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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Endocrine and Metabolic Agents	**Original Policy Date:**	November 12, 2021
Subject:	Kerendia	**Page:**	1 of 5

Last Review Date: September 6, 2024

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 (MRA) indicated to reduce the risk of sustained 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 (T2D) (1).

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

Diagnosis

Patient must have 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
c. 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
d. Prescriber agrees to monitor eGFR and serum potassium levels
e. **NO** adrenal insufficiency
f. **NO** concurrent therapy with strong CYP3A4 inhibitors (e.g., itraconazole)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have 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
    c. eGFR has improved or stabilized
    d. Prescriber agrees to monitor eGFR and serum potassium levels
    e. **NO** adrenal insufficiency
    f. **NO** concurrent therapy with strong CYP3A4 inhibitors (e.g., itraconazole)

Policy Guidelines

Pre–PA Allowance

None

Prior - Approval Limits

Quantity 90 tablets per 90 days

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. 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.; September 2022.
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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.