Clinical Policy: Finerenone (Kerendia)

Reference Number: ERX.NPA.160
Effective Date: 12.01.21
Last Review Date: 11.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 (T2D).

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. T2D;
2. Age ≥ 18 years;
3. Both of the following (a and b):
   a. eGFR between 25 and 75 mL/min/1.73 m^2;
   b. Urine albumin creatinine ratio (UACR) ≥ 30 mg/g;
4. Failure of ≥ 3 consecutive months of a sodium-glucose co-transporter 2 (SGLT2) inhibitor* (*Farxiga® and Jardiance® are preferred*), unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for SGLT2 inhibitors*
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. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;

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. 20 mg per day;
   b. 1 tablet per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

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
SGLT2: sodium-glucose co-transporter 2
T2D: type 2 diabetes
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
ACEIs		
captopril (Capoten®)	Doses vary	450 mg/day
enalapril (Vasotec®, Epaned®)		40 mg/day
fosinopril (Monopril®)		80 mg/day
lisinopril (Prinivil®, Zestril®, Qbrelis®)		80 mg/day
perindopril (Aceon®)		16 mg/day
quinapril (Accupril®)		80 mg/day
ramipril (Altace®)		20 mg/day
trandolapril (Mavik®)		8 mg/day
ARBs		
candesartan (Atacand®)	Doses vary	32 mg/day
losartan (Cozaar®)		100 mg/day
telmisartan (Micardis®)		80 mg/day
valsartan (Diovan®)		320 mg/day
SGLT2 Inhibitors		
Farxiga® (dapagliflozin)	10 mg PO QD	10 mg/day
Jardiance® (empagliflozin)	10-25 mg PO QD	25 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
- 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

VI. Product Availability

Tablets: 10 mg, 20 mg

VII. References

1. Kerendia Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2021. Available at: https://www.kerendia-us.com/. Accessed August 9, 2022.
2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2012 clinical practice guideline for the evaluation and management of chronic kidney disease. Kidney inter., Suppl. 2013; 3: 1–150.
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. American Diabetes Association Professional Practice Committee, Draznin B, Aroda VR, et al. 11. Chronic Kidney Disease and Risk Management: Standards of Medical Care in Diabetes-2022. Diabetes Care. 2022;45(Suppl 1):S175-S184.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.17.21	11.21
4Q 2022 annual review: added redirection to SGLT2 inhibitor per American Diabetes Association guideline with Farxiga and Jardiance as preferred based on 500/550 formulary status; references reviewed and updated.	08.10.22	11.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.