Sample Letter of Medical Necessity

The purpose of this sample letter of medical necessity or medical exception is to serve as a template if a patient's health plan has prescribing requirements or limitations for KERENDIA® (finerenone), such as a prior authorization, step therapy, or does not include KERENDIA on their formulary. In addition to a letter of medical necessity, health plans may also require the following items as supporting evidence:

- The patient's medical records, including any relevant lab and/or diagnostic results
- Clinical studies and relevant guidelines that support the choice of medication
- The Prescribing Information (PI) for the medication

Because each plan has its own medical exception process, the required information may vary, and additional supporting evidence may be required. Providing as much supporting information as possible may help with the health plan's timely consideration of your request.

The editable letter on the third page includes pink brackets that indicate variable fields that should be replaced with the relevant patient, physician, and office information. When submitting the letter, all brackets and the first 2 pages of this template should be removed and your office letterhead should be used.

This sample letter is offered as a model and is intended to be tailored according to the individual prescriber's and patient's needs.

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

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

IMPORTANT SAFETY INFORMATION (cont'd)

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:

- Adverse reactions reported in ≥1% of patients on KERENDIA and more frequently than placebo: hyperkalemia (18.3% vs. 9%), hypotension (4.8% vs. 3.4%), and hyponatremia (1.4% vs. 0.7%)

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

Sample Letter of Medical Necessity for KERENDIA® (finerenone)

[DATE]
[HEALTH PLAN NAME]
[HEALTH PLAN CONTACT NAME]
[HEALTH PLAN MAILING ADDRESS]

Patient: [PATIENT FULL NAME]
Subscriber ID: [#XXXXXXXXXX]
[Subscriber Group ID: #XXXXXXXXXXXXX]

Re: Request for KERENDIA® (finerenone)

Dear [NAME OF CONTACT AT PAYER],

I am writing on behalf of my patient, [NAME OF PATIENT], to request that [PAYER COMPANY NAME] approve coverage for KERENDIA. [INDICATION].

This letter documents the medical necessity for use of KERENDIA for my patient and provides information about [NAME OF PATIENT]'s medical history and treatment, relevant test results, American Diabetes Association (ADA) Guideline recommendation for use, and a copy of the KERENDIA Prescribing Information.

[NAME OF PATIENT] is [a/an] [AGE]-year-old [male/female] with a diagnosis of [PATIENT DIAGNOSIS] as of [DATE OF DIAGNOSIS]. [NAME OF PATIENT] has been in my care for [PATIENT DIAGNOSIS] since [DATE]. [Provide a brief discussion of patient's relevant medical history, condition/symptoms, diagnostic test results, and therapy to date, including other treatments attempted and results. If this patient has previously taken or is currently taking KERENDIA, include duration of therapy].

Further, the 2022 ADA Standards of Care include a Grade A recommendation for the use of KERENDIA to reduce chronic kidney disease (CKD) progression and cardiovascular events for patients like mine, who have CKD associated with type 2 diabetes and are at increased risk for cardiovascular events or CKD progression or are unable to use a sodium-glucose cotransporter 2 inhibitor.

Based on the above information, KERENDIA is indicated and medically necessary for [NAME OF PATIENT]'s treatment.

If you have any questions, please contact me at [PHYSICIAN TELEPHONE NUMBER].

Thank you in advance for your immediate attention to this request.

Sincerely,

[PRESCRIBER NAME AND SIGNATURE]

Reference: American Diabetes Association. Standards of medical care in diabetes–2022. *Diabetes Care*. 2022;45(suppl 1):S1-S264.

Attachments: [ORIGINAL CLAIM FORM, COPY OF DENIAL OR EXPLANATION OF BENEFITS (IF APPLICABLE), COPY OF PATIENT'S INSURANCE CARD, KERENDIA PRESCRIBING INFORMATION, FDA APPROVAL LETTER, FINERENONE PRIMARY PUBLICATION, ETC.]