Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2022**
Policy Number: PA.CP.PMN.266	**Effective Date: 10/2021** **Revision Date: 10/2022**
Policy Name: Finerenone (Kerendia)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

4Q 2022 annual review: added redirection to SGLT inhibitor per American Diabetes Association guideline; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Finerenone (Kerendia)

Reference Number: PA.CP.PMN.266
Effective Date: 10/2021
Last Review Date: 10/2022

Revision Log

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.

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. T2D;
2. Age ≥ 18 years;
3. Both of the following (a and b):
   a. eGFR ≥ 25 mL/min/1.73 m^2 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 preferred sodium-glucose co-transporter 2 (SGLT2) inhibitor (see *Appendix B* for examples), 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. 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. Chronic Kidney Disease (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.LTSS.PHAR.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. 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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.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
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 for all relevant lines of business 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
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

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 10, 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	10/2021	
4Q 2022 annual review: added redirection to SGLT inhibitor per American Diabetes Association guideline; references reviewed and updated.	10/2022	