LOUISIANA BLUE

Kerendia® (finerenone)

Policy # 00765
Original Effective Date: 12/13/2021
Current Effective Date: 12/09/2024

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 meets both of the following:
  - Patient has a urinary albumin to creatinine ratio (UACR) of ≥30 mg/g; AND
  - Patient has an estimated glomerular filtration rate (eGFR) of ≥ 25 ml/min/1.73m^2; AND

  *(Note: The above patient selection criteria are additional Company requirements for coverage eligibility, based on clinical trials, and will be denied as not medically necessary** if not met)*
- 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 selection 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 selection 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 selection 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 meets both of the following:
  - Patient has a UACR of ≥30 mg/g; AND
  - Patient has an estimated glomerular filtration rate (eGFR) of ≥ 25 ml/min/1.73m^2
- Patient is on a maximally tolerated labeled dose of an ACE-I OR a maximally tolerated labeled dose of an ARB
- 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.***

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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 m^2. 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 metformin and an SGLT-2 inhibitor. SGLT-2 inhibitors include Farxiga, Jardiance, Steglatro, Synjardy, Synjardy XR, Xigduo XR, Segluromet, etc. A nonsteroidal mineralocorticoid receptor antagonist, such as Kerendia, according to the 2022 update of the 2020 KDIGO guidelines, is suggested in patients with type 2 diabetes, an eGFR ≥ 25 ml/min per 1.73 m^2, normal serum potassium concentration, and albuminuria (≥ 30 mg/g) despite maximum tolerated dose of renin-angiotensin system (RAS) inhibitor (an ACE-I or ARB being first line). The guidelines also state that Kerendia can be added to a RAS inhibitor or an SGLT-2 inhibitor for the treatment of type 2 diabetes and CKD. 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.

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.

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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 FIDELIO-DKD and FIGARO-DKD studies were randomized, double-blind, placebo-controlled, multicenter studies in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). CKD associated with type 2 diabetes was 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 m^2 and diabetic retinopathy, or as having an UACR of ≥300 mg/g and an eGFR of 25 to 75 mL/min/1.73 m^2 in the FIDELIO-DKD trial and as having an UACR of 30 mg/g to < 300 mg/g and an eGFR of 25 to 90 mL/min/1.73m^2, or an UACR ≥ 300 mg/g and an eGFR ≥ 60 mL/min/1.73m^2 in the FIGARO-DKD trial. Both trials 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 m^2 and 20 mg once daily in patients with an eGFR ≥60 mL/min/1.73 m^2). The dose of Kerendia could be titrated during the study, with a target dose of 20 mg daily.

The primary objective of the FIDELIO-DKD study was to determine whether Kerendia reduced the incidence of a sustained decline in eGFR of ≥40%, kidney failure (defined as chronic dialysis, kidney transplantation, or a sustained decrease in eGFR to <15 mL/min/1.73m^2), or renal death. The secondary outcome was a composite of time to first occurrence of CV death, non-fatal MI, non-fatal stroke or hospitalization for heart failure.

The primary objective of the FIGARO-DKD study was to determine whether Kerendia reduced the time to first occurrence of CV death, non-fatal MI, non-fatal stroke or hospitalization for heart failure. The secondary outcome was a composite of time to kidney failure, a sustained decline in eGFR of 40% or more compared to baseline over at least 4 weeks, or renal death.

IN FIDELIO-DKD, 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/1.73m^2, with 55% of patients having an eGFR <45 mL/min/1.73m^2. 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 ≥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 ≥40% and progression to kidney failure. There were few renal deaths during the trial.

Kerendia also reduced the incidence of the secondary 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.

In FIGARO-DKD, a total of 7352 patients were randomized to receive Kerendia (N=3683) or placebo (N=3666) and were followed for 3.4 years. As compared to FIDELIO-DKD, baseline eGFR was higher in FIGARO-DKD (mean eGFR 68, with 62% of patients having an eGFR ≥ 60 mL/min/1.73 m2) and median UACR was lower (308 mg/g). Otherwise, baseline patient characteristics and background therapies were similar in the two trials.

In FIGARO-DKD, Kerendia reduced the incidence of the primary composite endpoint of CV death, non-fatal MI, nonfatal stroke or hospitalization for heart failure (HR 0.87, 95% CI 0.76-0.98, p = 0.026). The treatment effect was mainly driven by an effect on hospitalization for heart failure, though CV death also contributed to the treatment effect.

The purpose of this policy is the 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 conditions(s) are utilized prior to the use of Kerendia.

References

1. Kerendia [package insert]. Bayer Healthcare. Whippany, New Jersey. Updated September 2022.
2. Kerendia Drug Evaluation. Express Scripts. Updated August 2021.
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.
5. Supplement to Kidney International. KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney Int. 2022;102 (5S):S1-S127

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11/04/2021	Medical Policy Committee review
11/10/2021	Medical Policy Implementation Committee approval. New policy.
12/01/2022	Medical Policy Committee review
12/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. Updated eligibility criteria and relevant sections based on new trial, FIGARO-DKD. Removed diabetic retinopathy and eGFR and UACR ranges from policy criteria that were specific to FIDELIO-DKD study.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Removed criterion requiring a patient to NOT have New York Heart Association Class II-IV heart failure.
11/07/2024	Medical Policy Committee review
11/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 11/2025

*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 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.

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.