PRIOR AUTHORIZATION POLICY

POLICY: Diabetes – Kerendia Prior Authorization Policy
- Kerendia® (finerenone tablets – Bayer)

REVIEW DATE: 08/07/2024

OVERVIEW

Kerendia, a nonsteroidal mineralocorticoid receptor antagonist (MRA), is indicated in adults with **chronic kidney disease (CKD) associated with type 2 diabetes** to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular (CV) death, non-fatal myocardial infarction, and hospitalization for heart failure.[1]

Per the prescribing information, do not initiate treatment with Kerendia if serum potassium is > 5.0 mEq/L.[1] Additionally, initiation of Kerendia is not recommended in patients with eGFR < 25 mL/min/1.73 m^2. Kerendia labeling includes a Warning regarding hyperkalemia and notes that the risk increases with decreasing kidney function. Monitoring of serum potassium and eGFR is recommended.

Clinical Efficacy

Efficacy of Kerendia was evaluated in two published Phase III, placebo-controlled trials, FIDELIO-DKD (n = 5,734) and FIGARO-DKD (n = 7,352).[2,8] All patients were required to be treated with an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) at the maximum tolerated labeled dose for ≥ 4 weeks prior to the run-in visit. Additionally, patients were required to have a urinary albumin-to-creatinine ratio of ≥ 30 mg/g, in addition to other renal entry criteria.

Guidelines

The American Diabetes Association (ADA) Standards of Care (2024) recommend Kerendia for patients with type 2 diabetes and CKD with albuminuria treated with maximum tolerated doses of ACE inhibitors or ARBs, to improve CV outcomes and reduce the risk of CKD progression (level A recommendation).[3] In individuals with type 2 diabetes and diabetic kidney disease, Kerendia is recommended to reduce the risk of hospitalization for heart failure (level A recommendation).

Additionally, in the section regarding CKD (Chapter 11), it is noted that in patients with diabetic kidney disease and type 2 diabetes, use of sodium glucose co-transporter-2 inhibitors (if eGFR is ≥ 20 mL/min/1.73 m^2), a glucagon-like peptide-1 agonist, or Kerendia (if eGFR is ≥ 25 mL/min/1.73 m^2), should be considered for CV risk reduction (level A recommendation). In patients with CKD and albuminuria, who are at increased risk for CV events or CKD progression, Kerendia is recommended to reduce CKD progression and CV events (level A recommendation).

The Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline for Diabetes Management in CKD (2022) suggests use of Kerendia in patients with type 2 diabetes with eGFR ≥ 25 mL/min/1.73 m^2, normal serum potassium, and albuminuria (≥ 30 mg/g) despite maximal tolerated doses of a renin-angiotensin-aldosterone system (RAAS) inhibitor.[4] The rationale for adding an MRA to current standard of care, including ACE inhibitor or ARB, is that this combination has been proven to be an effective strategy to reduce albuminuria in patients with diabetes and CKD. The steroidal MRAs, spironolactone and eplerenone, have been shown to effectively reduce albuminuria; however, there are no data demonstrating that these agents reduce the risk of clinical outcomes. Kerendia reduces albuminuria and the risk of kidney and CV outcomes. The guidelines also note that Kerendia is most appropriate for patients with type 2 diabetes who are at high risk of CKD progression and CV events, because Kerendia

can be added to an ACE/ARB and a sodium glucose co-transporter-2 inhibitor for treatment of type 2 diabetes and CKD.

A consensus report from the ADA/KDIGO (2022) for diabetes management in CKD states that Kerendia is recommended for patients with type 2 diabetes, eGFR ≥ 25 mL/min/1.73 m^2, normal serum potassium concentration, and albuminuria (albumin:creatinine ratio ≥ 30 g/g) despite a maximum tolerated dose of RAAS inhibitor therapy.[10]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Kerendia. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Kerendia is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Diabetic Kidney Disease.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has a diagnosis of type 2 diabetes; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB); OR
       - **b)** According to the prescriber, patient has a contraindication to ACE inhibitor and ARB therapy; AND
     - **iv.** At baseline (prior to the initiation of Kerendia), patient meets ALL of the following (a, b, and c):
       - **a)** Estimated glomerular filtration rate ≥ 25 mL/min/1.73 m^2; AND
       - **b)** Urine albumin-to-creatinine ratio ≥ 30 mg/g; AND
       - **c)** Serum potassium level ≤ 5.0 mEq/L.
   - **B)** Patient is Currently Receiving Kerendia. Approve if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has a diagnosis of type 2 diabetes; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB); OR
       - **b)** According to the prescriber, patient has a contraindication to ACE inhibitor and ARB therapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Kerendia is not recommended in the following situations:

1. **Heart Failure (Treatment).** Patients with a clinical diagnosis of heart failure with reduced ejection fraction (New York Heart Association [NYHA] Class II through IV) were excluded from FIDELIO-DKD and FIGARO-DKD.[2,8] Kerendia was compared with eplerenone in the Phase IIb FINEARTS-HF trial (n = 1,066) among patients with heart failure with reduced ejection fraction and type 2 diabetes and/or chronic kidney disease.[5] The primary endpoint was proportion of patients with > 30% decline in N-terminal pro-B-type natriuretic peptide (NT-proBNP) level at Day 90. Kerendia induced a > 30% decrease in NT-proBNP levels in a similar proportion of patients compared with eplerenone. Further data are needed to characterize the role of Kerendia in chronic heart failure management. Kerendia is not addressed in heart failure guidelines (outside of patients with diabetes and chronic kidney disease [CKD]). In an update to American College of Cardiology heart failure guidelines (2022), mineralocorticoid receptor antagonists (MRAs) [spironolactone, eplerenone] are recommended in patients with heart failure with reduced ejection fraction and NYHA Class II to IV symptoms, if estimated glomerular filtration rate is > 30 mL/min/1.73 m^2 and serum potassium is < 5 mEq/L.[6] MRAs are also among the classes which may be considered for heart failure with mildly reduced ejection fraction and in selected patients with heart failure with preserved ejection fraction. An American College of Cardiology Expert Consensus Decision Pathway on Management of Heart Failure with Preserved Ejection Fraction (2023) lists Kerendia as a medication for patients with heart failure with preserved ejection fraction with concomitant diabetes and diabetic kidney disease.[9] A 2023 update of the 2021 European Society of Cardiology guidelines for the treatment of acute and chronic heart failure recommend Kerendia in patients with type 2 diabetes and CKD to reduce the risk of heart failure hospitalization (Class I, Level A).[11]
   Note: For a patient with concomitant diabetic kidney disease and heart failure, refer to FDA-Approved Indication.

2. **Hypertension (Treatment).** Kerendia has not been evaluated for use in essential hypertension and is not mentioned in American College of Cardiology/American Heart Association hypertension guidelines (2017).[7] Spironolactone and eplerenone are cited as secondary agents for management of hypertension and are noted to be common add-on therapies for resistant hypertension. Primary agents include thiazide diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, and calcium channel blockers.
   Note: For a patient with concomitant diabetic kidney disease and hypertension, refer to FDA-Approved Indication.

3. **Concomitant Use with Spironolactone or Eplerenone.** Spironolactone and eplerenone are steroidal mineralocorticoid receptor antagonists. Based on their mechanism of action, an increase in adverse events (e.g., hyperkalemia) would be expected if used concomitantly with Kerendia. Concomitant spironolactone or eplerenone use was not permitted in clinical trials.

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Kerendia® tablets [prescribing information]. Whippany, NJ: Bayer; September 2022.
2. Bakris GL, Agarwal R, Anker SD, et al; FIDELIO-DKD Investigators. Effect of finerenone on chronic kidney disease outcomes in type 2 diabetes. *N Engl J Med*. 2020;383(23):2219-2229.
3. American Diabetes Association. Standards of care in diabetes – 2024. *Diabetes Care*. 2024;47(Suppl 1):S1-S321.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group: Rossing P, Muiza Caramori M, Chan JCN, et al. KDIGO 2022 clinical practice guideline for diabetes management in chronic kidney disease. *Kidney Int.* 2022;102(5S):S1-S127.
5. Filippatos G, Anker SD, Böhm M, et al. A randomized controlled study of finerenone vs. eplerenone in patients with worsening chronic heart failure and diabetes mellitus and/or chronic kidney disease. *Eur Heart J*. 201614;37(27):2105-14.
6. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18):e895-e1032.
7. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Hypertension*. 2018;71(6):e13-e115.
8. Pitt B, Filippatos G, Agarwal R, et al; FIGARO-DKD Investigators. Cardiovascular events with finerenone in kidney disease and type 2 diabetes. *N Engl J Med*. 20219;385(24):2252-2263.
9. Kittleson MM, Panjrath GS, Amancherla K, et al. 2023 ACC expert consensus decision pathway on management of heart failure with preserved ejection fraction. *J Am Coll Cardiol*. 2023;81(18):1835-1878.
10. Boer IH, Khunti K, Sadusky T, et al. Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO). *Kidney Int.* 2022;102:974-989.
11. McDonagh TA, Metra M, Adamo M, et al; European Society of Cardiology (ESC) Scientific Document Group. 2023 focused update of the 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J*. 2023;44(37):3627-3639.