finerenone (Kerendia™)

EOCCO POLICY

Policy Type: PA Pharmacy Coverage Policy: EOCCO236

Description

Finerenone (Kerendia) is a selective, nonsteroidal mineralocorticoid receptor antagonist (MRA)

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
finerenone (Kerendia)	10 mg tablets	Adjunct therapy for chronic kidney disease in type 2 diabetes	30 tablets/30 days
	20 mg tablets		

Initial Evaluation

I. **Finerenone (Kerendia)** may be considered medically necessary when the following criteria are met:
   A. Member is 18 years of age or older; **AND**
   B. A diagnosis of **Type 2 Diabetes Mellitus (T2DM)** when the following are met:
      1. Member has chronic kidney disease (CKD) based on **one** of the following:
         i. Estimated glomerular filtration rate (eGFR) is 60 mL/min/1.73m^2 or less for at least 3 months; **OR**
         ii. Persistent moderate to severe albuminuria (urine albumin-to-creatinine ratio [UACR] 30 mg/g or greater, or 0.113 mg/mmol or greater) for at least 3 months; **AND**
      2. Documentation that treatment with an Angiotensin Converting Enzyme inhibitor (ACEI, e.g., lisinopril) or an Angiotensin Receptor Blocker (ARB, e.g., losartan) has been tried, unless all agents in these classes are contraindicated; **AND**
         i. Provider attests that the treatment with an ACEI or ARB will be continued, unless all are contraindicated; **AND**
      3. Treatment with ONE Sodium Glucose Co-transporter-2 (SGLT2) inhibitor (e.g., empagliflozin (Jardiance), dapagliflozin (Farxiga)) has been ineffective, not tolerated, or all are contraindicated

II. Finerenone (Kerendia) is considered investigational when used for all other conditions, including but not limited to:

A. Treatment of CKD in members less than 18 years of age
B. Treatment of hypertension
C. Treatment of cardiovascular disorder (e.g. myocardial infraction, heart failure)
D. Edema associated with nephrotic syndrome
E. Perioperative management of hyperaldosteronism

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
   A. Member has exhibited improvement or stability of disease symptoms (e.g. stabilization of eGFR, lack of hospitalization due to renal or cardiovascular disease); **OR**
   B. In the absence of improvement or stability of disease symptoms, the provider attests that continuation of therapy is medically necessary AND clinical rationale of medical necessity has been provided and reviewed by a health plan clinician.

Supporting Evidence

I. Finerenone (Kerendia) is a selective, nonsteroidal mineralocorticoid receptor antagonist (MRA) approved as an adjunct treatment to slow the progression of renal disease and to reduce the risk of cardiovascular (CV) outcomes in adult patients with chronic kidney disease (CKD) in type 2 diabetes (T2D). Efficacy and safety of finerenone (Kerendia) in the pediatric population has not been evaluated.
II. MR overactivation may lead to inflammation and fibrosis and contribute to cardiorenal risk in T2D via hemodynamic and metabolic mechanisms. These are considered major drivers of heart and kidney damage in patients with CKD in T2D. Finerenone (Kerendia) reduces inflammation and fibrosis by blocking MR overactivation promoted by cardiorenal disease or diabetes. Finerenone (Kerendia) is the first non-steroidal MRA for adjunct treatment for cardiorenal risk reduction for CKD in T2D.
III. The KIDIGO 2022 guideline for management of CKD in diabetes recommend control of hypertension and hyperglycemia. Recommended first line agents included renin-angiotensin blockers (e.g. ACEI, ARB) and SGLT2 inhibitors (SGLT2i) to prevent CKD progression and cardiovascular events regardless of glycemia. The choice of an SGLT2i should prioritize agents with documented kidney or cardiovascular benefits and take eGFR into account. Mineralocorticoid receptor antagonists (MRA) are recommended as an added agent to RASi and SGLT2i for the treatment of CKD in T2D.

IV. The clinical diagnosis of CKD in T2D is primarily based on the presence of albuminuria (urine-albumin-to-creatinine ratio [UACR] ≥ 30 mg/g) and/or eGFR < 60 mL/min/1.73 m^2 for ≥ 3 months, with the typical presentation generally considered to include a long duration of diabetes, albuminuria without hematuria, retinopathy, a gradually progressive decline in eGFR, and no other primary causes of kidney damage. Albuminuria is an essential marker for kidney disease, as well as a CV risk marker for myocardial infarction (MI) and stroke, in patients with T2D. Albuminuria is often the first clinical indicator of kidney disease, and frequently appears before a reduction in eGFR can be seen.

V. Two randomized, double-blind, placebo-controlled, Phase 3 trials for finerenone (Kerendia) have been completed. The new drug application (NDA) for finerenone (Kerendia) was submitted to the US-FDA based on data from one randomized, double-blind, placebo-controlled, Phase 3 trial (FIDELIO-DKD) in 5,734 patients with CKD in T2D. The primary endpoint for FIDELIO-DKD was a composite renal outcome consisting of kidney failure, a sustained decrease of ≥ 40% in eGFR, or death from renal causes. Composite CV outcomes were assessed as the key secondary endpoint. Another Phase 3 clinical trial (FIGARO-DKD) assessed composite CV outcomes as the primary endpoint, and composite renal outcomes as pre-specified secondary endpoint.

VI. The FIDELIO-DKD participants consisted of adults (mean age 65) with diagnoses of T2D and CKD, with the majority of patients (52%) having an eGFR between 25 and 45 mL/min at baseline. All participants were pretreated with an ACEI, ARB, or both at maximum tolerated doses. Other baseline antihypertensive and antidiabetic medications (e.g. insulin, metformin, DPP-4 inhibitors) were also continued. Clinical trial data points to finerenone (Kerendia) as an adjunct to baseline therapy, specifically to ACEI or ARB. Although contraindication to all ACEI and ARB agents is rare, in such situations, coverage for finerenone (Kerendia) may be warranted without requiring concurrent therapy with an ACEI or ARB. Of note, adverse reactions to one agent in these therapeutic classes may not constitute as a class contraindication. Some examples of contraindication may include hypersensitivity reactions, severe angioedema, and persistent severe hyperkalemia.

VII. The FIDELIO-DKD study demonstrated that, over a median follow-up period of 2.6 years, the primary composite renal outcomes was statistically significantly lower in the finerenone (Kerendia) group than the placebo group (17.8% [n= 504] vs 21.1% [n= 600]; HR: 0.82; (95% CI: 0.73, 0.93; p=0.001). Overall, 29 patients needed to be treated with finerenone (Kerendia) to prevent one primary outcome event (number needed to treat [NNT]; 95% CI: 16, 166) based on an absolute risk reduction of 3.4% (95% CI: 0.6, 6.2) after three years.

VIII. The FIGARO-DKD trial consisted of 7,437 participants who were predominately male (69.4%) and white (73.5%), with a mean age of 64.1 years and a mean duration of diabetes of 14.5 years. All participants were pretreated with an ACEI, ARB, or both at maximum tolerated doses. More than 60% of patients had an eGFR ≥60 mL/min/1.73 m2 and the proportion of patients with high or very high albuminuria at baseline was balanced. The use of GLP-1 and SGLT2 inhibitors at baseline was low (7.5 and 8.3%, respectively); additional 15.8% and 11.3% of patients, respectively, started treatment during the trial.

IX. The FIGARO-DKD study demonstrated that, over a median follow-up period of 3.4 years, the primary endpoint of composite CV outcomes was statistically significantly lower in the

finerenone (Kerendia) group than the placebo group (458 of 3,686 patients [12.4%] vs. 519 of 3,666 patients [14.2%]; hazard ratio, 0.87; 95% confidence interval [CI], 0.76 to 0.98; P = 0.03). The number of patients who needed to be treated with finerenone to prevent one primary outcome event was 47 (95% CI, 26 to 226), on the basis of an absolute between-group difference of 2.1 percentage points (95% CI, 0.4 to 3.8) after 3.5 years.

X. SGLT2i were not standard of care when the FIDELIO-DKD and FIGARO-DKD trials were initiated. However, 877 participants were using an SGLT2i at baseline, and the cardiovascular effects of finerenone (Kerendia), compared with placebo, appeared to be at least as beneficial among people using versus not using an SGLT2i. Guidelines rationalize that SGLT2i may reduce the risk of hyperkalemia for patients treated concomitantly with a RASi and nonsteroidal MRA. These data, combined with complementary mechanisms of action, suggest that the benefits of SGLT2i and finerenone may be additive.

Investigational or Not Medically Necessary Uses

I. There are ongoing clinical studies to assess efficacy and safety of finerenone (Kerendia) in other settings. Notably, clinical trials in the settings of diabetic nephropathy, heart failure with systolic and diastolic dysfunction (HFpEF, HFrEF), non-diabetic kidney disease are underway. However, finerenone (Kerendia) does not have sufficient clinical evidence to support efficacy and safety, and has not been FDA-approved, for treatment of these conditions. Finerenone (Kerendia) is considered investigational when used for all other conditions, including but not limited to:
   A. Treatment of CKD in members less than 18 years of age
   B. Treatment of hypertension
   C. Treatment of cardiovascular disorder (e.g. myocardial infraction, heart failure)
   D. Edema associated with nephrotic syndrome
   E. Perioperative management of hyperaldosteronism

Appendix

Table 1. Examples of baseline therapies for Chronic Kidney Disease (CKD) in Type 2 Diabetes Mellitus (T2DM)

Angiotensin-Converting Enzyme Inhibitors (ACEi)	Angiotensin II Receptor Blockers (ARB)	Sodium Glucose Co-Transporter-2 Inhibitors (SGLT2i)

benazepril captopril enalapril fosinopril lisinopril moexipril perindopril quinapril ramipril trandolapril	azilsartan candesartan eprosartan irbesartan losartan olmesartan telmisartan valsartan	canagliflozin (Invokana) dapagliflozin (Farxiga) empagliflozin (Jardiance) ertugliflozin (Steglatro) sotagliflozin (Inpefa)
		Combinations of SGLT2i with metformin and/ or other antidiabetic agents:
		cangliflozin+metformin (Invokamet) dapagliflozin+metformin (Xigduo XR) dapagliflozin+saxagliptin (Qtern) empagliflozin+linagliptin (Glyxambi) empagliflozin+metformin (Synjardy) empagliflozin+linagliptin+metformin (Trijardy XR)

References

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2. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. *Kidney Int*. 2022;102(5S):S1-S127. doi:10.1016/j.kint.2022.06.008
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6. Lovre D, Shah S, Sihota A, Fonseca VA. Managing diabetes and cardiovascular risk in chronic kidney disease patients. *Endocrinol Metab Clin North Am*. 2018;47(1):237-257.
7. Pitt B, Filippatos G, Agarwal R, et al. Cardiovascular Events with Finerenone in Kidney Disease and Type 2 Diabetes. N Engl J Med. 2021;385(24):2252-2263. doi:10.1056/NEJMoa2110956

Related Policies

Currently there are no related policies.

Policy Implementation/Update:

Action and Summary of Changes	Date
Removed criteria that disallows concomitant finerenone (Kerendia) with SGLT2 inhibitors. Updated supporting evidence section to include the FIGARO-DKD trial and KDIGO 2022 guideline for management of CKD in diabetes. Added related policy section.	07/2023
Policy created	08/2021