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Section:	Prescription Drugs	**Effective Date:**	July 1, 2026
Subsection:	Endocrine and Metabolic Agents	**Original Policy Date:**	November 12, 2021
Subject:	Kerendia	**Page:**	1 of 5

Last Review Date: June 11, 2026

Kerendia

Description

Kerendia (finerenone)

Background
Kerendia (finerenone) is a nonsteroidal, selective antagonist of the mineralocorticoid receptor (MR), which is activated by aldosterone and cortisol and regulates gene transcription. Kerendia blocks MR mediated sodium reabsorption and MR overactivation in both epithelial (e.g., kidney) and nonepithelial (e.g., heart, and blood vessels) tissues. MR overactivation is thought to contribute to fibrosis and inflammation. Kerendia has a high potency and selectivity for the MR and has no relevant affinity for androgen, progesterone, estrogen, and glucocorticoid receptors (1).

Regulatory Status
FDA-approved indication: Kerendia is a non-steroidal mineralocorticoid receptor antagonist (nsMRA) indicated to reduce the risk of: (1)

- 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 (CKD) associated with type 2 diabetes (T2DM).
- cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥ 40%.

Serum potassium levels and estimated glomerular filtration rate (eGFR) should be measured before initiation. Treatment should not be initiated if serum potassium is > 5.0 mEq/L (1).

Kerendia has a warning regarding hyperkalemia. The risk for developing hyperkalemia increases with decreasing kidney function and is greater in patients with higher baseline potassium levels or other risk factors for hyperkalemia (1).

Kerendia is contraindicated in patients with adrenal insufficiency and in patients who are receiving concomitant treatment with strong CYP3A4 inhibitors (1).

The FIDELIO-DKD study excluded patients on concomitant therapy with eplerenone, spironolactone, any renin inhibitor, or potassium-sparing diuretic which could not be discontinued ≥4 weeks prior to screening (2).

The safety and effectiveness of Kerendia in pediatric patients less than 18 years of age have not been established (1).

Related policies
SGLT2 Step Policy

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Kerendia may be considered **medically necessary** if the conditions indicated below are met.

Kerendia may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Chronic kidney disease (CKD) associated with Type 2 Diabetes Mellitus

a. Urine albumin >30 mg/g despite maximally tolerated dose of an ACE or ARB, unless medically contraindicated
b. Used in combination with maximally tolerated dose of an ACE or ARB, unless medically contraindicated
c. Used in combination with an antidiabetic agent, unless medically contraindicated

2. Heart failure (HF)
   a. Left ventricular ejection fraction (LVEF) ≥ 40%
   b. Used in combination with heart failure medical treatment

AND ALL of the following:

a. Patients on eplerenone, spironolactone, renin inhibitor, or potassium-sparing diuretic **ONLY**: patient will discontinue use of this medication at least 4 weeks before starting Kerendia
b. Prescriber agrees to monitor eGFR and serum potassium levels
c. **NO** adrenal insufficiency

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Chronic kidney disease (CKD) associated with Type 2 Diabetes Mellitus
   a. Used in combination with maximally tolerated dose of an ACE or ARB, unless medically contraindicated
   b. Used in combination with an antidiabetic agent, unless medically contraindicated
2. Heart failure (HF)
   a. Left ventricular ejection fraction (LVEF) ≥ 40%
   b. Used in combination with heart failure medical treatment

AND ALL of the following:

a. Prescriber agrees to monitor eGFR and serum potassium levels
b. **NO** adrenal insufficiency

Policy Guidelines

Pre–PA Allowance

None

Prior - Approval Limits

Quantity

Diagnosis	Quantity
Chronic Kidney Disease (CKD) in T2DM	20 mg per day **OR**
Heart failure (HF)	40 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Kerendia is a non-steroidal mineralocorticoid receptor antagonist indicated for use in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes and in adult patients with heart failure with LVEF ≥ 40%. Patients taking Kerendia will need to have their eGFR and serum potassium levels monitored due to the risk of developing hyperkalemia. Kerendia is contraindicated in patients with adrenal insufficiency and in patients who are receiving concomitant treatment with strong CYP3A4 inhibitors. The safety and effectiveness of Kerendia in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Kerendia while maintaining optimal therapeutic outcomes.

References

1. Kerendia [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2025.

2. Bakris GL, Agarwal R, Anker SD, et al. Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes (FIDELIO-DKD study). *N Engl J Med* 2020;383:2219-29.

Policy History

Date	Action
November 2021	Addition to PA
December 2021	Annual review. Per SME, added requirement that patients on eplerenone, spironolactone, renin inhibitor, or potassium-sparing diuretic must discontinue use of this medication at least 4 weeks before starting Kerendia
April 2022	Per FEP, added the option that the medication can be prescribed by or recommended by an endocrinologist
June 2022	Annual review
September 2022	Annual review. Per FEP, added the option that the medication can be prescribed by or recommended by a cardiologist
June 2023	Annual review and reference update
September 2023	Annual review. Per SME, removed specialist requirement
June 2024	Annual review
September 2024	Annual review
June 2025	Annual review
August 2025	Per PI update, added indication of heart failure
September 2025	Annual review
April 2026	Removed no dual therapy with a strong CYP3A4 inhibitor requirement
June 2026	Annual review and reference update. Per SME, added albuminuria requirement despite maximally tolerated ACE/ARB, removed requirement for improved/stabilized symptoms in renewal criteria

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.