

### 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<sup>a</sup>:

## 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

<sup>a</sup> 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.   |  |