Pharmacy Policy Bulletin

Title:	Finerenone (Kerendia®)
Policy #:	Rx.01.255

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **finerenone (Kerendia®)** as provided under the member's prescription drug benefit.

Description:

Chronic kidney disease exacerbates the cardiovascular risk associated with type 2 diabetes.

Mineralocorticoid receptor overactivation is associated with kidney and cardiovascular diseases, through inflammation and fibrosis that lead to progressive kidney and cardiovascular dysfunction.

Finerenone is a nonsteroidal, selective antagonist of the mineralocorticoid receptor (MR), which is activated by aldosterone and cortisol and regulates gene transcription. Finerenone blocks MR mediated sodium reabsorption and MR overactivation in both epithelial (e.g., kidney) and nonepithelial (e.g., heart, and blood vessels) tissues. MR overactivation is thought to contribute to fibrosis and inflammation. Finerenone has a high potency and selectivity for the MR and has no relevant affinity for androgen, progesterone, estrogen, and glucocorticoid receptors.

Kerendia® (finerenone) is indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes.

Policy:

INITIAL CRITERIA Finerenone (Kerendia®) is approved when ALL of the following are met:

A. Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D); and
B. Member is 18 years of age or older; and
C. One of the following:
    1. Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with ONE of the following:
        a. Generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril); or
        b. Generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan); or
    2. Member has contraindication or intolerance to ACE inhibitors or ARBs

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Finerenone (Kerendia®) is re-approved with documentation of positive clinical response to therapy (e.g., reduced incidence of a sustained declined in eGFR, kidney failure, or renal death)

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Pitt B, Filippatos G, Agarwal R, et al. Cardiovascular events with finerenone in kidney disease and type 2 diabetes. N Engl J Med. 2021;385(24):2252-2263. doi: 10.1056/NEJMoa2110956. Accessed October 04, 2022.

Kerendia® (finerenone) [package insert]. Whippany, NJ: Bayer HealthCare Pharma, Inc.; September 2022. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215341s000lbl.pdf. Accessed October 04, 2022.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Kerendia®	finerenone

Cross References:

Rx.01.33 Off Label Use

Policy Version Number:	2.00
P&T Approval Date:	September 15, 2022
Policy Effective Date:	January 01, 2023
Next Required Review Date:	September 15, 2023

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.