

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2024 P 1376-4
Program	Prior Authorization/Notification
Medication	Kerendia® (finerenone)
P&T Approval Date	12/2021, 12/2022, 1/2024, 10/2024
Effective Date	2/1/2025

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).

2. Coverage Criteria^a:

A. Initial Authorization

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

-AND-

b. **<u>Both</u>** of the following:

1) Urinary albumin-to-creatinine ratio (UACR) of greater than or equal to 30 mg/g

-AND-

2) An eGFR of greater than or equal to $25 \text{ mL/min}/1.73 \text{ m}^2$

-AND-

- c. Used to reduce the risk of <u>**any**</u> of the following:
 - 1) Sustained eGFR decline
 - 2) End-stage kidney disease
 - 3) Cardiovascular death
 - 4) Non-fatal myocardial infarction
 - 5) Hospitalization for heart failure

Authorization will be issued for 12 months

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B. Reauthorization

- 1. Kerendia will be approved based on the following criterion:
 - a. 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. September 2022.
- 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.	