Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

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 Description**

**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®)** are indicated for the treatment of hypertension; aliskiren (Tekturna®) and aliskiren HCT (Tekturna HCT®) are one of the first renin inhibitors approved by the US Food and Drug Administration (FDA).

**Amlodipine/olmesartan (Azor™)** is indicated for the treatment of hypertension, alone or in combination with other antihypertensive medications.

**Amlodipine/valsartan (Exforge®)** combination therapy is indicated for individuals whose blood pressure is not controlled on monotherapy with a calcium channel blocker or an angiotensin receptor blocker. Amlodipine/valsartan (Exforge®) is a new formulation that combines the generic drug, amlodipine, and Diovan.

**Amlodipine/valsartan/hydrochlorothiazide (Exforge HCT®)** combination therapy 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. Amlodipine/valsartan/hydrochlorothiazide (Exforge HCT®) is a new formulation that combines the generic drugs, amlodipine and hydrochlorothiazide, and Diovan for the treatment of hypertension.

The use of ARBs, aliskiren (Tekturna®), aliskiren HCT (Tekturna HCT®), amlodipine/olmesartan (Azor™), and amlodipine/valsartan (Exforge®) / amlodipine/valsartan/hydrochlorothiazide (Exforge HCT®) requires prior authorization (i.e., clinical pharmacy and/or Medical Director review).
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.

**Amlodipine/olmesartan (Azor™)** is a combination of amlodipine and olmesartan. 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 is an angiotensin II receptor blocker. By blocking the angiotensin II receptors, olmesartan decreases the vasoconstricting effects of angiotensin II and decreases blood pressure.

**Amlodipine/valsartan (Exforge®)** is a combination of amlodipine and valsartan. **Amlodipine/valsartan/hydrochlorothiazide (Exforge HCT®)** is a combination of amlodipine, valsartan, and hydrochlorothiazide. 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 is an angiotensin II receptor blocker. By blocking the angiotensin II receptors, olmesartan decreases 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.

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**Policy Guideline Inclusion**

**For new starts* only:**

**VALSARTAN (DIOVAN/DIOVAN HCT), OLMESARTAN (BENICAR/BENICAR HCT)**

Valsartan (Diovan®/Diovan HCT®), olmesartan (Benicar®/Benicar HCT®) are approved when one of the following inclusion criterion is met:

- Documentation of a minimum 30-day trial and failure of or intolerance to at least one angiotensin converting enzyme (ACE) inhibitor-containing product (eg, enalapril maleate, lisinopril, moexipril HCl, fosinopril sodium, benazepril HCl, captopril, quinapril HCl) or ramipril (Altace) within the past six months
- Diagnosis of Type 2 diabetes with renal insufficiency

**For new starts* only:**

**IRBESARTAN (AVAPRO®/AVALIDE®), CANDESARTAN (ATACAND®/ATACAND HCT®), LOSARTAN (COZAAR®/ HYZAAR®), TELMISARTAN (MICARDIS®/MICARDIS HCT®), EPROSARTAN (TEVETEN®/TEVETEN HCT®)**

Irbesartan (Avapro®/Avalide®), candesartan (Atacand®/Atacand HCT®), losartan (Cozaar®/Hyzaar®), telmisartan (Micardis®/Micardis HCT®), eprosartan (Teveten®/Teveten HCT®) are approved when the following inclusion criterion is met:

- Documentation of a minimum 30-day trial and failure of or intolerance to valsartan (Diovan)- and olmesartan (Benicar)-containing products [Benicar®/Benicar HCT® and
In addition, one of the following inclusion criteria must also be met in order for treatment with irbesartan (Avapro, Avalide), candesartan (Atacand/Atacand HCT), losartan (Cozaar, Hyzaar), telmisartan (Micardis/Micardis HCT), eprosartan (Teveten/Teveten HCT) to be approved:

- Documentation of a minimum 30-day trial and failure of or intolerance to at least one ACE inhibitor-containing product (eg, enalapril maleate, lisinopril, moexipril HCl, fosinopril sodium, benazepril HCl, captopril, quinapril HCl) or ramipril (Altace) within the past six months
- Documentation of a minimum 30-day trial and failure of or intolerance to at least one ACE inhibitor-containing product within the past six months
- Diagnosis of Type 2 diabetes with renal insufficiency

NOTE: Requests for any of the following angiotensin II receptor blockers (ARBs): irbesartan (Avapro, Avalide), candesartan (Atacand/Atacand HCT), losartan (Cozaar, Hyzaar), telmisartan (Micardis/Micardis HCT), eprosartan (Teveten/Teveten HCT) that have documentation of a minimum 30-day trial and failure of an ACE inhibitor-containing product within the past six months will receive an authorization for both valsartan (Diovan/Diovan HCT) and olmesartan (Benicar/Benicar HCT).

ALISKIREN (TEKTURNA®)/ALISKIREN HCT (TEKTURNA HCT®)

Aliskiren (Tekturna®) and aliskiren HCT (Tekturna HCT®) are approved when all of the following inclusion criteria are met:

- Documented diagnosis of hypertension
- Documentation of trial and failure of or contraindication/intolerance/allergy to an ACE inhibitor
- Documentation of trial and failure of or contraindication/intolerance/allergy to Diovan- or Benicar-containing products [Benicar®/Benicar HCT® and Diovan®/Diovan HCT® require prior authorization].
- Documentation of trial and failure of or contraindication/intolerance/allergy to an amlodipine-containing product

AMLODIPINE BESYLALE/OLMESARTAN (AZOR™)

Amlodipine besylate/Olmesartan (Azor™) is approved when the following inclusion criterion is met:

- Documentation of a trial and failure of one of the following agents:
  - olmesartan/olmesartan HCT (Benicar®/Benicar HCT®) [Benicar®/Benicar HCT® requires prior authorization]
  - an amlodipine-containing product
  - an angiotensin converting enzyme (ACE) inhibitor-containing product

AMLODIPINE BESYLALE/VALSARTAN (EXFORGE®)/AMLODIPINE BESYLALE/VALSARTAN/HYDROCHLOROTHIAZIDE (EXFORGE HCT®)

Amlodipine besylate/valsartan (Exforge®) / amlodipine/valsartan/hydrochlorothiazide (Exforge HCT®) is approved when all of the following inclusion criteria are met:

- Documentation of at least a 30-day trial of concurrent therapy of Valsartan/valsartan
HCT (Diovan®/Diovan HCT®) and an amlodipine-containing product [Benicar®/Benicar HCT® and Diovan®/Diovan HCT® require prior authorization].

- Documentation of non-compliance with valsartan/valsartan HCT (Diovan®/Diovan HCT®) and an amlodipine-containing product

*New start* is defined as a member who has not received ARB therapy prior to the submission of the request.

### Policy Guideline Exclusion

#### For new starts* only:

VALSARTAN (DIOVAN®/DIOVAN HCT®), OLMESARTAN (BENICAR®/BENICAR HCT®)

Valsartan (Diovan®/Diovan HCT®), olmesartan (Benicar®/Benicar HCT®) are denied when any of the following exclusion criteria are present:

- Use for a diagnosis that is experimental/investigational
- No documentation of a minimum 30-day trial and failure of or intolerance to at least one ACE inhibitor-containing product (eg, enalapril maleate, lisinopril, moexipril HCl, fosinopril sodium, benazepril HCl, captoril, quinapril HCl) or ramipril (Altace) within the past six months

#### For new starts* only:

IRBESARTAN (AVAPRO®/AVALIDE®), CANDESARTAN (ATACAND®/ATACAND HCT®), LOSARTAN (COZAAR®/HYZAAR®), TELMISARTAN (MICARDIS®/MICARDIS HCT®), EPROSARTAN (TEVETEN®/TEVETEN HCT®)

Irbesartan (Avapro®, Avalide®), candesartan (Atacand®/Atacand HCT®), losartan (Cozaar®, Hyzaar®), telmisartan (Micardis®/Micardis HCT®), eprosartan (Teveten®/Teveten HCT®) are denied when any of the following exclusion criteria are present:

- No documentation of a minimum 30-day trial and failure of or intolerance to valsartan (Diovan)- and olmesartan (Benicar)-containing products [Benicar®/Benicar HCT® and Diovan®/Diovan HCT® require prior authorization].
- No documentation of a minimum 30-day trial and failure of or intolerance to at least one ACE inhibitor-containing product (eg, enalapril maleate, lisinopril, moexipril HCl, fosinopril sodium, benazepril HCl, captoril, quinapril HCl) or ramipril (Altace) within the past six months
- No documented diagnosis of Type 2 diabetes with renal insufficiency

ALISKIREN (TEKTURNA®)/ALISKIREN HCT (TEKTURNA HCT®)

Aliskiren (Tekturna®) and aliskiren HCT (Tekturna HCT®) are denied when any of the following exclusion criteria are present:

- No documented diagnosis of hypertension
- No documentation of trial and failure of or contraindication/intolerance/allergy to an ACE inhibitor
- No documentation of trial and failure of or contraindication/intolerance/allergy to valsartan (Diovan)- or olmesartan (Benicar)-containing products [Benicar®/Benicar HCT® requires prior authorization].
- No documentation of trial and failure of or contraindication/intolerance/allergy to an amlodipine-containing product
AMLODIPINE BESYLATE/OLMESARTAN (azor™)

Amlodipine besylate/Olmesartan (Azor™) is denied when the following exclusion criterion is present:

- No documentation of a trial and failure of one of the following agents:
  - olmesartan/olmesartan HCT (Benicar®/Benicar HCT®) [Benicar®/Benicar HCT® requires prior authorization]
  - an amlodipine-containing product
  - an angiotensin converting enzyme (ACE) inhibitor-containing product

AMLODIPINE BESYLATE/VALSARTAN (EXFORGE®) / AMLODIPINE BESYLATE/VALSARTAN/HYDROCHLOROTHIAZIDE (EXFORGE HCT®)

Amlodipine besylate/Valsartan (Exforge®) / amlodipine/valsartan/hydrochlorothiazide (Exforge HCT®) is denied when any of the following exclusion criteria are present:

- No documentation of at least a 30-day trial of concurrent therapy of valsartan/valsartan HCT (Diovan®/Diovan HCT®) and an amlodipine-containing product [Diovan®/Diovan HCT® requires prior authorization]
- No documentation of non-compliance with valsartan/valsartan HCT (Diovan®/Diovan HCT®) and an amlodipine-containing product

*New start* is defined as a member who has not received ARB therapy prior to the submission of the request.

**Policy List of Applicable Drugs**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>Diovan</td>
<td>Valsartan</td>
</tr>
<tr>
<td>Diovan HCT</td>
<td>Valsartan/HCT</td>
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<tr>
<td>Benicar</td>
<td>Olmesartan</td>
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<tr>
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<td>Olmesartan/HCT</td>
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<tr>
<td>Avapro</td>
<td>Irbesartan</td>
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<tr>
<td>Avalide</td>
<td>Irbesartan/HCT</td>
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<tr>
<td>Atacand</td>
<td>Candesartan</td>
</tr>
<tr>
<td>Atacand HCT</td>
<td>Candesartan/HCT</td>
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<tr>
<td>Cozaar</td>
<td>Losartan</td>
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<tr>
<td>Hyzaar</td>
<td>Losartan/HCT</td>
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<tr>
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<td>Tekturna HCT</td>
<td>Aliskiren HCT</td>
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<tr>
<td>Azor</td>
<td>Amlodipine besylate/Olmesartan</td>
</tr>
</tbody>
</table>
Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References


Exforge HCT® (amlodipine, valsartan, and hydrochlorothiazide) [prescribing information]. East Hanover, NJ: Novartis Pharmaceutical Corp; 2009.


Joint National Committee (JNC). JNC VII guidelines for the treatment of hypertension. [National...


Policy Link to Related Policies

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