsartan, and telmisartan are angiotensin II receptor blockers (ARBs). By blocking the angiotensin II receptors, ARBs decrease the vasoconstricting effects of angiotensin II and decreases blood pressure.

Amlodipine/valsartan/hydrochlorothiazide (Exforge HCT®) is a combination products of amlodipine, hydrochlorothiazide and angiotensin II receptor blockers (ARBs). Amlodipine is a dihydropyridine calcium channel blocker that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. The decrease in calcium influx leads to reduced contraction of the vascular smooth muscle and vasodilation, which leads to a decrease in blood pressure. Olmesartan and valsartan are an angiotensin II receptor blockers. By blocking the angiotensin II receptors, olmesartan and valsartan decrease the vasoconstricting effects of angiotensin II and decreases blood pressure. Hydrochlorothiazide is a thiazide diuretic indicated for the management of hypertension alone or in combination in order to enhance the effectiveness of other antihypertensive drugs.

Policy guideline inclusion

Irbesartan (Avapro®/Avalide®) or candesartan (Atacand®/Atacand HCT®) or telmisartan (Micardis®/Micardis HCT®) or eprosartan (Teveten®/Teveten HCT®) or amlodipine besylate/valsartan (Exforge®) or amlodipine/valsartan/hydrochlorothiazide (Exforge HCT®) or amlodipine besylate/telmisartan (Twynsta®) or Aliskiren (Tekturna®/Tekturna HCT®) or Aliskiren/amlodipine (Tekamlo®) or Aliskiren, amlodipine and Hydrochlorothiazide (Amturnide®) or aliskiren/valsartan (Valturna®) or azilsartan (Edarbi®) is approved when the following inclusion criteria is met:

- Documentation of a trial and failure of two of the following agents:
 - A losartan/losartan-HCTZ containing product
 - A Diovan/Diovan HCT containing product

- A Benicar/Benicar HCT containing product

Brand losartan/losartan-HCTZ (Cozaar®/ Hyzaar®) is approved when the following inclusion criterion is met:
Documentation of trial and failure of or contraindication to generic losartan/losartan-HCTZ

Policy guideline exclusion

Irbesartan (Avapro®/Avalide®) or candesartan (Atacand®/Atacand HCT®) or telmisartan (Micardis®/Micardis HCT®) or eprosartan (Teveten®/Teveten HCT®) or amlodipine besylate/valsartan (Exforge®) or amlodipine/valsartan/hydrochlorothiazide (Exforge HCT®) or amlodipine besylate/telmisartan (Twynsta®) or Aliskiren (Tekturna®/Tekturna HCT®) or Aliskiren/amlodipine (Tekamlo®) or Aliskiren, amlodipine and Hydrochlorothiazide (Amturnide®) or aliskiren/valsartan (Valturna®) or azilsartan (Edarbi®) is denied when the following exclusion criteria is present:

- No documentation of a trial and failure of two of the following agents:
 - A losartan/losartan-HCTZ containing product
 - A Diovan/Diovan HCT containing product
 - A Benicar/Benicar HCT containing product

Brand losartan/losartan-HCTZ (Cozaar®/ Hyzaar®) is denied when the following exclusion criterion is present:
No documentation of trial and failure of or contraindication to generic losartan/losartan-HCTZ

Policy List of Applicable Drugs

Brand Name	Generic Name
Valturna	aliskiren/valsartan
Avapro	irbesartan
Avalide	irbesartan/HCT
Atacand	candesartan
Atacand HCT	candesartan/HCT
Cozaar	losartan
Hyzaar	losartan/HCT
Micardis	telmisartan
Micardis HCT	telmisartan/HCT
Teveten	eprosartan
Teveten HCT	eprosartan/HCT
Exforge	amlodipine besylate/valsartan
Exforge HCT	amlodipine besylate/valsartan/hydrochlorothiazide
Twynsta	amlodipine besylate/telmisartan
Tekturna	aliskiren
Tekturna HCT	aliskiren HCT
Tekamlo	Aliskiren/amlodipine
Amturnide	Aliskiren, amlodipine and hydrochlorothiazide
Edarbi	Azilsartan

Dosing and administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

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Policy link to related policies

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