LOUISIANA BLUE

Direct Renin Inhibitors and Direct Renin Inhibitor Combination Drugs

Policy # 00346
Original Effective Date: 03/20/2013
Current Effective Date: 04/01/2025

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**.******

Direct Renin Inhibitors and Direct Renin Inhibitor Combination Drugs

Policy # 00346
Original Effective Date: 03/20/2013
Current Effective Date: 04/01/2025

Background/Overview

Renin Inhibitors are approved for use in adults to treat hypertension.

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 federal regulations, other plan medical policies, and accredited national guidelines.

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

1. Tekturna tablets [package insert]. East Hanover, NJ: Novartis; November 2013.
2. Tekturna HCT [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; November 2013.
3. Tekamlo [package insert]. East Hanover, NJ: Novartis; November 2013.
4. Amturnide™‡ tablets [package insert]. East Hanover, NJ: Novartis; November 2013.
5. Valturna®‡ tablets [package insert]. East Hanover, NJ: Novartis; April 2012.
6. NPC Important Safety Information: US Label Changes for Tekturna® and other aliskiren-based products and Valturna® voluntary cease to market. Available at http://www.pharma.us.novartis.com/assets/pdf/Aliskiren%20FDA%20Update%20US%20Statement.pdf.
7. Parving HH, Brenner BM, McMurray JJV, et al. Aliskiren trial in type 2 diabetes using cardio-renal endpoints (ALTITUDE): rationale and study design. Nephrol Dial Transplant. 2009;24:1663-1671.
8. Parving HH, Brenner BM, McMurray JJV, et al. Baseline characteristics in the aliskiren trial in type 2 diabetes using cardio-renal endpoints (ALTITUDE). J Renin Angiotensin Aldosterone Syst. 2012 Feb 14. [Epub ahead of print].
9. Brown NJ, McInnes GT, Papst CC, et al. Aliskiren and the calcium channel blocker amlodipine combination as an initial treatment strategy for hypertension control (ACCELERATE): a randomized, parallel-group trial. Lancet. 2011;377:312-320.
10. Duggan ST, Chwieduk CM, Curran MP. Aliskiren. A review of its use as monotherapy and as combination therapy in the management of hypertension. Drugs. 2010;70(15):2011-2049.

11. 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. Available at http://www.ncbi.nlm.nih.gov/books/NBK61789/pdf/TOC.pdf.
12. Solomon SD, Appelbaum E, Manning WJ, et al, for the Aliskiren in Left Ventricular Hypertrophy (ALLAY) Trial Investigators. Effect of the direct renin inhibitor, aliskiren, the angiotensin receptor blocker losartan, or both on left ventricular mass in patients with hypertension and left ventricular hypertrophy. Circulation. 2009;119:530-537.
13. Solomon SD, Shin SH, Shah A, et al, for the Aliskiren Study in Post-MI Patients to Reduce Remodeling (ASPIRE) investigators. Effect of the direct renin inhibitor aliskiren on left ventricular remodeling following myocardial infarction with systolic dysfunction. Eur Heart J. 2011;32:1227-1234.
14. Parving HH, Persson F, Lewis JB, et al, for the AVOID Investigators. Aliskiren combined with losartan in type 2 diabetes and nephropathy. N Engl J Med. 2008;358(23):2433-2446.
15. Chobanian A, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. U.S. Department of Health and Human Services. National Institute of Health, National Heart, Lung and Blood Institute. NIH Publication No 03-5233. JNC-VII express available at http://www.nhlbi.nih.gov/guidelines/hypertension/express.pdf and JNC-VII complete report available at http://www.nhlbi. nih.gov/guidelines/hypertension/jnc7full.pdf.

Policy History

Original Effective Date: 03/20/2013
Current Effective Date: 04/01/2025

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.
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

Direct Renin Inhibitors and Direct Renin Inhibitor Combination Drugs

Policy # 00346
Original Effective Date: 03/20/2013
Current Effective Date: 04/01/2025

03/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/07/2019	Medical Policy Committee review
03/20/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2020	Medical Policy Committee review
03/11/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/04/2021	Medical Policy Committee review
03/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/03/2022	Medical Policy Committee review
03/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/02/2023	Medical Policy Committee review
03/08/2023	Medical Policy Implementation Committee approval. No change to coverage.
03/07/2024	Medical Policy Committee review
03/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2025	Medical Policy Committee review
03/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2026

**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.

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.