



Louisiana

Kerendia[®] (finerenone)

Policy # 00765

Original Effective Date: 12/13/2021

Current Effective Date: 12/13/2021

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 Kerendia[®] (finerenone) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Kerendia (finerenone) will be considered when the following criteria are met:

Initial

- Patient has a diagnosis of type 2 diabetes mellitus; AND
- Patient is ≥ 18 years of age; AND
- Patient does NOT have New York Heart Association (NHYA) class II, III, or IV heart failure; AND

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility, based on clinical trials, and will be denied as not medically necessary** if not met)*

- Patient meets one of the following:
 - Patient has a urinary albumin to creatinine ratio (UACR) of 30 to 300 mg/g AND an estimated glomerular filtration rate (eGFR) of 25-60 ml/min/1.73m² AND diabetic retinopathy; OR
 - Patient has a UACR ≥ 300 mg/g AND an eGFR of 25-75 mL/min/1.73m²; AND

*(Note: The above patient criteria are additional Company requirements for coverage eligibility, based on clinical trials, and will be denied as not medically necessary** if not met)*

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- Patient has a serum potassium level ≤ 5 mEq/L; AND
- Patient is on a maximally tolerated labeled dose of an angiotensin converting enzyme inhibitor (ACE-I) OR a maximally tolerated labeled dose of an angiotensin receptor blocker (ARB). Examples include lisinopril, trandolapril, benazepril, enalapril, losartan, valsartan, olmesartan, etc; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has tried and failed (e.g., intolerance or inadequate response) a sodium-glucose transporter 2 (SGLT-2) inhibitor (e.g., Farxiga™, Jardiance®, Steglatro™, Synjardy, Synjardy XR®, Xigduo XR™, or Segluromet™, etc.) † unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

Continuation

- Patient received an initial approval for the requested medication; AND
- Patient is tolerating the requested medication; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient's serum potassium level is ≤ 5.5 mEq/L

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Kerendia (finerenone) when the following criteria are not met to be **not medically necessary****:

- Patient does NOT have New York Heart Association (NHYA) class II, III, or IV heart failure
- Patient meets one of the following:
 - Patient has a UACR of 30 to 300 mg/g AND an eGFR of 25 -60 ml/min/1.73m² AND diabetic retinopathy; OR
 - Patient has a UACR ≥ 300 mg/g AND an eGFR of 25-75 mL/min/1.73m²
- Patient is on a maximally tolerated labeled dose of an ACE-I OR a maximally tolerated labeled dose of an ARB

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- Patient has tried and failed (e.g., intolerance or inadequate response) an SGLT-2 inhibitor (e.g., Farxiga, Jardiance, Steglatro, Synjardy, Synjardy XR, Xigduo XR, or Segluromet, etc.)
- For continuation requests: Patient is tolerating the requested medication

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Kerendia (finerenone) when the patient selection criteria are not met (with the exception of those denoted as **not medically necessary****) to be **investigational**.*

Background/Overview

Kerendia is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes. The recommended starting dosage is 10 mg or 20 mg orally once daily based on eGFR and serum potassium thresholds. Increase the dosage after 4 weeks to the target dose of 20 mg once daily based on eGFR and serum potassium thresholds. See the package insert for complete dosing details.

Chronic kidney disease (CKD) due to diabetes occurs in 20% to 40% of patients with diabetes. CKD can progress to end stage kidney disease, which could require dialysis or kidney transplantation and is associated with increased cardiovascular risk. The American Diabetes Association (ADA) states that in non-pregnant patients with diabetes and hypertension, either an angiotensin converting enzyme inhibitor (ACE-I) or an angiotensin receptor blocker (ARB) is recommended for those with modestly elevated urinary to albumin creatinine ratio (UACR) and is strongly recommended for those with UACR ≥ 300 mg/g creatinine and/or eGFR < 60 mL/min/1.73 m². Examples include lisinopril, trandolapril, benazepril, enalapril, losartan, valsartan, olmesartan, etc. ADA standards also note that metformin is the first line treatment for all patients with type 2 diabetes. Sodium-glucose transporter-2 (SGLT-2) inhibitors and glucagon like peptide 1 (GLP-1) inhibitors should be considered for patients with diabetes and CKD. The Kidney Disease Improving Global Outcomes (KDIGO) guidelines state that first line therapies for patients with diabetes and CKD include

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metformin and an SGLT-2 inhibitor. SGLT-2 inhibitors include Farxiga, Jardiance, Steglatro, Synjardy, Synjardy XR, Xigduo XR, Segluromet, etc. These recommendations are in place because the SGLT-2 inhibitors have gained renal related indications incorporating reductions in cardiovascular death as well as heart failure hospitalizations. Although cross comparisons are difficult to make, the reductions observed with select SGLT-2 inhibitors were more robust than those observed with Kerendia. Kerendia has not been incorporated into treatment guidelines at the time of this policy's publication.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Kerendia is a non-steroidal mineralocorticoid receptor antagonist indicated to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes.

Rationale/Source

The FIDELIO-DKD study was a randomized, double-blind, placebo-controlled, multicenter study in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D), defined as either having an urinary albumin to creatinine ratio (UACR) of 30 to 300 mg/g, estimated glomerular filtration rate (eGFR) 25 to 60 mL/min/1.73 m² and diabetic retinopathy, or as having an UACR of ≥ 300 mg/g and an eGFR of 25 to 75 mL/min/1.73 m². The trial excluded patients with known significant non-diabetic kidney disease. All patients were to have a serum potassium ≤ 4.8 mEq/L at screening and be receiving standard of care background therapy, including a maximum tolerated labeled dose of an angiotensin-converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB). Patients with a clinical diagnosis of chronic heart failure with reduced ejection fraction and persistent symptoms (New York Heart Association class II to IV) were excluded. The starting dose of Kerendia was based on screening eGFR (10 mg once daily in patients with an eGFR of 25 to < 60 mL/min/1.73 m² and 20 mg once daily in patients with an eGFR ≥ 60 mL/min/1.73 m²). The dose of Kerendia could be titrated during the study, with a target dose of 20 mg daily.

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The primary objective of the study was to determine whether Kerendia reduced the incidence of a sustained decline in eGFR of $\geq 40\%$, kidney failure (defined as chronic dialysis, kidney transplantation, or a sustained decrease in eGFR to < 15 mL/min/1.73m²), or renal death.

A total of 5,674 patients were randomized to receive Kerendia (N=2,833) or placebo (N=2,841) and were followed for a median of 2.6 years. At baseline, the mean eGFR was 44 mL/min/1.73m², with 55% of patients having an eGFR < 45 mL/min/1.73m². Median UACR was 852 mg/g, and mean glycated hemoglobin A1c (HbA1c) was 7.7%. Approximately 46% of patients had a history of atherosclerotic cardiovascular disease.

At baseline, 99.8% of patients were treated with an ACE-I or ARB. Approximately 97% were on an antidiabetic agent (insulin [64.1%], biguanides [44%], glucagon-like peptide-1 [GLP-1] receptor agonists [7%], sodium-glucose cotransporter 2 [SGLT-2] inhibitors [5%]), 74% were on a statin, and 57% were on an antiplatelet agent.

Kerendia reduced the incidence of the primary composite endpoint of a sustained decline in eGFR of $\geq 40\%$, kidney failure, or renal death (HR 0.82, 95% CI 0.73-0.93, p=0.001). The treatment effect reflected a reduction in a sustained decline in eGFR of $\geq 40\%$ and progression to kidney failure. There were few renal deaths during the trial.

Kerendia also reduced the incidence of the composite endpoint of cardiovascular (CV) death, non-fatal myocardial infarction (MI), non-fatal stroke or hospitalization for heart failure (HR 0.86, 95% CI 0.75-0.99, p=0.034). The treatment effect reflected a reduction in CV death, non-fatal MI, and hospitalization for heart failure.

The purpose of this policy is to ensure that Kerendia is being used per its FDA approved indication as well as to ensure that the most effective and proven medications for the condition(s) are utilized prior to the use of Kerendia.

References

1. Kerendia [package insert]. Bayer Healthcare. Whippany, New Jersey. Updated July 2021.
2. Kerendia Drug Evaluation. Express Scripts. Updated August 2021.

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3. American Diabetes Association. Standards of medical care in diabetes – 2021. Diabetes Care. 2021;44(Suppl 1):S1-S232.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney Int. 2020;98(4S):S1-S115.

Policy History

Original Effective Date: 12/13/2021

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11/04/2021 Medical Policy Committee review

11/10/2021 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 11/2022

*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 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.

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****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.

‡ 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.

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