Angiotensin II Receptor Blockers and Angiotensin II Receptor Blocker Combination Drugs

Policy #  00348
Original Effective Date:  03/20/2013
Current Effective Date:  01/01/2015

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.

For Patients With “Step Therapy” (generic before brand) ONLY:
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 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.**
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For Patients With “Prior Authorization” ONLY:
Based on review of available data, the Company may consider Edarbi (azilsartan) and Edarbyclor (azilsartan/chlorthalidone) to be eligible for coverage when the below patient selection criteria are met:

Patient Selection Criteria
Coverage eligibility will be considered for Edarbi (azilsartan) or Edarbyclor (azilsartan/chlorthalidone) when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of Benicar (olmesartan) or Benicar HCT (olmesartan/hydrochlorothiazide) will be/was 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 Edarbi (azilsartan) or Edarbyclor (azilsartan/chlorthalidone) WITHOUT clinical evidence or patient history that suggests the use of Benicar (olmesartan) or Benicar HCT (olmesartan/hydrochlorothiazide) will be/was ineffective or will/did cause an adverse reaction to the patient to be not medically necessary.

For Patients With BOTH “Prior Authorization” AND “Step Therapy”:
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 their respective patient selection criteria are 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 their respective criteria are met:

- For brand name angiotensin II receptor blocker (ARBs) and brand name angiotensin II receptor blocker (ARB) combination drug products EXCEPT Edarbi (azilsartan) and Edarbyclor (azilsartan/chlorthalidone):
  - 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
- For Edarbi (azilsartan) and Edarbyclor (azilsartan/chlorthalidone) ONLY:
  - 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 Edarbi (azilsartan) or Edarbyclor (azilsartan/chlorthalidone); OR
  - The patient meets BOTH of the following criteria:
    - 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) UNLESS there is clinical evidence or patient history that suggests the generically available drug classes listed will be/were ineffective or will/did cause an adverse reaction to the patient; AND
    - There is clinical evidence or patient history that suggests the use of Benicar (olmesartan) or Benicar HCT (olmesartan/hydrochlorothiazide) will be/was 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 the requested brand name angiotensin II receptor blocker (ARB) or brand name angiotensin II receptor blocker combination product when the respective drug’s patient selection criteria are not met or for usage not included in the drug’s patient selection criteria to be not medically necessary.**

Schematic
The schematic below gives a general overview of coverage when the appropriate criteria are met. In general, step 1 products should be used first, followed by preferred products, and then non-preferred products.

<table>
<thead>
<tr>
<th>Program</th>
<th>Step 1</th>
<th>Preferred</th>
<th>Non-Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step Therapy ONLY</td>
<td>Generic (ACE inhibitor/ACE inhibitor combo, ARB/ARB combo)</td>
<td>Any Brand ARB/ARB Combo</td>
<td></td>
</tr>
<tr>
<td>Prior Authorization ONLY</td>
<td>N/A</td>
<td>Benicar, Benicar HCT</td>
<td>Edarbi, Edarbyclor</td>
</tr>
<tr>
<td>Prior Authorization AND Step Therapy</td>
<td>Generic (ACE inhibitor/ACE inhibitor combo, ARB/ARB combo)</td>
<td>Benicar, Benicar HCT</td>
<td>Edarbi, Edarbyclor</td>
</tr>
</tbody>
</table>

Background/Overview
Angiotensin II receptor blockers and ARB combination drugs are used to treat various indications including hypertension, heart failure, and myocardial infarctions.
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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). For patients with Step Therapy, it 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. For patients with Prior Authorization, this policy takes into account clinical evidence or patient history that suggests the use of Benicar or Benicar HCT will be/was 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. Also, in the absence of the above mentioned caveats, there is no advantage of using Edarbi or Edarbyclor over Benicar or Benicar HCT.

References

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

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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.

Next Scheduled Review Date: 10/2015

**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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