Sample Tiering Exception Request Letter for KERENDIA® (finerenone)

Understanding the Tiering Exception Process

A tiering exception request letter can help make KERENDIA more affordable for patients when KERENDIA is on a health plan's formulary but is placed in a non-preferred tier that has a higher co-pay or co-insurance. This may be especially helpful for patients who may not be eligible to participate in savings programs and may need assistance covering their drug costs.

A tiering exception request letter can help a patient gain access by outlining the reasons why a treatment is necessary to meet the medical needs of the patient.

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 the tiering exception letter, the following documentation may be submitted to support the tiering exception 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
- The patient's medical records, including any relevant lab and/or diagnostic results and previous drug history
- Diagnosis and ICD-10 Code and clinical rationale for treatment with KERENDIA
- A statement of financial hardship, written by your patient

Note: Because each plan has its own tiering exception process, the required information may vary, and additional supporting evidence or rationale may be required. Health insurance plans may provide specific tier exception request forms that must be used when making the request. These forms may be downloaded from each plan's website.

Considerations When Requesting a Tiering Exception for KERENDIA

- Photocopy all documents that are being submitted, as well as any formal correspondence with the health plan
- Deadlines should be verified with the plan once a tiering exception request has been authorized as the duration for authorizations can vary by plan
- 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 tiering exception 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 Tiering Exception Request Letter 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

Please see additional Important Safety Information on the 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:

- 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 Tiering Exception Request Letter for KERENDIA® (finerenone)

[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]

Re: Tiering Exception Request for KERENDIA® (finerenone)

Dosage: [INSERT DOSAGE AND FREQUENCY]

Dear [NAME OF MEDICAL OR PHARMACY DIRECTOR],

I am writing to formally submit a request for a tiering exception for my patient, [INSERT PATIENT NAME] for their KERENDIA prescription.

I am requesting a tiering exception because the cost associated with the assigned tier for KERENDIA would present a financial hardship for [INSERT PATIENT NAME] and prevent [HIS/HER] from being able to access a medication that will help manage [HIS/HER] diagnosis of [DIAGNOSIS AND ICD-10 CODE].

I have enclosed a copy of the patient's medical records along with a Letter of Medical Necessity. The letter details the reasons why KERENDIA is medically necessary for [INSERT PATIENT NAME]'s care over the preferred drugs listed in the plan's formulary. In the past, [INSERT PATIENT NAME] has attempted other treatments for [DIAGNOSIS], but they failed due to either inadequate efficacy or intolerance to those medications.

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

Sincerely,
[PRESCRIBER NAME AND SIGNATURE]

Please find attached:
[INCLUDE A LIST OF SUPPORTING DOCUMENTATION BEING INCLUDED AS PART OF THIS SUBMISSION SUCH AS A LETTER OF MEDICAL NECESSITY, PATIENT'S MEDICAL RECORDS, PATIENT STATEMENT OF FINANCIAL HARDSHIP, KERENDIA PRESCRIBING INFORMATION, ETC.]