

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

| Program Number | 2025 P 1376-5 |
|-------------------|---|
| Program | Prior Authorization/Notification |
| Medication | Kerendia® (finerenone) |
| P&T Approval Date | 12/2021, 12/2022, 1/2024, 10/2024, 9/2025 |
| Effective Date | 11/1/2025 |

1. Background:

Kerendia (finerenone) 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). Kerendia is also indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) \geq 40%.

2. Coverage Criteria^a:

A. Chronic kidney disease associated with type 2 diabetes

1. Initial Authorization

- a. Kerendia will be approved based on all of the following criteria:
 - 1) Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

-AND-

2) An eGFR of greater than or equal to 25 mL/min/1.73 m²

-AND-

3) Serum potassium is less than or equal to 5 mEq/L prior to initiating treatment

-AND-

- 4) Used to reduce the risk of <u>any</u> of the following:
 - a) Sustained eGFR decline
 - b) End-stage kidney disease
 - c) Cardiovascular death
 - d) Non-fatal myocardial infarction
 - e) Hospitalization for heart failure

Authorization will be issued for 12 months



2. Reauthorization

- a. Kerendia will be approved based on the following criterion:
 - 1) Documentation of positive clinical response to therapy

Authorization will be issued for 12 months

B. Heart failure

1. Initial Authorization

- a. Kerendia will be approved based on all of the following criteria:
 - 1) Diagnosis of heart failure

-AND-

2) Left ventricular ejection fraction (LVEF) greater than or equal to 40%

-AND-

3) An eGFR of greater than or equal to 25 mL/min/1.73 m²

-AND-

4) Serum potassium is less than or equal to 5 mEq/L prior to initiating treatment

-AND-

- 5) Used to reduce the risk of **any** of the following:
 - a) Cardiovascular death
 - b) Hospitalization for heart failure
 - c) Urgent heart failure visits

Authorization will be issued for 12 months

2. Reauthorization

- a. **Kerendia** will be approved based on the following criterion:
 - 1) Documentation of positive clinical response to therapy

Authorization will be issued for 12 months

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.



3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits or Prior Authorization/Medical Necessity may be in place.

4. References:

- 1. Kerendia [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc. July 2025..
- 2. Bakris, GL, Agarwal R, Anker SD, Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes. *NEJM*. 2020; 383:2219-29.
- 3. 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). Diabetes Care 2022.
- 4. KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney International. 2024 (105): S114-314

| Program | Prior Authorization/Notification – Kerendia |
|----------------|---|
| Change Control | |
| Date | Change |
| 12/2021 | New program |
| 12/2022 | Based on updated guidelines modified UACR to greater than or equal to 30 mg/g and eGFR to greater than or equal to 25 mL/min/1.73 m2 for diagnosis of chronic kidney disease and updated policy to change the reduction risk criteria from all to any. Increased the initial authorization to 6 months. Updated references. |
| 1/2024 | Annual review. Updated references. |
| 10/2024 | Updated diagnosis language. Updated references. |
| 9/2025 | Annual review. Added new heart failure indication, removed UACR requirement and updated references. |