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 only)
- Micardis® (telmisartan tablets – Boehinger-Ingelheim, generic)
- valsartan oral solution (generic only)

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)

REVIEW DATE: 06/18/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE

SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

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]

Valsartan oral solution 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, 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. 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; May 2025.
3. Cozaar® tablets [prescribing information]. Jersey City, NJ: Organon; April 2023.
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. Benicar® tablets [prescribing information]. South Plainfield, NJ: Cosette; February 2022.
7. Edarbi® tablets [prescribing information]. Woburn, MA: Takeda and Azurity; January 2024.
8. Hyzaar® tablets [prescribing information]. Jersey City, NJ: Organon; March 2023.
9. Diovan® HCT tablets [prescribing information]. East Hanover, NJ: Novartis; April 2021.
10. Avalide® tablets [prescribing information]. Bridgewater, NJ: sanofi-aventis; May 2025.
11. Atacand HCT® tablets [prescribing information]. Baudette, MN and Sodertalje, Sweden: ANI and AstraZeneca; August 2020.
12. Micardis HCT® tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; December 2022.
13. Benicar HCT® tablets [prescribing information]. South Plainfield, NJ: Cosette; February 2022.
14. Edarbyclor® tablets [prescribing information]. Osaka, Japan and Atlanta, GA: Takeda and Arbor; March 2020.
15. Exforge® tablets [prescribing information]. East Hanover, NJ: Novartis; April 2021.
16. Exforge® HCT tablets [prescribing information]. East Hanover, NJ: Novartis; February 2021.
17. Azor® tablets [prescribing information]. South Plainfield, NJ: Cosette; February 2022.
18. Tribenzor® tablets [prescribing information]. South Plainfield, NJ: Cosette; February 2022.
19. Valsartan oral solution [prescribing information]. Baudette, MN: ANI; August 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/08/2023
Annual Revision	**Prexxartan:** Prexxartan was removed as a Step 2 Product (not available). **Valsartan oral solution:** Valsartan oral solution was listed as a Step 2 Product.	10/02/2024

	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.	
Early Annual Revision	**Twynsta:** Twynsta was removed as a Step 2 Product (not available). **Criteria**: The exception to approve a Step 2 Product if the patient met ALL of the following criteria was removed from the policy: the generic equivalent is not available in Step 1 AND patient was hospitalized and discharged within the previous 30 days for a cardiovascular event AND patient has been started on stabilized on a Step 2 product.	06/18/2025