

Prior Authorization Checklist

Consider these common prior authorization (PA) criteria when submitting PA requests on behalf of your KERENDIA patients:



Medication information:

- Documentation of current and previous prescription medications
 - Indicate current and previously prescribed ACEi/ARB
 (eg, Zestril® [lisinopril], Cozaar® [losartan]), SGLT2i (eg,
 Jardiance® [empagliflozin], Farxiga®[dapagliflozin]), or
 MRA medications (eg, Aldactone® [spironolactone]) that
 the patient has tried, as well as those that the patient
 cannot tolerate*

To learn more about financial

assistance options offered by Bayer, your patients can call

1-888-537-3634

www.kerendia.com/ savingsandsupport

or visit

- Specify if the patient has taken KERENDIA before (including free samples)
- Include accurate dispensing information for KERENDIA, including all doses (10 mg and 20 mg)



Additional supporting documentation:

- Patient chart notes
- KERENDIA <u>Prescribing Information</u> (to describe the efficacy, safety, and appropriateness of KERENDIA)



ICD-10-CM diagnosis codes:

 E11.22 (type 2 diabetes mellitus with diabetic CKD)



Relevant laboratory values (if available):

- Estimated glomerular filtration rate (eGFR)
- Urine albumin/creatinine ratio (UACR)
 - Include any documentation of proteinuria or albuminuria
- Serum potassium (K+)

Note: Diagnostic criteria for CKD may include eGFR \geq 25 mL/min/1.73 m² or albuminuria (UACR) \geq 30 mg/g. The generally accepted normal range for K+ is 3.5-5 mEq/L.



Ensure that all questions on the PA form are answered to help avoid a PA denial or delays in processing

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CKD, chronic kidney disease; ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*; MRA, mineralocorticoid receptor antagonist; SGLT2i, sodium-glucose cotransporter 2 inhibitor.

*Product names are listed as examples of each therapeutic class and do not imply a comparison of efficacy or safety. The products listed above may not represent all the products for the therapeutic class.

Submit a PA request online at www.covermymeds.com



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



1-866-452-5017 (M-F 8 AM-11 PM and Saturday 8 AM-6 PM EST)

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 page 2 and full <u>Prescribing Information</u>.

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 see full **Prescribing Information**.



