Kerendia® (finerenone) tablets
10 mg • 20 mg • 40 mg

Prior Authorization (PA) and Appeal Checklist for KERENDIA in patients with Chronic Kidney Disease associated with Type 1 Diabetes

KERENDIA is now approved for adult patients with chronic kidney disease (CKD) associated with type 1 diabetes (T1D). This indication expands upon its established indications for CKD associated with type 2 diabetes (T2D) and heart failure with left ventricular ejection fraction ≥40%.

It may take time for health plans that require a PA for KERENDIA to update their PA criteria and PA forms to reflect this new indication. PA requests should be submitted but may be denied during this interim period. If a PA request is denied, the health plan will inform you of the reason. **Submitting an appeal following a PA denial is a crucial next step to ensure your patients with CKD associated with T1D can access KERENDIA.**

PA Request

The list below includes common supporting evidence to include when submitting a PA request:

Diagnosis and Relevant Diagnostic Results:

- Diagnosis: CKD associated with T1D
- Diagnosis code: If an ICD-10-CM diagnosis code is required, you may use **E10.22**
- Urine albumin-creatinine ratio (**UACR**) value
- Estimated glomerular filtration rate (eGFR): **≥25 to <90 mL/min/1.73m²**
- Serum potassium levels (K+): **≤4.8 mEq/L**

Medication Information:

- Specify whether the patient has previously taken KERENDIA (including samples)
  - Include accurate dispensing information for KERENDIA, including dose (10 mg or 20 mg)

Additional Supporting Documentation:

- Patient chart notes
- FDA Approval Letter

Note: Other fields relevant to specific tests or medications may be left blank if not required.

FDA, US Food and Drug Administration; CKD, Chronic Kidney Disease; T1D, Type 1 Diabetes; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Appeal of PA Denial

The list below includes common supporting evidence to include when submitting an appeal:

Diagnosis and Relevant Diagnostic/Laboratory Results:

- Diagnosis: CKD associated with T1D
- Diagnosis code: If an ICD-10-CM diagnosis code is required, you may use **E10.22**
- Urine albumin-creatinine ratio (**UACR**) value
- Estimated glomerular filtration rate (eGFR) : **≥25 to <90 mL/min/1.73m²**
- Serum potassium levels (K+) : **≤4.8 mEq/L**

Medication Information:

- Specify whether the patient has previously taken KERENDIA (including samples)
  - Include accurate dispensing information for KERENDIA, including dose (10 mg or 20 mg)

Additional Supporting Documentation:

- Patient chart notes
- FDA Approval Letter
- Letter of Appeal and Letter of Medical Necessity
  - Note: The patient's authorization of information release must be included
- Copies of the denial letter, benefits information, and the original claim/prescription request

See next page for additional information for Appeal of PA Denial.

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) (10 mg, 20 mg tablets)
- reduce urinary albumin-to-creatinine ratio (UACR), which is expected to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline and end-stage kidney disease in adults with CKD associated with Type 1 diabetes (T1D) (10 mg, 20 mg tablets)
- 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 (HF LVEF) ≥40% (10 mg, 20 mg, 40 mg tablets)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

- Hypersensitivity to any component of this product
- Concomitant use with strong CYP3A4 inhibitors
- Patients with adrenal insufficiency

Please read additional Important Safety Information on the back page and click here for full Prescribing Information for KERENDIA.

Appeal of PA Denial (continued)

Medication(s) for CKD and/or T1D:

If a PA request is denied and an appeal is required, the health plan may request documentation of current and prior CKD and/or T1D treatments, including therapies the patient has previously tried, experienced inadequate response to, or could not tolerate, such as:

- ACE inhibitors (eg. Zestril® [lisinopril], Vasotec® [enalapril])
- ARBs (eg, Cozaar® [losartan])
- Insulin

Click the links below to download

Sample Letter of Appeal

FDA Approval Letter

covermymeds®

Bayer works with CoverMyMeds to provide PA and appeals support for your practice to help get your patients access to KERENDIA.

Submit a PA request online at **www.covermymeds.com**.

LIVE CHAT

Live chat support and demos are available through the CoverMyMeds portal.

1-866-452-5017

(Monday to Friday from 8 AM to 11 PM and Saturday from 8 AM to 6 PM ET)

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 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.

MOST COMMON ADVERSE REACTIONS:

- 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%). Events related to worsening renal function were reported more frequently in the KERENDIA group (18%) compared with placebo (12%) in patients with HF LVEF ≥40%.

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 40 mg:*** Monitor patients more frequently for adverse reactions caused by sensitive CYP2C8 substrates if KERENDIA 40 mg is coadministered 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 click here for full Prescribing Information for KERENDIA.

ACEi, Angiotensin-converting enzyme inhibitor; ARB, Angiotensin II receptor blocker; CKD, Chronic Kidney Disease; T1D, Type 1 Diabetes; FDA, US Food and Drug Administration; PA, prior authorization.

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