Clinical Policy: Finerenone (Kerendia)

Reference Number: PA.CP.PMN.266
Effective Date: 10/2021
Last Review Date: 10/2025

Description
Finerenone (Kerendia®) is a non-steroidal mineralocorticoid receptor antagonist.

FDA Approved Indication(s)
Kerendia is indicated 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)
- Cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥ 40%

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Kerendia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Kidney Disease (must meet all)**:**

1. Diagnosis of both of the following (a and b):
   a. CKD;
   b. T2DM;
2. Age ≥ 18 years;
3. All of the following (a, b and c):
   a. eGFR ≥ 25 mL/min/1.73 m^2;
   b. Urine albumin creatinine ratio (UACR) ≥ 30 mg/g;
   c. Serum potassium ≤ 5.0 mEq/L;
4. One of the following (a or b):
   a. Member is currently receiving a preferred sodium-glucose co-transporter 2 (SGLT2) inhibitor (see *Appendix B* for examples);
   b. Failure of ≥ 3 consecutive months of a preferred SGLT2 inhibitor, unless contraindicated or clinically significant adverse effects are experienced;
5. Member is currently receiving an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) at maximally tolerated doses for ≥ 4 weeks, unless clinically significant adverse effects are experienced or all are contraindicated;
6. Dose does not exceed both of the following (a and b):
   a. 20 mg per day;
   b. 1 tablet per day.

Approval duration: 12 months

B. Heart Failure (must meet all)**:**
1. Diagnosis of heart failure of New York Heart Association (NYHA) Class II, III, or IV;
2. Prescribed by or in consultation with a cardiologist;
3. Age ≥ 18 year;
4. Member has a LVEF ≥ 40% (i.e., heart failure with mildly reduced or preserved ejection fraction);
5. Both of the following (a and b):
   a. eGFR ≥ 25 mL/min/1.73 m^2;
   b. Serum potassium ≤ 5.0 mEq/L;
6. Failure of one other mineralocorticoid receptor antagonist (i.e., spironolactone, eplerenone), unless contraindicated or clinically significant adverse effects are experienced;
7. One of the following (a or b):
   a. Member is currently receiving a preferred SGLT2 inhibitor* (see *Appendix B* for examples);
   b. Failure of ≥ 3 consecutive months of a preferred SGLT2 inhibitor*, unless contraindicated or clinically significant adverse effects are experienced;

   **Prior authorization may be required for SGLT2 inhibitors*
8. Dose does not exceed both of the following (a and b):
   a. 40 mg per day;
   b. 1 tablet per day.

Approval duration: 12 months

C. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 1 tablet per day;
   b. One of the following (i or ii)
      i. For CKD: 20 mg per day;
      ii. For heart failure: 40 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACE: angiotensin converting enzyme
ARB: angiotensin receptor blocker
CKD: chronic kidney disease
eGFR: estimated glomerular filtration rate
FDA: Food and Drug Administration
NYHA: New York Heart Association
SGLT2: sodium-glucose co-transporter 2
T2DM: type 2 diabetes mellitus
UACR: urine albumin creatinine ratio

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ACE inhibitors		
captopril (Capoten®)	Initially, 6.25 mg PO 3 times daily, then increase to 50 mg PO 3 times daily if tolerated.	450 mg/day
enalapril (Vasotec®, Epaned®)	Initially, 2.5 mg PO twice daily, then increase to 10 to 20 mg PO twice daily if tolerated.	40 mg/day
fosinopril (Monopril®)	Initially, 5 to 10 mg PO once daily, then increase to 40 mg/day if tolerated.	80 mg/day
lisinopril (Prinivil®, Zestril®, Qbrelis®)	Initially, 2.5 to 5 mg PO once daily, then increase to 20 to 40 mg/day if tolerated.	80 mg/day
perindopril (Aceon®)	Initially, 4 mg PO once daily for 2 weeks, then increase to 8 mg PO once daily if tolerated.	16 mg/day
quinapril (Accupril®)	Initially, 5 mg PO twice daily, then increase to 20 mg PO twice daily of tolerated.	80 mg/day
ramipril (Altace®)	Initially, 2.5 mg PO once daily. Gradually titrate to 5 mg/day PO, then increase if tolerated to the target dosage of 10 mg/day PO, given in 1 to 2 divided doses.	20 mg/day
trandolapril (Mavik®)	Initially, 1 mg PO once daily, then increase to 4 mg/day if tolerated.	8 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ARBs		
candesartan (Atacand®)	Initially, 4 to 8 mg PO once daily, then increase to 32 mg/day if tolerated.	32 mg/day
losartan (Cozaar®)	Initially, 25 to 50 mg PO once daily, then increase to 50 to 150 mg/day if tolerated.	100 mg/day
telmisartan (Micardis®)	80 mg PO once daily	80 mg/day
valsartan (Diovan®)	Initially, 20 to 40 mg PO twice daily, then increase dose to 160 mg PO twice daily if tolerated.	320 mg/day
SGLT2 Inhibitors		
Farxiga® (dapagliflozin)	10 mg PO QD	10 mg/day
Jardiance® (empagliflozin)	10-25 mg PO QD 25 mg only if eGFR ≥30mL/minute/1.73m^2	25 mg/day
Invokana® (canagliflozin)	100 mg-300 mg PO QD 300 mg only if eGFR ≥60mL/minute/1.73m^2	300 mg/day
Mineralocorticoid Receptor Antagonists		
spironolactone (Aldactone®)	25-50 mg PO QD	50 mg/day
eplerenone (Inspra®)	50 mg PO QD	50 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): concomitant use with strong CYP3A4 inhibitors, adrenal insufficiency; hypersensitivity to any component of this product
- Boxed warning(s): none

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CKD associated with T2D	10 mg or 20 mg PO QD based on eGFR and serum potassium thresholds. Increase to target dose of 20 mg PO QD after 4 weeks based on eGFR and serum potassium thresholds.	20 mg/day
Heart failure	10 mg or 20 mg PO QD based on eGFR and serum potassium thresholds. Increase to target dose of 40 mg PO QD after 4 weeks based on eGFR and serum potassium thresholds.	40 mg/day

VI. Product Availability

Tablets: 10 mg, 20 mg, 40 mg

VII. References

1. Kerendia Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2025. Available at: https://www.kerendia-us.com/. Accessed August 15, 2025.
   CKD
2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney Int. 2022;102(5S):S1-S127
3. Bakris GL, Agarwal R, Anker SD, et al. Effect of finerenone on chronic kidney disease outcomes in type 2 diabetes. N Engl J Med. 2020 Dec;383(23):2219-2229.
4. de 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(5):974-989.
5. American Diabetes Association Professional Practice Committee.. Standards of Care in Diabetes-2025. Diabetes Care. 2025;48(Suppl 1):S1-S352.
   Heart failure
6. Solomon SD, McMurray JJV, Vaduganathan M, et al. Finerenone in heart failure with mildly reduced or preserved ejection fraction. N Engl J Med. (2024) 391(16):1475–85.
7. 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. J Am Coll Cardiol. 2022 May, 79 (17) e263–e421.
8. 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;81(18):1835-1878.

Reviews, Revisions, and Approvals	Date
Policy created	10/2021
4Q 2022 annual review: added redirection to SGLT inhibitor per American Diabetes Association guideline; references reviewed and updated.	10/2022
4Q 2023 annual review: no significant changes; references reviewed and updated.	10/2023
4Q 2024 annual review: for initial criteria, added concurrent SGLT inhibitor use as an option to failure of an SGLT2 inhibitor per guidelines; references reviewed and updated.	10/2024
4Q 2025 annual review: RT4: added new heart failure indication and accompanying 40 mg dosage strength; for CKD, added criterion requiring serum potassium ≤ 5.0 mEq/L per PI; references reviewed and updated.	10/2025