Drug Coverage Policy

Effective Date 11/15/2025
Coverage Policy Number.....IP0314
Policy Title.....Kerendia

Non-Steroidal Mineralocorticoid Receptor Antagonist – Kerendia

- Kerendia® (finerenone tablets – Bayer)

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.

Kerendia, a non-steroidal mineralocorticoid receptor antagonist (MRA), 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 in adults with **chronic kidney disease (CKD) associated with type 2 diabetes**; and
- CV death, hospitalization for heart failure, and urgent heart failure visits in adults with **heart failure** 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 (DKD) .[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 heart failure (New York Heart Association Class II to IV) with LVEF ≥ 40% (n = 6,001).[12]

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 treated with 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 heart failure.

Additionally, in the section regarding CKD , it is noted that in patients with type 2 diabetes and CKD, use of sodium glucose co-transporter-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 rationale for adding an MRA to current standard of care, including ACE inhibitor or ARB, is that this combination has been proven to be an effective strategy to reduce albuminuria in patients with diabetes and CKD. Kerendia reduces albuminuria and the risk of kidney and CV outcomes. The guidelines also note 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 a sodium glucose co-transporter-2 inhibitor for 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:creatinine 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 Guidelines 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 heart failure have not yet been incorporated into current heart failure guidelines. However, guidelines recognize that Kerendia has demonstrated benefit in reducing heart failure outcomes in patients with type 2 diabetes and CKD.

Two sodium glucose co-transporter-2 (SGLT-2) inhibitors (Farxiga® [dapagliflozin tablets, authorized generic] and Jardiance® [empagliflozin tablets]) have demonstrated a significant reduction in the composite of CV death and HHF among patients with HFpEF and HFmrEF. Both agents are recommended for all patients with HFpEF and HFmrEF.[6,9,11] Inpefa® (sotagliflozin tablets) is indicated to reduce the risk of CV death, HHF, and urgent heart failure visits in adults with heart failure[14]; however, the agent has not been incorporated into recommendations for HFpEF or HFmrEF.[6,9,11]

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 HHF as well as improve health status unless contraindicated.[9] In patients with LVEF < 55% to 60%, use of a mineralocorticoid receptor antagonist (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 ESC Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure, developed by the Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure of the European Society of Cardiology (ESC) with the special contribution of the Heart Failure Association (HFA) of the ESC recommends dapagliflozin or Jardiance to reduce the risk of HHF 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 (AHA)/Heart Failure Society of America Guideline for the Management of Heart Failure (2022) note that SGLT-2 inhibitors are beneficial to decrease HHF 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%.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Kerendia. All approvals are provided for the duration noted below.

Kerendia is considered medically necessary when the following are met:

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, iv, and v):

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
v. Preferred product criteria is met for the product as listed in the below table

B. Patient is Currently Receiving Kerendia. 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.
iv. Preferred product criteria is met for the product as listed in the below table

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. At baseline (prior to the initiation of Kerendia), patient meets ALL 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.
iv. Preferred product criteria is met for the product as listed in the below table

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. Preferred product criteria is met for the product as listed in the below table

Employer Plans:

Product	Criteria
Kerendia (Finerenone)	Heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in a patient ≥ 18 years of age: Approve if the patient meets ONE of the following (A or B): A. Patient has tried, or is currently taking, ONE of Farxiga or Jardiance; OR Note: If the patient has tried or is currently receiving a dapagliflozin-containing product, empagliflozin-containing

Product	Criteria
	product, or Inpefa (sotagliflozin) [requires prior authorization] this would satisfy the requirement. B. According to the prescriber, the patient has a contraindication or has experienced significant intolerance to SGLT-2 inhibitor therapy.

Individual and Family Plans:

Product	Criteria
Kerendia (Finerenone)	Patient meets **ONE** of the following: 1. Chronic kidney disease in a patient ≥ 18 years of age with type 2 diabetes. Approve if the patient meets ONE of the following (A or B): A. Patient has tried, or is currently taking, **ONE** of Farxiga or Jardiance; OR Note: A trial of, or if the patient is currently taking, another SGLT-2 inhibitor or SGLT-2 inhibitor-containing combination product also satisfies this requirement. B. Note: Examples of SGLT-2 inhibitors include Jardiance, Steglatro, Farxiga or dapagliflozin, Invokana. Examples of SGLT-2 combination products include Invokamet XR, Invokamet, Xigduo XR or dapagliflozin-metformin ER, Synjardy XR, Synjardy, Segluromet.According to the prescriber, the patient has a contraindication or has experienced significant intolerance to SGLT-2 inhibitor therapy. 2. Heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in a patient ≥ 18 years of age: Approve if the patient meets ONE of the following (A or B): A. Patient has tried, or is currently taking, ONE of Farxiga or Jardiance; OR Note: If the patient has tried or is currently receiving a dapagliflozin-containing product, empagliflozin-containing product, or Inpefa (sotagliflozin) [requires prior authorization] this would satisfy the requirement. B. According to the prescriber, the patient has a contraindication or has experienced significant intolerance to SGLT-2 inhibitor therapy.

Conditions Not Covered

Kerendia for any other use is considered not medically necessary, 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 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 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*. 2024;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*. 20219;385(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

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	**Diabetic Kidney Disease.** **Added** "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); b. According to the prescriber, patient has a contraindication to ACE inhibitor and ARB therapy" **Added** "At baseline (prior to the initiation of Kerendia), individual meets ALL of the following (a, b, and c): a. Estimated glomerular filtration rate ≥ 25 mL/min/1.73 m^2; b. Urine albumin-to-creatinine ratio ≥ 30 mg/g; c. Serum potassium level ≤ 5.0 mEq/L" **Added** preferred product requirement criteria for Individual and Family Plans	12/1/2024
Selected Revision	**Preferred Product Table – Individual and Family Plans:** **Updated from** "Documented failure, contraindication, or intolerance to ONE of the following (A or B):" **to** "Patient has tried, or is currently taking ONE of the following (A or B):" **Updated** note **from** "A trial of another SGLT-2 inhibitor or SGLT-2 inhibitor-containing combination product also satisfies this requirement" **to "**A trial of, or if the patient is currently taking another SGLT-2 inhibitor or SGLT-2 inhibitor-containing combination product also satisfies this requirement."	5/15/2025
Annual Revision	**Policy Title.** The policy name was changed to Non-Steroidal Mineralocorticoid Receptor Antagonist – Kerendia, previously Finerenone. **Chronic Kidney Disease in a Patient with Type 2 Diabetes.** This condition was updated, previously "Diabetic Kidney Disease". Initial Therapy. The following criterion was modified to add "or significant intolerance": According to the prescriber, the patient has a contraindication or significant intolerance to ACE or ARB therapy. Added criteria for Patient is Currently Receiving Kerendia. **Heart Failure.** This indication was added to the policy as an approvable condition. Other criteria apply. **Conditions Not Covered.** **Removed** Heart Failure (Treatment) **Preferred Product Table.** **Added** "According to the prescriber, the patient has a contraindication or has experienced significant intolerance to SGLT-2 inhibitor therapy." for Chronic kidney disease in a patient ≥ 18 years of	11/15/2025

	age with type 2 diabetes for Individual and Family Plans **Added** criteria for "Heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in a patient ≥ 18 years of age." for Employer Plans and Individual and Family Plan	

The policy effective date is in force until updated or retired.