PRIOR AUTHORIZATION POLICY

POLICY: Non-Steroidal Mineralocorticoid Receptor Antagonist – Kerendia Prior Authorization Policy
- Kerendia® (finerenone tablets – Bayer)

REVIEW DATE: 07/30/2025; selected revision 08/13/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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 non-steroidal mineralocorticoid receptor antagonist (nsMRA), is indicated to reduce the risk of:[1]
- Sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular (CV) death, non-fatal myocardial infarction, and hospitalization for heart failure (HF) in adults with **chronic kidney disease (CKD) associated with type 2 diabetes**; and
- CV death, hospitalization for HF, and urgent HF visits in adults with **HF with left ventricular ejection fraction (LVEF) ≥ 40%**.

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

FIDELIO-DKD (n = 5,734) and FIGARO-DKD (n = 7,352), two published Phase III, placebo-controlled trials, assessed the efficacy of Kerendia in adults with diabetic kidney disease.[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. FINEARTS-HF, a published Phase III, placebo-controlled, event-driven trial evaluated Kerendia in adults with HF (New York Heart Association Class II to IV) with LVEF ≥ 40% (n = 6,001).[12] Patients continued their HF medications; approximately 14% of patients were taking a sodium glucose co-transporter-2 (SGLT-2) inhibitor at baseline.

Guidelines

Diabetes and CKD

The American Diabetes Association (ADA) Standards of Care (2025) recommend Kerendia for patients with type 2 diabetes and CKD with albuminuria who are receiving maximum tolerated doses of ACE inhibitors or ARBs, to improve CV outcomes and reduce the risk of CKD progression.[3] In individuals with type 2 diabetes and CKD, Kerendia is recommended to reduce the risk of hospitalization for HF.

Additionally, in the section regarding CKD , it is noted that in patients with type 2 diabetes and CKD, use of an SGLT-2 inhibitor with demonstrated benefit (if eGFR is ≥ 20 mL/min/1.73 m^2) or a glucagon-like peptide-1 agonist with demonstrated benefit is recommended to reduce CKD progression and CV events. Kerendia (if eGFR is ≥ 25 mL/min/1.73 m^2) is recommended to reduce CV events and CKD progression in patients with CKD and albuminuria.

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 addition of a mineralocorticoid receptor antagonist (MRA) to current standard of care, including ACE inhibitor or ARB, has been proven to reduce albuminuria in patients with diabetes and CKD. Kerendia reduces albuminuria and the risk of kidney and CV outcomes. The guideline also notes 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 an SGLT-2 inhibitor for the 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]

The KDIGO Clinical Practice Guideline for the Evaluation and Management of CKD (2024) reaffirms the statements in the KDIGO 2022 Clinical Practice Guideline for Diabetes Management in CKD.[4,13] In addition, the following points are made regarding Kerendia in patients with type 2 diabetes and CKD: Kerendia is most appropriate for those who are at high risk of CKD progression and CV events with persistent albuminuria despite other standard-of-care therapies; and Kerendia may be added to a RAAS inhibitor and an SGLT-2 inhibitor for the treatment of type 2 diabetes and CKD.

Heart Failure

The FINEARTS-HF trial data for Kerendia in HF have not yet been incorporated into current HF guidelines. However, guidelines recognize that Kerendia has demonstrated benefit in reducing HF outcomes in patients with type 2 diabetes and CKD.

Two SGLT-2 inhibitors (Farxiga® [dapagliflozin tablets, authorized generic] and Jardiance® [empagliflozin tablets]) have demonstrated a significant reduction in the composite of CV death and hospitalization for HF among patients with HF with LVEF > 40% (encompassing HF with preserved ejection fraction [HFpEF] and HF with mildly reduced ejection fraction [HFmrEF]). Both agents are recommended for all patients with HFpEF and HFmrEF.[6,9,11] Inpefa® (sotagliflozin tablets), an SGLT-2 and sodium glucose co-transporter-1 inhibitor, is indicated to reduce the risk of CV death, hospitalization for HF, and urgent HF visits in adults with HF[14]; however, the agent has not been incorporated into recommendations for HFpEF or HFmrEF.[6,9,11] Current guidelines recommend dapagliflozin or Jardiance for all patients with HFpEF or HFmrEF, unless contraindicated. The most current recommendations are summarized below.

The American College of Cardiology (ACC) Expert Consensus Decision Pathway for HFpEF (2023) recommends dapagliflozin or Jardiance for all patients with HFpEF to reduce CV death and hospitalization for HF as well as improve health status unless contraindicated.[9] In patients with LVEF < 55% to 60%, use of an MRA, angiotensin neprilysin inhibitor (ARNI), or ARB (when an ARNI is not feasible) may be considered (ACE inhibitors are not a reasonable alternative).

A 2023 Focused Update of the 2021 European Society of Cardiology (ESC) Guidelines for the Diagnosis and Treatment of Acute and Chronic HF (developed by the Task Force for the Diagnosis and Treatment of Acute and Chronic HF of the ESC with the special contribution of the HF Association of the ESC) recommends dapagliflozin or Jardiance to reduce the risk of hospitalization for HF or CV death in patients with HFmrEF or HFpEF.[11] In addition, the management of both HFmrEF or HFpEF includes diuretics for symptom management. Additional therapies for HFmrEF may include an ACE inhibitor/ARNI/ARB, MRA, and/or a beta-blocker. Patients with HFpEF may be additionally managed with agents aimed at treating the cause(s) of HFpEF as well as CV and non-CV comorbidities.

The ACC/American Heart Association/HF Society of America Guidelines for the Management of HF (2022) note that SGLT-2 inhibitors are beneficial to decrease hospitalization for HF and CV mortality in patients with HFpEF.[9] MRA, ARB, and/or

ARNI may be considered to decrease hospitalization in selected patients, especially those with LVEF < 50%.

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 Indications

1. **Chronic Kidney Disease in a Patient with Type 2 Diabetes.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of 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, the patient has a contraindication or has experienced significant intolerance 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; OR
   - **B)** Patient is Currently Receiving Kerendia. Approve if the patient meets ALL of 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, the patient has a contraindication or has experienced significant intolerance to ACE inhibitor and ARB therapy.

2. **Heart Failure.** Approve for 1 year if the patient meets ONE of the following (A or B):

A) Initial Therapy: Approve if the patient meets ALL of the following (i, ii, iii, and iv):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient has left ventricular ejection fraction ≥ 40%; AND
- **iii.** Patient meets ONE of the following (a or b):
  - **a)** Patient has tried or is currently receiving ONE of the following sodium glucose co-transporter-2 (SGLT-2) inhibitors [(1), (2), or (3)]:
    - **(1)** Farxiga (dapagliflozin tablets, authorized generic); OR
    - **(2)** Inpefa (sotagliflozin tablets); OR
    - **(3)** Jardiance (empagliflozin tablets); OR
  - **b)** According to the prescriber, the patient has a contraindication or has experienced significant intolerance to SGLT-2 inhibitor therapy; AND
- **iv.** At baseline (prior to the initiation of Kerendia), patient meets BOTH of the following (a and b):
  - **a)** Estimated glomerular filtration rate ≥ 25 mL/min/1.73 m^2; AND
  - **b)** Serum potassium level ≤ 5.0 mEq/L; OR

B) Patient is Currently Receiving Kerendia. Approve if the patient meets ALL of the following (i, ii, and iii):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient has left ventricular ejection fraction ≥ 40%; AND
- **iii.** Patient meets ONE of the following (a or b):
  - **a)** Patient has tried or is currently receiving ONE of the following sodium glucose co-transporter-2 (SGLT-2) inhibitors [(1), (2), or (3)]:
    - **(1)** Farxiga (dapagliflozin tablets, authorized generic); OR
    - **(2)** Inpefa (sotagliflozin tablets); OR
    - **(3)** Jardiance (empagliflozin tablets); OR
  - **b)** According to the prescriber, the patient has a contraindication or has experienced significant intolerance to SGLT-2 inhibitor therapy.

CONDITIONS NOT COVERED

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

is(are) considered not medically necessary 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. **Hypertension (Treatment).** Kerendia has not been evaluated for use in essential hypertension and is not mentioned in the 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, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, and calcium channel blockers.
   Note: For a patient with concomitant chronic kidney disease associated with type 2 diabetes and hypertension, refer to FDA-Approved Indication.

2. **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 with Kerendia was not permitted in clinical trials.[1,5,8,12]

REFERENCES

1. Kerendia® tablets [prescribing information]. Whippany, NJ: Bayer; July 2025.
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;383(23):2219-2229.
3. American Diabetes Association. Standards of care in diabetes – 2025. *Diabetes Care*. 2025;48(Suppl 1):S1-S352.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group: Rossing P, Muiza Caramori M, Chan JCN, et al. KDIGO 2022 clinical practice guideline for diabetes management in chronic kidney disease. *Kidney Int.* 2022;102(5S):S1-S127.
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*. 201614;37(27):2105-14.
6. Heidenreich PA, Bozkurt B, Aguilar D, 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. *Circulation*. 2022;145(18):e895-e1032.
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;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*. 2021385(24):2252-2263.
9. Kittleson MM, Panjrath GS, Amancherla K, et al. 2023 ACC expert consensus decision pathway on management of heart failure with preserved ejection fraction. *J Am Coll Cardiol*. 2023;81(18):1835-1878.
10. Boer IH, Khunti K, Sadusky T, et al. Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO). *Kidney Int.* 2022;102:974-989.
11. McDonagh TA, Metra M, Adamo M, et al; European Society of Cardiology (ESC) Scientific Document Group. 2023 focused update of the 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J*. 2023;44(37):3627-3639.
12. Solomon SD, McMurray JJV, Vaduganathan M, et al; for the FINEHEARTS-HF Committees and Investigators. Finerenone in heart failure with mildly reduced or preserved ejection fraction. *N Engl J Med.* 2024;391(16):1475-1485.
13. Kidney Diseases: Improving Global Outcomes (KDIGO). KDIGO 2024 clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney Int*. 2024;105(4S):S117-S314.
14. Inpefa® tablets [prescribing information]. The Woodlands, TX: Lexicon; January 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/02/20223
Annual Revision	No criteria changes.	08/07/2024

Early Annual Revision	The policy name was changed to Non-Steroidal Mineralocorticoid Receptor Antagonist – Kerendia PA Policy, previously Diabetes – Kerendia PA Policy. **Chronic Kidney Disease in a Patient with Type 2 Diabetes.** This condition was updated, previously "Diabetic Kidney Disease." Initial Therapy and Patient is Currently Receiving Kerendia. The following criterion was modified to add "or significant intolerance": According to the prescriber, the patient has a contraindication or significant intolerance to angiotensin converting enzyme or angiotensin receptor blocker therapy. **Heart Failure.** This condition and criteria for approval were added to the policy. **Condition Not Recommended for Approval – Heart Failure (Treatment).** This condition was removed from this section and added to the FDA-Approved Indication section.	07/30/2025
Selected Revision	**Heart Failure.** Initial Therapy and Patient is Currently Receiving Kerendia. The following criterion was updated to add "or is currently receiving": added: Patient has tried or is currently receiving ONE of the following sodium glucose co-transporter-2 (SGLT-2) inhibitors: Farxiga (dapagliflozin tablets, authorized generic), Inpefa (sotagliflozin tablets), or Jardiance (empagliflozin tablets).	08/13/2025