

STEP THERAPY POLICY

- POLICY:** Angiotensin Receptor Blocker Step Therapy Policy
- Atacand[®] (candesartan tablets – AstraZeneca/Ani Pharmaceuticals, generic)
 - Avapro[®] (irbesartan tablets – sanofi-aventis, generic)
 - Benicar[®] (olmesartan tablets – Daiichi Sankyo, generic)
 - Cozaar[®] (losartan tablets – Merck, generic)
 - Diovan[®] (valsartan tablets – Novartis, generic)
 - Edarbi[®] (azilsartan tablets – Takeda/Arbor Pharmaceuticals)
 - eprosartan tablets – generic
 - Micardis[®] (telmisartan tablets – Boehringer-Ingelheim, generic)
 - Atacand HCT[®] (candesartan/hydrochlorothiazide tablets – AstraZeneca, generic)
 - Avalide[®] (irbesartan/hydrochlorothiazide tablets – sanofi-aventis, generic)
 - Benicar HCT[®] (olmesartan/hydrochlorothiazide tablets – Daiichi Sankyo, generic)
 - Diovan HCT[®] (valsartan/hydrochlorothiazide tablets – Novartis, generic)
 - Edarbyclor[®] (azilsartan/chlorthalidone tablets – Takeda/Arbor Pharmaceuticals)
 - Hyzaar[®] (losartan/hydrochlorothiazide tablets – Merck, generic)
 - Micardis[®] HCT (telmisartan/hydrochlorothiazide tablets – Boehringer Ingelheim, generic)
 - Azor[®] (olmesartan/amlodipine tablets – Daiichi Sankyo Pharma, generic)
 - Exforge[®] (valsartan/amlodipine tablets – Novartis, generic)
 - Exforge HCT[®] (valsartan/amlodipine/hydrochlorothiazide tablets – Novartis, generic)
 - Prexxartan[®] (valsartan oral solution – BioRamo/Medicure)
 - Tribenzor[®] (olmesartan/amlodipine/hydrochlorothiazide tablets – Daiichi Sankyo, generic)
 - Twynsta[®] (telmisartan/amlodipine tablets – Boehringer Ingelheim, generic)

REVIEW DATE: 10/14/2020

OVERVIEW

Angiotensin receptor blockers (ARBs) [also known as angiotensin II receptor antagonists] are all indicated for the treatment of adults with hypertension.¹⁻⁸ Some ARBs have other indications as well. Several clinical outcome trials with ARBs have shown positive results. All ARBs, except Edarbi, have a dosage form available that also contains hydrochlorothiazide (HCTZ).⁹⁻¹⁴ Edarbi is available as a combination product containing chlorthalidone (Edarbyclor).¹⁵ There are several products that combine an ARB with amlodipine (plus or minus HCTZ); these products are indicated for the treatment of hypertension.¹⁶⁻²⁰

Prexxartan, an oral solution containing valsartan, is indicated for the following uses:²¹

- Treatment of hypertension in adult and children ≥ 6 years of age, to lower blood pressure
- Management of heart failure (New York Heart Association [NYHA] Class II to IV) to reduce the risk of hospitalization for heart failure in patients who are unable to swallow valsartan tablets.
- Reduce the risk of cardiovascular death in clinically stable patients with left ventricular failure or left ventricular dysfunction following myocardial infarction in patients who are unable to swallow valsartan tablets.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 drug prior to the use of a Step 2 drug. If the Step Therapy rule is not met for a Step 2 drug at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1 drug within the 130-day look-back period is excluded from Step Therapy.

Step 1: candesartan, candesartan/HCTZ, eprosartan, irbesartan, irbesartan/HCTZ, losartan, losartan/HCTZ, telmisartan, telmisartan/amlodipine, telmisartan/HCTZ, olmesartan, olmesartan/HCTZ, olmesartan/amlodipine, olmesartan/amlodipine/HCTZ, valsartan, valsartan/HCTZ, valsartan/amlodipine, valsartan/amlodipine/hydrochlorothiazide

Step 2: Atacand HCT, Atacand, Avalide, Avapro, Azor, Benicar, Benicar HCT, Cozaar, Diovan, Diovan HCT, Edarbi, Edarbyclor, Exforge, Exforge HCT, Hyzaar, Micardis, Micardis HCT, Twynsta, Tribenzor, Prexxartan

CRITERIA

1. If the patient has tried one Step 1 drug, approve a Step 2 drug.
2. Approve a Step 2 drug if the patient meets the following criteria (A, B, and C):
 - A) There is not a generic equivalent available in Step 1; AND
 - B) Patient was hospitalized and discharged within the previous 30 days for a cardiovascular event; AND

Note: Examples of a cardiovascular event include a myocardial infarction, a hypertensive emergency, and decompensated heart failure.

 - C) Patient has been started and stabilized on the drug.
3. If the patient has difficulty swallowing tablets, approve Prexxartan.

REFERENCES

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3. Cozaar[®] tablets [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; October 2018.
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5. Micardis[®] tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; July 2020.
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21. Prexxartan[®] oral solution [prescribing information]. Somerset, NJ: BioRamo/Medicure; January 2018.