UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2250-7
Program	Prior Authorization/Medical Necessity
Medication	Kerendia® (finerenone)
P&T Approval Date	9/2021, 12/2021, 3/2022, 9/2022, 12/2022, 9/2023, 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 **all** of the following criteria:

   a. Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

   -AND-

   b. Both of the following:

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

      -AND-

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

      -AND-

   c. Used to reduce the risk of **any** 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

      -AND-

   d. Serum potassium level is less than or equal to 5 mEQ/L prior to initiating treatment

   -AND-

e. **One** of the following:

1) Patient is on a stabilized dose and receiving concomitant therapy with **one** of the following:

a) maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
b) maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

-OR-

2) Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARB

-AND-

f. One of the following:

1) Patient is on a stabilized dose and receiving concomitant therapy with a SGLT2 inhibitor (e.g. Jardiance)

-OR-

2) History of failure, contraindication, or intolerance to a SGLT2 inhibitor (e.g. Jardiance)

Authorization will be issued for 12 months

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 re-authorization 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 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. American Diabetes Association. Standard of Medical Care in Diabetes- 2022. Diabetes Care 2022;45 (Supplement 1)
4. 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.
5. KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney International. 2024 (105): S114-314.

Program	Prior Authorization/Medical Necessity – Kerendia
Change Control	
Date	Change
9/2021	New program
12/2021	Added a SGLT2 (Jardiance) as a step requirement. Updated references.
3/2022	Updated policy to change the reduction risk criteria from all to any and updated potassium threshold from less than 5 mEq/L to less than or equal to 5 mEq/L.
9/2022	Removed diabetic retinopathy and prescriber requirement. Updated references.
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 removed the eGFR bypass for Jardiance since guidelines allow SGLT-2 inhibitors to an eGRF to 20 mL/min/1.73 m2. Increased the initial authorization to 6 months. Updated references.
9/2023	Updated to allow concomitant therapy with a SGLT2.
10/2024	Updated diagnosis language. Updated references.