Kerendia® (finerenone)

Prior Authorization (PA) and Appeal Checklist for KERENDIA in patients with heart failure with left ventricular ejection fraction (HF LVEF) ≥40%

KERENDIA is now approved for adult patients with HF LVEF ≥40%, in addition to its established indication for chronic kidney disease associated with type 2 diabetes

It may take a few months after this approval for plans that require a PA for KERENDIA to update their PA criteria and 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 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: HFpEF or HFmrEF
- Diagnosis code: If an ICD-10-CM diagnosis code is required, you may use I50 (heart failure), with or without additional characters that depict a more specific heart failure diagnosis
- Estimated glomerular filtration rate (eGFR)
- Serum potassium levels (K+)

Medication information:

- Specify whether the patient has previously taken KERENDIA (including samples)
  - Include accurate dispensing information for KERENDIA, including dose (10 mg, 20 mg, or 40 mg)

Additional supporting documentation:

- Patient chart notes

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

Appeal of PA Denial

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

Diagnosis and relevant diagnostic and/or laboratory results:

- Diagnosis: HFpEF or HFmrEF
- Diagnosis code: If an ICD-10-CM diagnosis code is required, you may use I50 (heart failure), with or without additional characters that depict a more specific heart failure diagnosis
- LVEF value
  - Health plans may require documentation or attestation that the patient's LVEF is ≥40%
- Estimated glomerular filtration rate (eGFR)
- Serum potassium levels (K+)

Medication information:

- Specify whether the patient has previously taken KERENDIA (including samples)
  - Include accurate dispensing information for KERENDIA, including dose (10 mg, 20 mg, or 40 mg)

Additional supporting documentation:

- Patient chart notes
- Letter of Appeal and Letter of Medical Necessity (including statement indicating the reason a patient cannot take an alternative treatment on formulary)
  - Note: The patient's authorization of information release must be included
- FDA Approval Letter
- Copies of the denial letter, benefits information, and the original claim/prescription request

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

FDA, US Food and Drug Administration; HF, heart failure; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; LVEF, left ventricular ejection fraction.

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) (10mg, 20mg tablets)
- 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% (10mg, 20mg, 40mg 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 next page and click here for full Prescribing Information for KERENDIA.

Appeal of PA Denial (continued)

Heart failure medication:

If a health plan denies a PA and requires an appeal, they may request documentation of current and previously prescribed heart failure medications, or those for which the patient has tried, as well as those the patient cannot tolerate, such as:

- Diuretics (eg, Lasix® [furosemide], Bumex® [bumetanide], Demadex® [torsemide])
- ARBs (eg, Cozaar® [losartan])
- ARNis (eg, Entresto® [sacubitril/valsartan])
- SGLT2 inhibitors (eg, Jardiance® [empagliflozin], Farxiga® [dapagliflozin])
- MRAs (eg, Aldactone® [spironolactone], Inspra® [eplerenone])

Click the links below to download

Sample letters

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:

- ***CKD associated with T2D*:** From the pooled data of FIDELIO-DKD and FIGARO-DKD, 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%).
- ***HF LVEF ≥40%:*** From FINEARTS-HF, the adverse reactions reported in ≥1% of patients on KERENDIA and more frequently than placebo were hyperkalemia (9.7% vs 4.2%), hypotension (7.6% vs 4.7%), and hyponatremia (1.9% vs 0.9%). Events related to worsening renal function were reported more frequently in the KERENDIA group (18%) compared with placebo (12%).

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 *40mg:*** Monitor patients more frequently for adverse reactions caused by sensitive CYP2C8 substrates if KERENDIA 40mg is co-administered 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.

ARB, angiotensin receptor blocker; ARNi, angiotensin receptor-neprilysin inhibitor; FDA, US Food and Drug Administration; MRA, mineralocorticoid receptor antagonist; PA, prior authorization; SGLT2, sodium-glucose cotransporter-2.

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