Sample Letter of Medical Exception

The Sample Medical Exception Letter on the third page serves as a helpful template when a patient's health plan does not include KERENDIA® (finerenone) on the formulary/prescription drug list.

In addition to the formal request presented in a Medical Exception Letter, 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 for the medication
- A Letter of Medical Necessity
  - *Sample Letters of Medical Necessity for KERENDIA are also available. If you do not have any copies, please reach out to your Bayer representative, or download a template at https://www.KERENDIAhcp.com/access-and-savings#access-resources*
- The patient's authorization of information release must be included

Because each plan has an individual pathway for the medical exception process, the required information may vary, and the list above may be incomplete per each plan's specific criteria. 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 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 2 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

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

eGFR, estimated glomerular filtration rate.

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:

- 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%)

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 Exception 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: #XXXXXXXXXXXX]

Re: Medical Exception Request for KERENDIA® (finerenone)

To Whom It May Concern,
I am writing to formally submit a request for a medical exception for [PATIENT FULL NAME] for KERENDIA, which 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 for this patient, and should be covered and reimbursed for treatment.

[PATIENT FIRST NAME] has been overseen at my practice for CKD associated with T2D since [DIAGNOSIS DATE/DATE OF FIRST APPOINTMENT]. As part of this submission and request, please find attached [PATIENT FIRST NAME's] relevant medical history, my validation for this choice of treatment, [American Diabetes Association (ADA) recommendations for treatment with KERENDIA], and the Prescribing Information for KERENDIA.

Please consider the following as part of your review:

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

In summation, I believe that the presented and attached information reinforces my choice of KERENDIA for the treatment of [PATIENT FULL NAME], and supports the request for treatment approval. Further, this treatment approach is aligned with the 2022 ADA Standards of Care that 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

Please call my office at [OFFICE PHONE NUMBER] if further information is needed or if I can clarify my position so that [PATIENT FIRST NAME] can [begin/continue] treatment.

Sincerely,

[PRESCRIBER NAME AND SIGNATURE]

References: 1. KERENDIA [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2022. **2.** American Diabetes Association. Addendum. Accessed June 13, 2022. https://diabetesjournals.org/care/article/doi/10.2337/dc22-ad08/147053/Addendum-10-Cardiovascular-Disease-and-Risk **3.** American Diabetes Association. Standards of medical care in diabetes–2022. *Diabetes Care*. 2022;45(suppl 1):S1-S264.

Please find attached: [LIST OF SUPPORTING ITEMS THAT ARE INCLUDED AS PART OF THIS SUBMISSION]