

Initial Prior Authorization

Kerendia

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Kerendia	finerenone

Indications

FDA-approved Indications

Kerendia is 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).

Coverage Criteria

Chronic Kidney Disease (CKD) Associated with Type 2 Diabetes (T2D)

Authorization may be granted when the patient has a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) when ONE of the following criteria are met:

- The patient is currently receiving a maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) OR angiotensin receptor blocker (ARB).
- The patient has experienced an intolerance to an ACEi or ARB.

Reference number(s)
4871-A

- The patient has a contraindication that would prohibit a trial of an ACEi or ARB.

Duration of Approval (DOA)

- 4871-A: DOA: 12 months

References

1. Kerendia [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 24, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/24/2024).
4. Chronic Kidney Disease and Risk Management: Standards of Medical Care in Diabetes – 2023. Diabetes Care. Dec 2022;46:S191-S202.
5. KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney International. 2022;102(Suppl 5S):S1-S127.

Document History

Written by: UM Development (EC)

Date Written: 07/2021

Revised: (DFW) 10/2021 (removed SGLT2 step); (DRS) 10/2022 (no clinical changes); (VLS) 10/2023 (no clinical changes); (DMH) 10/2024 (no clinical changes)

Reviewed: Medical Affairs: (CHART) 08/05/2021, 10/28/2021, 01/20/2022, 10/27/2022, 10/26/2023, 10/24/2024

External Review: 08/2021, 02/2022, 03/2023, 02/2024, 02/2025

CRITERIA FOR APPROVAL

- | | | | |
|---|--|-----|----|
| 1 | Does the patient have a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D)? | Yes | No |
|---|--|-----|----|

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[If Yes, then go to 2. If No, then no further questions.]

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|---|--|-----|----|
| 2 | Is the patient currently receiving a maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB)?
[If Yes, then no further questions. If No, then go to 3.] | Yes | No |
| 3 | Has the patient experienced an intolerance to an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB)?
[If Yes, then no further questions. If No, then go to 4.] | Yes | No |
| 4 | Does the patient have a contraindication that would prohibit a trial of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB)?
[No further questions] | Yes | No |

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is for chronic kidney disease associated with type 2 diabetes. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
2.	Approve, 12 Months	Go to 3	
3.	Approve, 12 Months	Go to 4	

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4.	Approve, 12 Months	Deny	<p>Your plan only covers this drug if you have tried an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin receptor blocker (ARB), and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Step Therapy]</p>
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