MEDICAL MUTUAL®

Drug Policy

Policy:	Kerendia (finerenone)	Annual Review Date: 09/19/2024 Last Revised Date: 09/19/2024

OVERVIEW

Kerendia, a nonsteroidal mineralocorticoid receptor antagonist (MRA), is indicated in adults with **chronic kidney disease (CKD) associated with type 2 diabetes** to the 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.

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.

POLICY STATEMENT

This policy involves the use of Kerendia. Prior authorization is recommended for pharmacy benefit coverage of Kerendia. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. <u>Diabetic Kidney Disease</u>

Criteria. *Patient must meet the following criteria (A <u>or</u> B):*

A) <u>Initial Therapy</u>. Approve if the patient meets the following criteria (i, ii, iii, <u>and</u> 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 <u>or</u> b):
  - **a)** Patient is currently receiving a maximally tolerated labeled dosage of angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB); OR

b) According to the prescriber, patient has a contraindication to ACE inhibitor or 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 OR stage 2, 3, or 4 CKD; 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 the following criteria (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 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.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Kerendia has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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 ARTS-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) 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. In an update to American College of Cardiology heart failure guidelines (2022), MRAs (spironolactone, eplerenone) are recommended in patients with heart failure with reduced ejection fraction and NYHA Class II to IV symptoms, if eGFR 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] The American Diabetes Association Standards of Care (2023) note that the pooled FIDELITY trial analysis confirms and strengthens the positive cardiovascular and renal outcomes with Kerendia across the spectrum of chronic kidney disease, irrespective of baseline atherosclerotic cardiovascular disease history (with the *exclusion* of those with heart failure with reduced ejection fraction).[3]
   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, ACE inhibitors, ARBs, 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.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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3. American Diabetes Association. Standards of care in diabetes – 2024. Diabetes Care. 2024;47(Suppl 1):S1-S321.
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