Sample Letter of Appeal for KERENDIA® (finerenone)

Navigating the Appeals Process

It is possible that a prescription for Kerendia may be rejected or denied as not covered by the patient's health plan. In this case, a general process can be followed to appeal this denial by filing an appeal with the patient's health insurance plan.

Supporting Documentation

Providing as much supporting information as possible may help with the health plan's timely consideration for your request. In addition to the formal request presented in an appeal letter, the following documentation may be submitted to support the appeals process:

- A letter of medical necessity
    - If you need a sample letter of medical necessity, please contact your Bayer representative or download a template online at [Kerendiahcp.com]
- Photocopies of the patient's health plan and/or prescription cards
- Copies of the denial letter, benefits information, and the original claim/prescription request
- Kerendia Prescribing Information
- The patient's medical records, including any relevant lab and/or diagnostic results

Note: Because each plan has its own appeals process, the required information may vary, and additional supporting evidence or rationale may be required.

Considerations When Filing an Appeal for KERENDIA

- Photocopy all documents that are being submitted, as well as any formal correspondence with the health plan
- The patient's benefit information should be verified to ensure that the appeal request is valid
- Appeal guidelines vary from plan to plan and should be confirmed before submitting an appeal. Plan-specific guidelines may include a deadline filing an appeal, a submission fax number or mailing address that is specifically used for appeal or similar requests, how many times an appeal may be submitted, and whether the patient or the physician is required to submit the appeal
- Appeal departments for health plans generally have readily available contact information, with individuals who can answer any questions that you or your office may have as it relates to the appeal process
- Verification of submission should be obtained. Receipt of faxed submissions can be verified with a follow-up phone call shortly after submission, and mailed submissions can be sent with tracking information, with a scheduled verification phone call 2 to 3 business days after the package is delivered

How to Use the Sample Letter of Appeal Template

The editable letter template on page 4 includes pink brackets that indicate variable fields that should be appropriately replaced with the relevant patient, healthcare provider, and office information. When submitting the letter, all brackets that indicate these placeholder fields should be removed, as well as the first 3 pages of this document. Your office letterhead should be used.

This templated letter is a sample for informative purposes only, and any non-bracketed information can also be adjusted to better individualize and support the request for your patient.

INDICATION:

- KERENDIA is indicated to reduce the risk of sustained 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)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

- Concomitant use with strong CYP3A4 inhibitors
- Patients with adrenal insufficiency

WARNINGS AND PRECAUTIONS:

- ***Hyperkalemia:*** KERENDIA can cause hyperkalemia. The risk for developing hyperkalemia increases with decreasing kidney function and is greater in patients with higher baseline potassium levels or other risk factors for hyperkalemia. Measure serum potassium and eGFR in all patients before initiation of treatment with KERENDIA and dose accordingly. Do not initiate KERENDIA if serum potassium is >5.0 mEq/L

  Measure serum potassium periodically during treatment with KERENDIA and adjust dose accordingly. More frequent monitoring may be necessary for patients at risk for hyperkalemia, including those on concomitant medications that impair potassium excretion or increase serum potassium

MOST COMMON ADVERSE REACTIONS:

- From the pooled data of 2 placebo-controlled studies, the adverse reactions reported in ≥1% of patients on KERENDIA and more frequently than placebo were hyperkalemia (14% vs 6.9%), hypotension (4.6% vs 3.9%), and hyponatremia (1.3% vs 0.7%)

Please see additional Important Safety Information on the next page.
Please read the Prescribing Information for KERENDIA.

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS:

- ***Strong CYP3A4 Inhibitors:*** Concomitant use of KERENDIA with strong CYP3A4 inhibitors is contraindicated. Avoid concomitant intake of grapefruit or grapefruit juice
- ***Moderate and Weak CYP3A4 Inhibitors:*** Monitor serum potassium during drug initiation or dosage adjustment of either KERENDIA or the moderate or weak CYP3A4 inhibitor and adjust KERENDIA dosage as appropriate
- ***Strong and Moderate CYP3A4 Inducers:*** Avoid concomitant use of KERENDIA with strong or moderate CYP3A4 inducers

USE IN SPECIFIC POPULATIONS:

- ***Lactation:*** Avoid breastfeeding during treatment with KERENDIA and for 1 day after treatment
- ***Hepatic Impairment:*** Avoid use of KERENDIA in patients with severe hepatic impairment (Child Pugh C) and consider additional serum potassium monitoring with moderate hepatic impairment (Child Pugh B)

Please read the Prescribing Information for KERENDIA.

Kerendia® (finerenone) tablets 10 mg • 20 mg

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[Date]

[Contact name and Title – usually the health plan's medical or pharmacy director]
[Name of Health Insurance Plan]
[Health Plan Mailing Address]

Insured: [First and Last Name]
Patient (if different from insured): [First and Last Name]
Patient Date of Birth: [Insert MM/DD/YEAR]
Policy Number: [Insert Number]
Group Number: [Insert Number]

Reference Number: [Denial Reference Number / Appeal Number]

Dear [NAME OF MEDICAL OR PHARMACY DIRECTOR],

I am writing on behalf of my patient, [INSERT PATIENT NAME], to request an appeal by a Medical Advisor of the above-mentioned denial for coverage of KERENDIA. Based on the letter of denial, it is my understanding KERENDIA has been denied for the following reason(s):

[INSERT DENIAL REASON FROM THE DENIAL LETTER]

Based on my medical expertise, I ask that you reconsider this decision. KERENDIA 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).[1] It is my professional medical opinion that KERENDIA is appropriate and necessary to treat the diagnosis of [DIAGNOSIS AND ICD-10 CODE]. I believe that [INSERT PATIENT NAME] would benefit from KERENDIA for the following reason(s):

- [SUMMARY OF MEDICAL HISTORY AND RELEVANT POINTS]
- [PAST DRUG AND TREATMENT HISTORY, INCLUDING ADVERSE EVENTS]
- [PREVIOUS OR CURRENT TREATMENT WITH KERENDIA AND DURATION OF THERAPY]
- [MOST RECENT CLINICAL SYMPTOMS]

In summary, I believe that the presented and attached documentation reinforces my choice of KERENDIA for the treatment of [INSERT PATIENT NAME] and supports the request for treatment approval. Furthermore, this treatment approach is aligned with the 2022 ADA Standards of Care which include 2 Grade A recommendations for the use of KERENDIA for patients like mine who have CKD associated with T2D[2,3]:

- Recommendation 10.44: For patients with T2D and CKD treated with maximum tolerated doses of angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, addition of KERENDIA should be considered to improve cardiovascular outcomes and reduce the risk of CKD progression
- Recommendation 11.3c: In patients with CKD who are at an increased risk for cardiovascular events or CKD progression or are unable to use a sodium-glucose cotransporter 2 inhibitor, a nonsteroidal mineralocorticoid receptor antagonist KERENDIA is recommended to reduce CKD progression and CV events

Thank you in advance for your review and consideration for coverage. If you have any questions or require additional information regarding this patient, please contact me at [PHYSICIAN TELEPHONE NUMBER].

Sincerely,

[PRESCRIBER NAME AND SIGNATURE]

References: 1. KERENDIA [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2022. **2.** American Diabetes Association Professional Practice Committee; Addendum. 10. Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes—2022. Diabetes Care 2022;45(Suppl. 1): S144–S174. Diabetes Care 1 September 2022; 45 (9): 2178–2181.

https://doi.org/10.2337/dc22-ad08. Accessed December 4, 2023. **3**. American Diabetes Association; Standards of Medical Care in Diabetes—2022 Abridged for Primary Care Providers. Clin Diabetes 1 January 2022; 40 (1): 10–38. https://doi.org/10.2337/cd22-as01. Accessed December 4, 2023.

Please find attached:

[INCLUDE A LIST OF SUPPORTING DOCUMENTATION BEING INCLUDED WITH THE SUBMISSION SUCH AS THE ORIGINAL CLAIM FORM, COPY OF DENIAL OR EXPLANATION OF BENEFITS (IF APPLICABLE), KERENDIA PRESCRIBING INFORMATION, ANY CLINICAL STUDIES TO SUPPORT CHOICE OF MEDICATION, ETC.]