PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/02/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.[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 Phase III, placebo-controlled trials, FIDELIO-DKD (published) [n = 5,734] and FIGARO-DKD (published) [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 (2023) recommend Kerendia for patients with type 2 diabetes and CKD 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] 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 not 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:reatinine 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.

- **Kerendia™ (finerenone tablets – Bayer)**

is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Diabetic Kidney Disease.** Approve for 1 year if the patient meets the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets 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 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 COVERED

- **Kerendia™ (finerenone tablets – Bayer)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.

REFERENCES

1. Kerendia™ tablets [prescribing information]. Whippany, NJ: Bayer; September 2022.
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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.
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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/03/2022
Annual Revision	No criteria changes.	08/02/20223