KERENDIA® (finerenone) Sample Letters of Appeal

Navigating the Appeals Process

If a prior authorization or medical exception request is denied, **an appeal may be required**. Health plans will notify you of the reason the initial request for coverage was denied. Oftentimes, **providing complete and accurate information** that was missing from the original submission will help correct the denial.

Resubmitting the request through an appeal is a **crucial step to ensuring that your patient has access to KERENDIA**. One way to request an appeal is by submitting a letter of appeal via fax or mail.

Supporting Documentation

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

- A Sample Letter of Medical Necessity for KERENDIA is available at KERENDIA Access Resources
- 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
    - The patient's authorization of information release **must be included**

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 for filing, a submission fax number or mailing address that is specifically used for an 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 relating 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 a Sample Letter of Appeal Template

The letter templates starting on page 4 include pink brackets to indicate variable fields that should be appropriately replaced with the relevant patient, healthcare provider, and office information.

When submitting the letter, your office letterhead should be used. All brackets and placeholder language should be removed as well as the first 3 pages of this document.

These templated letters are samples for informative purposes only. Any non-bracketed information can be adjusted to individualize and support your specific request.

INDICATIONS:

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) (10mg, 20mg tablets)
- cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (HF LVEF) ≥40% (10mg, 20mg, 40mg tablets)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

- Hypersensitivity to any component of this product
- 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 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.

- ***Worsening of Renal Function in Patients with Heart Failure:*** KERENDIA can cause worsening of renal function in patients with heart failure. Rarely, severe events associated with worsening renal function, including events requiring hospitalization, have been observed

  Measure eGFR in all patients before initiation of treatment or with dose titration of KERENDIA and dose accordingly. Initiation of KERENDIA in patients with heart failure and an eGFR <25 mL/min/1.73 m^2 is not recommended. Measure eGFR periodically during maintenance treatment with KERENDIA in patients with heart failure. Consider delaying up-titration or interrupting treatment with KERENDIA in patients who develop clinically significant worsening of renal function

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

IMPORTANT SAFETY INFORMATION (cont'd)

MOST COMMON ADVERSE REACTIONS:

- ***CKD associated with T2D:*** From the pooled data of FIDELIO-DKD and FIGARO-DKD, 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%), and hyponatremia (1.3% vs 0.7%).
- ***HF LVEF ≥40%:*** From FINEARTS-HF, the adverse reactions reported in ≥1% of patients on KERENDIA and more frequently than placebo were hyperkalemia (9.7% vs 4.2%), hypotension (7.6% vs 4.7%), and hyponatremia (1.9% vs 0.9%). Events related to worsening renal function were reported more frequently in the KERENDIA group (18%) compared with placebo (12%).

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.
- ***Sensitive CYP2C8 Substrates at KERENDIA 40mg:*** Monitor patients more frequently for adverse reactions caused by sensitive CYP2C8 substrates if KERENDIA 40mg is co-administered with such substrates, since minimal concentration changes may lead to serious adverse reactions.

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 full Prescribing Information for KERENDIA.

Kerendia® (finerenone)

Sample Letter of Appeal for KERENDIA® (finerenone) for HF With LVEF ≥40%

[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 cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥40%.[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 LAB VALUES (eg, LVEF, eGFR, and serum potassium)]
- [TREATMENT HISTORY]
- [PREVIOUS OR CURRENT TREATMENT WITH KERENDIA AND DURATION OF THERAPY]
- [PAST THERAPY RESPONSE, INCLUDING ADVERSE EVENTS]
- [REASON PATIENT CANNOT TAKE AN ALTERNATIVE TREATMENT ON FORMULARY]
- [MOST RECENT CLINICAL SYMPTOMS]
- [KERENDIA Prescribing Information]

In summary, the presented and attached documentation reinforces my choice of KERENDIA for the treatment of [DIAGNOSIS] for [INSERT PATIENT NAME] and supports the request for treatment approval. KERENDIA has been approved by the US Food and Drug Administration (FDA) based on results from the FINEARTS-HF clinical trial, which demonstrated clinical benefit in adult patients with heart failure with LVEF ≥40%.

FINEARTS-HF Clinical Trial Outcomes

The FINEARTS-HF trial was a multicenter, randomized, double-blind, placebo-controlled study evaluating the effect of KERENDIA in adult patients aged ≥40 years with heart failure with LVEF ≥40%. A total of 6001 patients were randomly assigned 1:1 to receive either KERENDIA (n=3003) 10, 20, or 40 mg daily or placebo (n=2998), in addition to background heart failure therapy. The median follow-up duration was 2.7 years.

- **Primary composite outcome:** The primary endpoint was the composite of cardiovascular death and total (first and recurrent) heart failure events comprised of hospitalization for heart failure and urgent heart failure visits
    - KERENDIA significantly reduced the risk of the primary composite endpoint by 16% compared with placebo (RR=0.84; 95% CI, 0.74-0.95; *P*=0.007)
- **Safety:** The adverse reactions reported in ≥1% of patients on KERENDIA and more frequently than placebo were hyperkalemia (9.7% vs 4.2%), hypotension (7.6% vs 4.7%), and hyponatremia (1.9% vs 0.9%). Adverse reactions related to worsening renal function

were reported more frequently in the KERENDIA group (18%) compared with placebo (12%) including renal impairment (7% vs 4%), eGFR decreased (5% vs 4%), acute kidney injury (4% vs 2%), and renal failure (3% vs 2%)

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]

Reference: KERENDIA (finerenone) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; July 2025.

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, FDA APPROVAL LETTER, ETC.]

Sample Letter of Appeal for KERENDIA® (finerenone) for CKD Associated With T2D

[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 LAB VALUES (eg, eGFR, UACR, and serum potassium)]
- [TREATMENT HISTORY]
- [PREVIOUS OR CURRENT TREATMENT WITH KERENDIA AND DURATION OF THERAPY]
- [PAST THERAPY RESPONSE, INCLUDING ADVERSE EVENTS]
- [REASON PATIENT CANNOT TAKE AN ALTERNATIVE TREATMENT ON FORMULARY]
- [MOST RECENT CLINICAL SYMPTOMS]
- [KERENDIA Prescribing Information]

In summary, I believe that the presented and attached documentation reinforces my choice of KERENDIA for the treatment of [DIAGNOSIS] for [INSERT PATIENT NAME] and supports the request for treatment approval. Furthermore, this treatment approach is aligned with the [2025] ADA Standards of Care, which include 3 Grade A recommendations for the use of KERENDIA for patients like mine who have CKD associated with T2D[2,3]:

- [Recommendation 10.44: For individuals with type 2 diabetes and CKD with albuminuria treated with maximum tolerated doses of ACE inhibitor or ARB, recommend treatment with a nonsteroidal MRA with demonstrated benefit to improve cardiovascular outcomes and reduce the risk of CKD progression]
- [Recommendation 10.46e: In individuals with type 2 diabetes and CKD, recommend treatment with a nonsteroidal MRA with demonstrated benefit to reduce the risk of hospitalization for heart failure]
- [Recommendation 11.5c: To reduce cardiovascular events and CKD progression in people with CKD and albuminuria, a nonsteroidal MRA that has been shown to be effective in clinical trials is recommended (if eGFR is ≥25 mL/min/1.73 m^2). Potassium levels should be monitored]

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.; July 2025. **2.** American Diabetes Association Professional Practice Committee. *Diabetes Care*. 2025;48(suppl 1):S207-S238. **3.** American Diabetes Association Professional Practice Committee. *Diabetes Care*. 2025;48(suppl 1):S239-S251.

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, CLINICAL GUIDELINES, ETC.]