VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/28/2021; selected revision 09/08/2021

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 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. These patients were also excluded from the pivotal study, FIDELIO-DKD.[2] Kerendia labeling includes a Warning regarding hyperkalemia and notes that the risk increases with decreasing kidney function.[1] 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 (2021) were annotated as of June 16, 2021 to acknowledge data from FIDELIO-DKD.[3] Per the revised ADA Standards, MRAs have not been well studied in diabetic kidney disease because of the risk of hyperkalemia. However, data that do exist suggest benefit on albuminuria reduction that is sustained. It is noted that in FIDELIO-DKD, Kerendia reduced the incidence of the primary composite endpoint relative to placebo. No formal recommendations are made regarding Kerendia use. The ADA Standards recommend optimization of blood pressure and glucose control to reduce the risk or slow the progression of CKD. In non-pregnant patients with diabetes and hypertension, either an ACE inhibitor or an ARB is recommended for those with modestly elevated urinary albumin-to-creatinine ratio (ACR) and is strongly recommended for those with urinary ACR ≥ 300 mg/g creatinine and/or eGFR < 60 mL/min/1.73 m^2.

The KDIGO Clinical Practice Guideline for Diabetes Management in CKD (2020) does not have recommendations regarding Kerendia. Regarding MRAs overall, the guideline states that MRAs are effective for the management of refractory hypertension but may cause hyperkalemia or a reversible decline in glomerular filtration, particularly among patients with a low eGFR.[4] It is noted that the steroidal MRAs (spironolactone and eplerenone) lack long-term data regarding clinical benefits in this population. Whether newer non-steroidal MRAs (e.g., finerenone) may provide benefit in diabetes and CKD with fewer adverse events is noted to be an area of ongoing research. ACE inhibitors or ARBs are recommended to be initiated in patients with diabetes, hypertension, and albuminuria; these should be titrated to the highest approved dose that is tolerated.

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 recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Diabetic Kidney Disease.** Approve for 1 year if the patient meets the following criteria (A or B):
   - **A)** Initial Therapy. Approve if the patient meets the following criteria (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 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 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 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.[2,3] 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. In an update to American College of Cardiology heart failure guidelines (2021), aldosterone antagonists (spironolactone, eplerenone) are recognized as add-on therapy to ACE inhibitors, ARBs, or angiotensin receptor-neprilysin inhibitors for patients with NYHA class II through IV symptoms meeting renal and

serum potassium criteria (class I recommendation).[6] Kerendia is not addressed in heart failure guidelines.
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.

REFERENCES

1. Kerendia™ tablets [prescribing information]. Whippany, NJ: Bayer; July 2021.
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 Dec 3;383(23):2219-2229.
3. American Diabetes Association. Standards of medical care in diabetes – 2021. *Diabetes Care*. 2021;44(Suppl 1):S1-S232.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. *Kidney Int*. 2020 Oct;98(4S):S1-S115.
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*. 2016 Jul 14;37(27):2105-14.
6. Writing Committee, Maddox TM, Januzzi JL Jr, et al. 2021 update to the 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: answers to 10 pivotal issues about heart failure with reduced ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol*. 2021 Feb 16;77(6):772-810.
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 Jun;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*. 2021 Aug 28 [Epub ahead of print].

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/28/2021
Selected Revision	**Diabetic Kidney Disease:** In the requirement that the patient is receiving an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB), the phrase "maximally tolerated" was clarified to mean "maximally tolerated labeled dosage". In initial therapy criteria, the criterion requiring a contraindication to an ACE inhibitor or ARB was revised to a contraindication to an ACE inhibitor and ARB, to align with existing criteria for a patient currently receiving Kerendia. The requirement for eGFR < 75 mL/min/1.73 m^2 was removed based on updated FIGARO-DKD data.	09/08/2021