Effective Date: 01/01/2022
Reviewed: 10/2021, 9/2022, 5/2023, 6/2024, 12/2024, 6/2025, 9/2025 Scope: Medicaid

Kerendia (finerenone)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA Approved Indications
   a. To 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 in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2DM).
   b. To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥ 40%.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR APPROVAL

An authorization of 12 months may be granted when all the following criteria are met:

A. Patient is 18 years or older; AND
B. The medication is prescribed by, or in consultation with, a cardiologist, endocrinologist, or nephrologist; AND
C. Patient has documented diagnosis of chronic kidney disease associated with type 2 diabetes OR a documented history of diagnosis of NYHA Class II–IV HF with documented LVEF ≥40%; AND
D. Documentation the patient has BOTH of the following:
   a. Estimated glomerular filtration rate (eGFR) of ≥ 25 mL/min/1.73m2
   b. Serum potassium level ≤ 5.0 mEq/L; AND
E. Documentation that patient is currently receiving a maximally tolerated and stabilized dose of an Angiotensin Converting Enzyme inhibitor (ACEi, e.g., lisinopril) or an Angiotensin Receptor Blocker (ARB, e.g., losartan), unless all agents in these classes are contraindicated; AND
F. Documentation that patient is currently receiving a maximally tolerated dose of a sodium-glucose co-transporter 2 (SGLT2) inhibitor with renal benefit (e.g., dapagliflozin [Farxiga]) or has experienced a documented intolerance or contraindication that would prohibit a trial of a SGLT2 inhibitor with renal benefit (e.g., dapagliflozin [Farxiga])

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members when the following criteria are met:

A. Patients meets all initial criteria; AND
B. Patient has exhibited improvement or stability of disease symptoms (e.g., stabilization of eGFR, lack of hospitalization due to renal or cardiovascular disease); OR 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.

IV. QUANTITY LIMIT

Kerendia 10mg, 20mg or 40 mg: one tablet per day

V. COVERAGE DURATION

- 12 months

VI. REFERENCES

1. Kerendia [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2022.
2. Chronic Kidney Disease and Risk Management: Standards of Medical Care in Diabetes – 2023. *Diabetes Care. Dec* 2022;46:S191-S202.
3. KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. *Kidney International.* 2022;102(Suppl 5S):S1-S127.