



Louisiana

Angiotensin II Receptor Blockers and Angiotensin II Receptor Blocker Combination Drugs

Policy # 00348

Original Effective Date: 03/20/2013

Current Effective Date: 09/14/2020

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.

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) and Tribenzor[®] (olmesartan/amlodipine/hydrochlorothiazide) 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

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name angiotensin II receptor blocker (ARB) combination drug that does NOT have a generic equivalent; OR

- 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

The patient selection criteria presented in this policy takes 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

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Policy History

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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.
08/06/2020 Medical Policy Committee review
08/12/2020 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 08/2021

*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

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diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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
- 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.

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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.

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