Kerendia (finerenone)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Diabetes is a leading cause of chronic kidney disease (CKD). Treatment for diabetic kidney disease includes controlling blood pressure and blood sugar levels, reducing dietary protein intake, avoiding medications that may damage the kidneys, treating urinary tract infections and exercise and weight loss

Kerendia is a nonsteroidal, selective antagonist of the mineralocorticoid receptor (MR), which is activated by aldosterone and cortisol. Kerendia blocks MR mediated sodium reabsorption and MR overactivation in both epithelial (e.g., kidney) and nonepithelial (e.g., heart, and blood vessels) tissues. MR overactivation is thought to contribute to fibrosis and inflammation.

Definitions

"Chronic Kidney Disease" is the gradual loss of kidney function.

"Heart failure" refers to the condition when a person's heart muscle does not pump blood as well as it should. Contributing factors of heart failure include damage, weakening, stiffness, or insufficient filling of the ventricles.

"Left ventricular ejection fraction" or "LVEF" refers to the measurement of how well the heart is pumping and is used to help classify heart failure and guide treatment. In a normal healthy heart, the ejection fraction is above 50%, meaning that more than half of the blood that fills the ventricle is pumped out with each beat.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the applicant does not qualify.

"Type 2 Diabetes" is a metabolic disorder characterized by insufficient insulin production or insulin resistance in the body cells. It is more common than Type 1 and is often managed through lifestyle changes, non-insulin medications, and, if necessary, insulin injections.

"[s]" indicates state mandates may apply.

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers Kerendia (finerenone) medically necessary when ALL of the following criteria are met:

1. The member is 18 years of age or older; *AND*
2. The member meets ALL of the following:
    a. No evidence the member's serum potassium is > 5.0 mEq/L; *and*

b. No evidence the member's estimated glomerular filtration rate (eGFR) < 25 mL/min/1.73m^2; *AND*

3. Kerendia (finerenone) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication*; AND*
   The Plan's Quantity Limit for Kerendia (finerenone) is 30 tablets every 30 days.
4. The member meets the applicable Medical Necessity Criteria for Initial Clinical Review or Subsequent Clinical Review listed below.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Chronic Kidney Disease (CKD) associated with Type 2 Diabetes (T2DM)

The Plan considers Kerendia (finerenone) medically necessary when ALL of the following criteria are met:

5. The member meets the above General Medical Necessity Criteria; *AND*
6. The member has a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2DM); *AND*
7. The member meets ONE of the following[s]:
   a. The member is currently receiving an angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril, lisinopril) OR angiotensin receptor blocker (ARB) (e.g., candesartan, losartan, valsartan)*; or*
   b. The member is unable to use an angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril, lisinopril) OR angiotensin receptor blocker (ARB) (e.g., candesartan, losartan, valsartan)*; AND*
8. The member meets ONE of the following[s]:
   a. The member is currently receiving an evidence-based sodium-glucose transport protein 2 (SGLT2) inhibitor (e.g., canagliflozin, dapagliflozin, empagliflozin)*; or*
   b. The member is unable to use an evidence-based sodium-glucose transport protein 2 (SGLT2) inhibitor (e.g., canagliflozin, dapagliflozin, empagliflozin).

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Heart Failure With Left Ventricular Ejection Fraction (LVEF)

The Plan considers Kerendia (finerenone) medically necessary when ALL of the following criteria are met:

5. The member meets the above General Medical Necessity Criteria; *AND*
6. The member has a diagnosis of heart failure with left ventricular ejection fraction (LVEF) ≥ 40%; *AND*
7. The member is currently receiving the following therapies or is unable to use ALL of the following therapies[s]:

a. An evidence-based sodium-glucose cotransporter 2 [SGLT2] inhibitor (e.g., dapagliflozin, empagliflozin); *and*
b. IF the member has fluid retention with NYHA class II-IV, a loop diuretic agent (e.g., furosemide, torsemide, bumetanide)*; and*
c. IF the member is a woman [all ejections fractions (EFs)] OR a man with LVEF <55-60%, ONE of the following:
    i. an angiotensin-converting enzyme [ACE] inhibitor (e.g., captopril, enalapril, lisinopril)*; or*
    ii. angiotensin receptor blocker [ARB] (e.g., candesartan, losartan, valsartan)*; or*
    iii. angiotensin receptor–neprilysin inhibitor [ARNi] (e.g., sacubitril-valsartan); *AND*

8. The member is unable to use, or has tried and failed spironolactone or eplerenone[s]*; AND*
9. No evidence the member is using a nonsteroidal mineralocorticoid receptor antagonist (MRA) (e.g., Kerendia) with an MRA (e.g., spironolactone, eplerenone).

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent General Medical Necessity Criteria

Chronic Kidney Disease (CKD) associated with Type 2 Diabetes (T2DM) OR Heart Failure With Left Ventricular Ejection Fraction (LVEF)

The Plan considers Kerendia (finerenone) medically necessary when ALL of the following criteria are met:

1. The member meets the above applicable General Medical Necessity Criteria and/or Initial Indication-Specific Criteria; *AND*
2. The member requires continued therapy with Kerendia (finerenone); *AND*
3. There is no evidence of unacceptable toxicity or adverse reactions to Kerendia (finerenone).

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Experimental or Investigational or unproven[s]

Kerendia (finerenone) for any other indication or use is considered experimental, investigational, or unproven.

Applicable Billing Codes

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
J8499	Kerendia Prescription drug, oral, non chemotherapeutic, nos

Table 2	
ICD-10 diagnosis codes considered medically necessary with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease
I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I50.1	Left ventricular failure, unspecified
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart

Table 2	
ICD-10 diagnosis codes considered medically necessary with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
	failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified
I97.130	Postprocedural heart failure following cardiac surgery
I97.131	Postprocedural heart failure following other surgery

References

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2. Heidenreich PA 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. J Am Coll Cardiol. 2022;79(17):e263-421
3. Kerendia (finerenone) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; August 2025.

4. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney Int. 2024 Apr;105(4S):S117-S314.
5. Kittleson MM, Panjrath GS, Amancherla K, et al. 2023 ACC Expert Consensus Decision Pathway on Management of Heart Failure With Preserved Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2023 May 9;81(18):1835-1878. doi: 10.1016/j.jacc.2023.03.393. Epub 2023 Apr 19.
6. National Kidney Foundation. Diabetes and Chronic Kidney Disease. Available at: https://www.kidney.org/diabetes-and-chronic-kidney-disease. Accessed August 26, 2025.

Clinical Guideline Revision / History Information

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