Direct Renin Inhibitors and Direct Renin Inhibitor Combination Drugs

Policy # 00346
Original Effective Date: 03/20/2013
Current Effective Date: 03/21/2018

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 direct renin inhibitors (DRIs) and direct renin inhibitor (DRI) combination drugs including, but not limited to, Tekturna®‡ (aliskiren), Tekturna HCT®‡ (aliskiren/hydrochlorothiazide), Tekamlo®‡ (aliskiren/amlodipine), and Amturnide®‡ (aliskiren/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 direct renin inhibitors (DRIs) and direct renin inhibitor (DRI) combination drugs when one of the following criteria is met:

- The patient has tried and failed one brand or generic oral angiotensin converting enzyme-inhibitor (ACE-I) OR one brand or generic angiotensin converting enzyme-inhibitor (ACE-I) combination drug; or
- The patient has tried and failed one brand or generic angiotensin II receptor blocker (ARB) OR one brand or generic angiotensin II receptor blocker (ARB) combination drug; or
- There is clinical evidence or patient history that suggests the drug classes mentioned above will be ineffective or 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 direct renin inhibitors (DRIs) and direct renin inhibitor (DRI) 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
Renin Inhibitors are approved for use in adults to treat hypertension.

Rationale/Source
The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the drug classes mentioned in the patient selection criteria will be ineffective or cause

an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using a direct renin inhibitor or a direct renin inhibitor combination drug over the available brand or generic ACE-I's, ACE-I combination drugs, ARBs or ARB combination drugs.

References

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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.
03/05/2015	Medical Policy Committee review
03/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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03/03/2016	Medical Policy Committee review
03/16/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/02/2017	Medical Policy Committee review
03/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/01/2018	Medical Policy Committee review
03/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2019

**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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