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(finerenone) tablets
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Prior Authorization, Medical Exceptions, and Appeals Guide for KERENDIA® (finerenone)

Many health plans require a prior authorization (PA) for products like KERENDIA® (finerenone). This is a common practice to establish appropriate utilization for newly approved medications, and **it may mean that your office will need to obtain authorization from the health plan before KERENDIA coverage is approved**.

Please see Important Safety Information on pages 2 and 7 and full Prescribing Information.

BAYER

Securing Patient Access to KERENDIA® (finerenone)

The following information will **help you navigate the PA, medical exceptions, and appeals processes** and avoid delays in patient access to KERENDIA.

Submitting PA Requests

Please keep in mind that:

Each health plan **may have its own unique PA criteria** and many plans will require completion of specific PA request forms, available on their website

If you already know that a certain health plan requires a PA for KERENDIA, **you may proactively submit the necessary paperwork**, rather than waiting for the patient's claim to be denied

You can submit an electronic PA through CoverMyMeds®* (see pages 4 and 5 for more information) for faster processing or by faxing a paper form to the health plan

Submitting **complete and accurate PA forms** along with supporting documentation can help to avoid delays in processing or avoid a PA denial

If the initial PA request is denied, **an appeal or medical exception may be required** (see page 6 for more information about how to navigate medical exceptions). Health plans will notify you of the reason the request was denied

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

*CoverMyMeds is an independent party.

Please see additional Important Safety Information on page 7 and full Prescribing Information.

According to data from CoverMyMeds

The Top 3 PA Denial Reasons Are:

1. **Failure to document an accurate diagnosis code** for chronic kidney disease (CKD) associated with type 2 diabetes (T2D) **(E11.22 - Type 2 diabetes mellitus with diabetic chronic kidney disease)**
2. **Neglecting to report** a failure, contraindication, or intolerance to formulary alternatives
3. Patient **is not** currently receiving **a maximum tolerated dose** of ACEi or ARB therapy or does not have a documented contraindication to an ACEi or ARB

Tips to Ensure Your PA Requests Are Approved

Remember to use clear handwriting, **include all necessary signatures,** and avoid providing incomplete information

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker.

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Preparing to Submit a Prior Authorization*

Consider the following PA criteria for KERENDIA® (finerenone) when preparing to submit a PA on behalf of your patient.

Patient Information
Include **a complete record** of the patient's personal and beneficiary information

Prescriber Information
Include **all relevant prescriber information** in this section

Note: It is **not required** to include a DEA number on prescriptions for KERENDIA

Relevant Laboratory Values (if available)
- Estimated glomerular filtration rate **(eGFR)**
- Urinary albumin-to-creatinine ratio **(UACR)**
  - Other documentation of **proteinuria** or **albuminuria**
- Serum potassium level (K^+)

Note: Diagnostic criteria for CKD may include **eGFR <60 mL/min/1.73 m^2** or **albuminuria (UACR) ≥30 mg/g for >3 months**. The generally accepted normal range for potassium is **3.5-5 mEq/L**

KERENDIA Medication Information
- Specify the complete strength, quantity, and sig code, including dosage form, route of administration, and frequency of KERENDIA
- It is critical to include the ICD-10-CM diagnosis code that most closely describes the patient's diagnosis of CKD associated with T2D
- Please make sure to add the following diagnosis code(s):
  - **E11.22 (type 2 diabetes mellitus with diabetic chronic kidney disease)**

*Information provided in this resource is for informational purposes only and does not guarantee that codes will be appropriate or that coverage will result. Customers should consult with their payers for all relevant coverage and coding.

Please see Important Safety Information on pages 2 and 7 and full Prescribing Information.

Previous Therapies Tried and/or Failed
- Health plans may require a record of current and previous prescription medications **(ACEi/ARB, SGLT2i, or MRA)**, as well as those the patient cannot tolerate
- Specify if the patient has taken KERENDIA before (including free samples)
- Drug names, strength, and therapy duration are required, as well as a description of any therapeutic problems, such as adverse events or suboptimal product efficacy. It is important to provide all information to underscore the medical necessity of KERENDIA

Note: If the payer requires that a patient take another medicine before starting KERENDIA, "Step Therapy Exception" **should be included as a justification** for the PA or Medical Exception

Additional Supporting Documentation
To assist the health plan's review of the PA submission, prescription documentation for KERENDIA may be provided.

Make sure to include Prescribing Information (PI) to describe the efficacy, safety, and appropriateness of KERENDIA.

Note: The doctor's signature must be included before submitting a PA form

DEA, Drug Enforcement Agency; ICD-10-CM, *International Classification of Diseases, Tenth Revision Clinical Modification*; MRA, mineralocorticoid receptor antagonist; SGLT2i, sodium-glucose cotransporter 2 inhibitors.

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Medical Exceptions and Appeals

Requesting Medical Exceptions

Plans may require **a formal request from the physician** via a medical exception letter with additional evidence to explain, in detail, why the HCP believes that KERENDIA® (finerenone) is the appropriate medication for this patient. A sample medical exception letter and sample appeal letter can be found at **www.KERENDIAhcp.com**.

Navigating the Appeals Process

If the PA or medical exception request is denied **an appeal may be required**. Health plans will notify you of the reason the initial request for coverage was denied, and often this can be corrected by **providing complete and accurate information** that was missing from the original submission.

To support your appeal, include recommendations 10.44 and 11.3c (level of evidence: A) from the 2022 American Diabetes Association Standards of Care, which support the use of KERENDIA in appropriate patients with CKD associated with T2D.[1,2]

Resubmitting the request through an appeal **is a crucial step to ensuring that your patient has access** to KERENDIA.

Click the links below to view recommendations 10.44 and 11.3c from the 2022 ADA Standards of Care

Recommendation 10.44

Recommendation 11.3c

Peer-to-peer (P2P) Reviews May Enable KERENDIA Coverage Even When PAs and Medical Exceptions Are Denied

P2P reviews take place when the prescribing HCP discusses the clinical need for KERENDIA with another physician who works for the patient's health plan, following an adverse PA or medical exception determination. When properly implemented, the process can be helpful, and a doctor's persuasive explanation of their medical decision may be more compelling than formal written requests.[3]

ADA, American Diabetes Association; HCPs, healthcare providers.

Please see Important Safety Information on pages 2 and 7 and full Prescribing Information.

Indication and Important Safety Information

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

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 in pocket.

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Access Services by Bayer™

is working with covermymeds® to provide your practice with PA, appeals, and real-time agent support for your patients.*

To submit an electronic PA (ePA) or for appeals support, **visit CoverMyMeds.com**

If you have patients who need help paying for their KERENDIA® (finerenone) prescription, have them call **1-888-KERENDIA (537-3634)** or visit **www.KERENDIA.com** to learn more about the affordability solutions offered by Bayer.

*Patients are eligible if formulary coverage determination has not been made or they are experiencing delays in PA processing.

Please see Important Safety Information on pages 2 and 7 and full Prescribing Information.

References: 1. American Diabetes Association. Addendum. Accessed June 17, 2022. https://diabetesjournals.org/care/article/doi/10.2337/dc22-ad08/147053/Addendum-10-Cardiovascular-Disease-and-Risk **2.** American Diabetes Association. Standards of medical care in diabetes–2022. *Diabetes Care*. 2022;45(suppl 1):S1-S264. **3.** American Medical Association. 8 prior authorization terms that drive every doctor crazy. Accessed August 23, 2022. https://www.ama-assn.org/practice-management/prior-authorization/8-prior-authorization-terms-drive-every-doctor-crazy