Clinical Policy Title:	finerenone
Policy Number:	RxA.699
Drug(s) Applied:	Kerendia®
Original Policy Date:	08/18/2021
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Kerendia® is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained 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).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
finerenone (Kerendia®)	CKD associated with T2D	eGFR 60 mL/min/1.73 m^2 or greater: 20 mg orally once daily; eGFR 25 to less than 60 mL/min/1.73 m^2: 10 mg orally once daily	20 mg orally per day

Dosage Forms

- Tablets: 10 mg and 20 mg.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. CKD associated with Type 2 Diabetes (must meet all):

1. Diagnosis of chronic kidney disease associated with type 2 diabetes;
2. Prescribed by or in consultation with Nephrologists, endocrinologists;
3. Age ≥ 18 years;
4. Member has an eGFR of ≥25 mL/min/1.73 m2 or stage 2, 3, or 4 CKD;
5. Member has a serum potassium ≤4.8 mEq/L at initiation of therapy;
6. Member is on concurrent therapy with an ACE inhibitor or ARB;
7. Member has tried and failed both SGLT2 inhibitors : Farxiga®, Invokana® ;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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8. Dose does not exceed 20 mg orally per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. CKD associated with Type 2 Diabetes (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, dose does not exceed 20 mg orally per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

CKD: chronic kidney disease
T2D: type 2 diabetes
MRA: mineralocorticoid receptor antagonist
eGFR: Estimated glomerular filtration rate
ACE: Angiotensin-converting enzyme
ARB: Angiotensin receptor blockers

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
Farxiga®	10 mg orally once daily	10 mg orally once daily
Invokana®	100 mg orally once daily in the morning. May increase to 300 mg once daily in those tolerating 100 mg well, have an eGFR of 60 mL/min/1.73 m2 or greater and require additional glycemic control	300 mg orally once daily

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Concomitant use with strong CYP3A4 inhibitors;
  - Adrenal insufficiency.

- Boxed Warning(s):
  - None reported.

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APPENDIX D: General Information

- Hyperkalemia: Patients with decreased kidney function and higher baseline potassium levels are at increased risk. Monitor serum potassium levels and adjust dose as needed.

References

1. Kerendia® Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; July 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215341s000lbl.pdf . Accessed on August 18, 2021.
2. IPD Analytics RxInsights_New Drug Review_ Kerendia®_08 2021. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Kerendia. Accessed August 19, 2021.
3. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2021. Accessed with subscription at: http://www.clinicalkey.com. Updated June 03, 2021. Accessed August 19, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/19/2021	09/14/2021

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