

Angiotensin II Receptor Blockers and Angiotensin II Receptor Blocker Combination Drugs

Policy # 00348

Original Effective Date: 03/20/2013

Current Effective Date: 08/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider brand name angiotensin II receptor blockers (ARBs) and brand name angiotensin II receptor blocker combination drugs including, but not limited to, Benicar[®]† (olmesartan), Benicar HCT[®]† (olmesartan/hydrochlorothiazide), Diovan[®]† (valsartan), Micardis[®]† (telmisartan), Micardis HCT[®]† (telmisartan/hydrochlorothiazide), Exforge[®]† (amlodipine/valsartan), Exforge HCT[®]† (amlodipine/valsartan/hydrochlorothiazide), Azor[®]† (amlodipine/olmesartan), Edarbi[®]† (azilsartan), Edarbyclor[®]† (azilsartan/chlorthalidone) Tribenzor[®]† (olmesartan/amlodipine/hydrochlorothiazide), Widaplik[™]† (telmisartan, amlodipine and indapamide), and branded Azilsartan to be **eligible for coverage**** when ONE of the below patient selection criteria is met:

Patient Selection Criteria

Coverage eligibility will be considered for brand name angiotensin II receptor blockers (ARBs) and brand name angiotensin II receptor blocker (ARB) combination drugs when ONE of the following criteria is met:

- The patient has tried and failed ONE generic angiotensin converting enzyme (ACE) inhibitor (e.g. lisinopril), ONE generic angiotensin converting enzyme-inhibitor (ACE-I) combination drug (e.g. lisinopril/hydrochlorothiazide), ONE generic angiotensin II receptor blocker (ARB [e.g. irbesartan, losartan]), or ONE generic angiotensin II receptor blocker (ARB) combination drug (e.g. irbesartan/hydrochlorothiazide, losartan/hydrochlorothiazide); OR
- The patient was hospitalized and discharged within the previous 30 days for a cardiovascular event (e.g. myocardial infarction, hypertensive emergency, decompensated heart failure) and was started and stabilized on a brand name angiotensin II receptor blocker (ARB) or brand name angiotensin II receptor blocker (ARB) combination drug that does NOT have a generic equivalent; OR

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- There is clinical evidence or patient history that suggests the generically available drug classes listed above will be/were ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name angiotensin II receptor blockers (ARBs) and brand name angiotensin II receptor blocker (ARB) combination drugs when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary**.**

Background/Overview

Angiotensin II receptor blockers and ARB combination drugs are used to treat various indications including hypertension, heart failure, and myocardial infarctions.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy take into consideration whether or not the patient was hospitalized in the previous 30 days for a cardiovascular event and had been started and stabilized on the requested brand name ARB or ARB combination drug (that does not have a generic equivalent). This policy also takes into account clinical evidence or patient history that suggests the generically available drug classes mentioned in the patient selection criteria will be/were ineffective or will/did cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using a brand name ARB or brand name ARB combination drug over the available generic ACE-I's, generic ACE-I combination drugs, generic ARBs, or generic ARB combination drugs. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

References

1. Sanders GD, Coeytaux R, Dolor RJ, et al. Angiotensin-converting enzyme inhibitors (ACEIs), angiotensin II receptor antagonists (ARBs), and direct renin inhibitors for treating essential hypertension: an update [internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2011 June. Report No.: 11-EHC063-EF.
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2. Hunt SA, Abraham WT, Chin MH, et al. 2009 focused update incorporated into the ACC/AHA 2005 guidelines for the diagnosis and management of heart failure in adults. *Circulation*. 2009;119:e391-e479.
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4. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction—executive summary. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to revise the 1999 guidelines for the management of patients with acute myocardial infarction). J Am Coll Cardiol. 2004;44(3):671-719.
5. Antman EM, Hand M, Armstrong PW, et al. 2007 focused update of the ACC/AHA 2004 guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association task force on practice guidelines: developed in collaboration with the Canadian Cardiovascular Society endorsed by the American Academy of Family Physicians: 2007 writing group to review new evidence and update the ACC/AHA 2004 guidelines for the management of patients with ST-elevation myocardial infarction, writing on behalf of the 2004 writing committee. Circulation. 2008;117:296-329. Accessed 4/4/2012 at <http://circ.ahajournals.org/cgi/reprint/117/2/296>
6. Anderson JL, Adams CD, Antman EM, et al. 2011 ACCF/AHA focused update incorporated into the ACC/AHA 2007 guidelines for the management of patients with unstable angina/non ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2011;123(18):e426-e579. Available at <http://circ.ahajournals.org/cgi/reprint/CIR.0b013e318212bb8bv1>

Policy History

Original Effective Date: 03/20/2013

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03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. New policy.
03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. Implemented a PA for non-preferred products to use preferred products, which are Benicar and Benicar HCT.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. No change to coverage.
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. Removed the PA portion of the policy from Edarbi and reverted back to a step therapy policy.
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. No change to coverage.
08/01/2019	Medical Policy Committee review
08/14/2019	Medical Policy Implementation Committee approval. No change to coverage.

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08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. No change to coverage.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. No change to coverage.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. No change to coverage.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2024	Medical Policy Committee review
08/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/07/2025	Medical Policy Committee review
08/13/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/21/2026	Pre Pharmacy & Therapeutics Committee review
07/22/2026	Pharmacy & Therapeutics Committee review approval. Added new drugs, branded Azilsartan and Widaplik, to the policy with relevant criteria.

Next Scheduled Review Date: 07/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.