BlueCross BlueShield
Federal Employee Program

KERENDIA
(finerenone)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

Summary

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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.