



STEP THERAPY POLICY

POLICY: Angiotensin Receptor Blocker Step Therapy Policy
Single-Entity Products

- Atacand® (candesartan tablets – AstraZeneca/Ani, generic)
- Avapro® (irbesartan tablets – sanofi-aventis, generic)
- Benicar® (olmesartan tablets – Cosette, generic)
- Cozaar® (losartan tablets – Organon, generic)
- Diovan® (valsartan tablets – Novartis, generic)
- Edarbi® (azilsartan tablets – Takeda/Azurity)
- eprosartan tablets – generic
- Micardis® (telmisartan tablets – Boehinger-Ingelheim, generic)

Combination Products

- Atacand HCT® (candesartan/hydrochlorothiazide tablets – AstraZeneca, generic)
- Avalide® (irbesartan/hydrochlorothiazide tablets – sanofi-aventis, generic)
- Azor® (olmesartan/amlodipine tablets – Cosette, generic)
- Benicar HCT® (olmesartan/hydrochlorothiazide tablets – Cosette, generic)
- Diovan HCT® (valsartan/hydrochlorothiazide tablets – Novartis, generic)
- Edarbyclor® (azilsartan/chlorthalidone tablets – Takeda/Arbor)
- Exforge® (valsartan/amlodipine tablets – Novartis, generic)
- Exforge HCT® (valsartan/amlodipine/hydrochlorothiazide tablets – Novartis, generic)
- Hyzaar® (losartan/hydrochlorothiazide tablets – Merck, generic)
- Micardis® HCT (telmisartan/hydrochlorothiazide tablets – Boehringer Ingelheim, generic)
- Tribenzor® (olmesartan/amlodipine/hydrochlorothiazide tablets – Cosette, generic)
- Twynsta® (telmisartan/amlodipine tablets – Boehringer Ingelheim, generic)
- Valsartan oral solution (generic)

REVIEW DATE: 10/02/2024

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Angiotensin receptor blockers (ARBs) [also known as angiotensin II receptor antagonists] are all indicated for the treatment of adults with **hypertension**; selected agents are also indicated for use in pediatric patients.¹⁻⁸ Some ARBs have other indications as well. Several clinical outcome trials with ARBs have shown positive results. All ARBs, except Edarbi, are also available as combination products with 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 adults 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 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

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

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

Angiotensin Receptor Blocker Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. Approve a Step 2 Product if the patient meets the following (A, B, and C):
 - A)** The generic equivalent is not 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 Step 2 Product.
3. If the patient cannot swallow or has difficulty swallowing tablets, approve valsartan oral solution.

REFERENCES

1. Diovan® tablets [prescribing information]. East Hanover, NJ: Novartis; April 2021.
2. Avapro® tablets [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; September 2021.
3. Cozaar® tablets [prescribing information]. Jersey City, NJ: Organon; October 2021.
4. Atacand® tablets [prescribing information]. Baudette, MN and Sodertalje, Sweden: ANI and AstraZeneca; December 2022.
5. Micardis® tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; December 2022.
6. Teveten® tablets [prescribing information]. North Chicago, IL: AbbVie; June 2018.
7. Benicar® tablets [prescribing information]. South Plainfield, NJ: Cosette; February 2022.
8. Edarbi® tablets [prescribing information]. Woburn, MA: Takeda and Azurity; January 2024.
9. Hyzaar® tablets [prescribing information]. Jersey City, NJ: Organon; March 2023.
10. Diovan® HCT tablets [prescribing information]. East Hanover, NJ: Novartis; August 2020.
11. Avalide® tablets [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; September 2021.
12. Atacand HCT® tablets [prescribing information]. Baudette, MN and Sodertalje, Sweden: ANI and AstraZeneca; August 2020.
13. Micardis HCT® tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; December 2022.
14. Benicar HCT® tablets [prescribing information]. South Plainfield, NJ: Cosette; February 2022.
15. Edarbyclor® tablets [prescribing information]. Osaka, Japan and Atlanta, GA: Takeda and Arbor; March 2020.
16. Exforge® tablets [prescribing information]. East Hanover, NJ: Novartis; April 2021.
17. Exforge® HCT tablets [prescribing information]. East Hanover, NJ: Novartis; February 2021.
18. Azor® tablets [prescribing information]. South Plainfield, NJ: Cosette; February 2022.
19. Twynsta® tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; November 2018.

20. Tribenzor® tablets [prescribing information]. South Plainfield, NJ: Cosette; February 2022.
 21. Valsartan oral solution [prescribing information]. New Brunswick, NJ: Lifsa Drugs; April 2022.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|------------------|--|-------------|
| Annual Revision | No criteria changes. | 11/08/2023 |
| Annual Revision | <p>Prexxartan: Prexxartan was removed as a Step 2 Product (not available).</p> <p>Valsartan oral solution: Valsartan oral solution was listed as a Step 2 Product.</p> <p>Criteria: The exception to approve Prexxartan if the patient cannot swallow or has difficulty swallowing tablets was changed to approve valsartan oral solution if the patient cannot swallow or has difficulty swallowing tablets.</p> | 10/02/2024 |

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