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Prior Authorization 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 of medications, and **it may mean that your office will need to obtain authorization from the health plan before KERENDIA coverage is approved for your patient**.

BAYER

CONTINUE

Prior Authorizations
Medical/Tiering Exceptions
Appeals
Access Support

Inside This Brochure

Click on a page number below or on the sectioned tabs on the right to find detailed information on specific PA-related topics within this resource.

Securing Patient Access to KERENDIA® (finerenone)

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

Submitting PA Requests

Please keep in mind that:

You can submit an electronic PA through CoverMyMeds®* for faster processing or fax a paper form to the health plan

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

- KERENDIA coverage falls under your patient's pharmacy benefit and not the medical benefit, and therefore, your patient's pharmacy benefit information **must be included** to ensure the correct form is selected and reviewed

If you already know that a certain health plan requires a PA for KERENDIA **you may proactively submit the necessary paperwork** to the health plan before sending the prescription to the pharmacy

Submitting **complete and accurate PA forms** along with supporting documentation can help to avoid delays in processing or avoid a PA denial (see pages 5 and 6 for more information)

If the initial PA request is denied, **an appeal may be required** (see pages 9 and 10 for information about the appeals process). 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 13 and full Prescribing Information.

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According to data from CoverMyMeds[1]

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). The most common ICD-10-CM code for CKD associated with T2D is **E11.22**

2. **Neglecting to report** a discontinuation, 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 Avoid PA Denials

- Ensure accurate reporting of diagnosis and current/previous therapies
- Use clear handwriting
- Include all necessary signatures
- Provide complete information as prompted

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

Please see additional Important Safety Information on pages 3 and 13 and full Prescribing Information.

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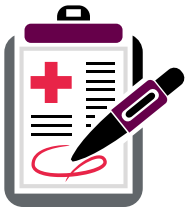
Preparing to Submit a Prior Authorization*

Consider the following PA criteria for KERENDIA® (finerenone) when preparing to submit a PA on behalf of your patient. Including this information may prevent a PA denial.



Patient Information

Include **a complete record** of the patient's personal and member/beneficiary information. The patient's **pharmacy benefit member ID** should be provided for fields requesting an Insurance ID#.

Prescriber Information

Include **all relevant prescriber information** in this section.

Note: If completing a PA through CoverMyMeds, this information may already be populated by the pharmacy.

Relevant Laboratory Values

- 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 m²** or **albuminuria (UACR) ≥30 mg/g for >3 months**. The generally accepted normal range for potassium is **3.5-5 mEq/L**.

KERENDIA Prescription Information

- Include accurate dispensing information for KERENDIA, including prescribed dose (eg, 10 mg or 20 mg), quantity, frequency, and sig code where required
- Provide the patient's diagnosis and corresponding ICD-10-CM code(s). Multiple ICD-10-CM codes may be included as applicable to the patient
  - **The most common ICD-10-CM code for CKD associated with T2D is E11.22**

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

*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.

DEA, Drug Enforcement Agency; ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*.

Preparing to Submit a Prior Authorization (cont'd)

Current and Previously Prescribed Therapies

- Indicate current and previously prescribed medications, or those for which the patient has an intolerance or contraindication, specifically*:
  - **ACEi/ARBs** (eg, Zestril® [lisinopril], Cozaar® [losartan])
  - **SGLT2is** (eg, Jardiance® [empagliflozin], Farxiga® [dapagliflozin])
  - **MRAs** (eg, Aldactone® [spironolactone])
- Specify if the patient has taken KERENDIA® (finerenone) before (including free samples)
- Include dose, treatment duration, and reason for discontinuation (if applicable) for **each** medication listed. 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, the patient's chart notes and prescription documentation for KERENDIA may be provided.

- Make sure to include the KERENDIA Prescribing Information (PI) to describe the efficacy, safety, and appropriateness of KERENDIA. Please click here to access the KERENDIA PI.

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

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

MRAs, mineralocorticoid receptor antagonists; SGLT2is, sodium-glucose cotransporter 2 inhibitors.

Please see additional Important Safety Information on pages 3 and 13 and full Prescribing Information.

Medical and Tiering Exceptions

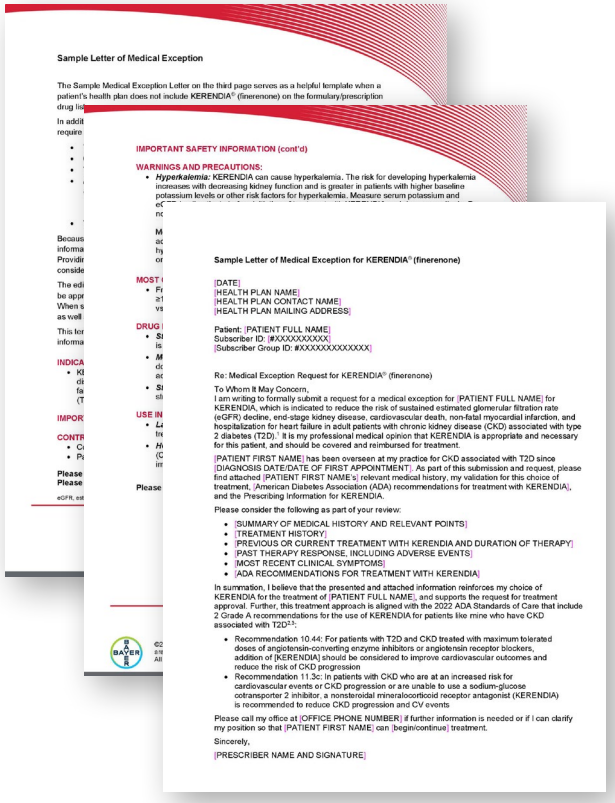
Requesting a Medical Exception

Coverage scenario You have prescribed KERENDIA® (finerenone) for your patient, but it is not covered under the patient's health plan.

You may submit a **Letter of Medical Exception** along with a **Letter of Medical Necessity** to request formulary coverage for your patient.

Plans may require this to be **a formal request from the physician** via a letter of medical exception with additional evidence to explain, in detail, why you believe that KERENDIA is the appropriate medication for your patient. In addition, a letter of medical necessity may be submitted along with the letter of medical exception to describe why KERENDIA is medically necessary if your patient doesn't meet the health plan's full prior authorization criteria for coverage.

Sample Letter of Medical Exception


Sample Letter of Medical Exception

The Sample Medical Exception Letter on the third page serves as a helpful template when a patient's health plan does not include KERENDIA® (finerenone) on the formulary/prescription

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

Sample Letter of Medical Exception for KERENDIA® (finerenone)

[DATE]
[HEALTH PLAN NAME]
[HEALTH PLAN CONTACT NAME]
[HEALTH PLAN MAILING ADDRESS]

Patient: [PATIENT FULL NAME]
Subscriber ID: [#XXXXXXXXXX]
[Subscriber Group ID: #XXXXXXXXXXXX]

Re: Medical Exception Request for KERENDIA® (finerenone)

To Whom It May Concern,
I am writing to formally submit a request for a medical exception for [PATIENT FULL NAME] for KERENDIA, which 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).[1] It is my professional medical opinion that KERENDIA is appropriate and necessary for this patient, and should be covered and reimbursed for treatment.

[PATIENT FIRST NAME] has been overseen at my practice for CKD associated with T2D since [DIAGNOSIS DATE/DATE OF FIRST APPOINTMENT]. As part of this submission and request, please find attached [PATIENT FIRST NAME's] relevant medical history, my validation for this choice of treatment, [American Diabetes Association (ADA) recommendations for treatment with KERENDIA], and the Prescribing Information for KERENDIA.

Please consider the following as part of your review:

- [SUMMARY OF MEDICAL HISTORY AND RELEVANT POINTS]
- [TREATMENT HISTORY]
- [PREVIOUS OR CURRENT TREATMENT WITH KERENDIA AND DURATION OF THERAPY]
- [PAST THERAPY RESPONSE, INCLUDING ADVERSE EVENTS]
- [MOST RECENT CLINICAL SYMPTOMS]
- [ADA RECOMMENDATIONS FOR TREATMENT WITH KERENDIA]

In summation, I believe that the presented and attached information reinforces my choice of KERENDIA for the treatment of [PATIENT FULL NAME], and supports the request for treatment approval. Further, this treatment approach is aligned with the 2022 ADA Standards of Care that include 2 Grade A recommendations for the use of KERENDIA for patients like mine who have CKD associated with T2D[2,3]:

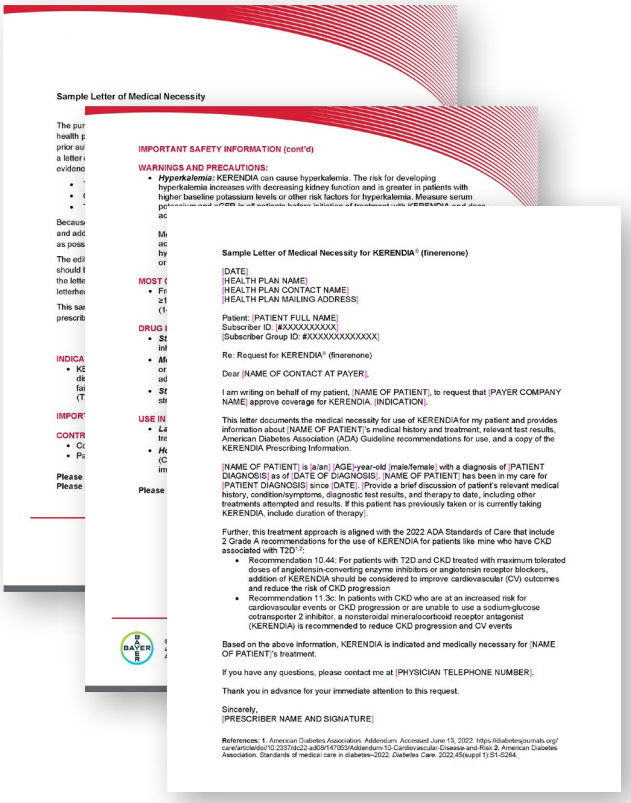
- Recommendation 10.44: For patients with T2D and CKD treated with maximum tolerated doses of angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, addition of [KERENDIA] should be considered to improve cardiovascular outcomes and reduce the risk of CKD progression
- Recommendation 11.3c: In patients with CKD who are at an increased risk for cardiovascular events or CKD progression or are unable to use a sodium-glucose cotransporter 2 inhibitor, a nonsteroidal mineralocorticoid receptor antagonist (KERENDIA) is recommended to reduce CKD progression and CV events

Please call my office at [OFFICE PHONE NUMBER] if further information is needed or if I can clarify my position so that [PATIENT FIRST NAME] can [begin/continue] treatment.

Sincerely,

[PRESCRIBER NAME AND SIGNATURE]

Sample Letter of Medical Necessity


Sample Letter of Medical Necessity

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

Sample Letter of Medical Necessity for KERENDIA® (finerenone)

[DATE]
[HEALTH PLAN NAME]
[HEALTH PLAN CONTACT NAME]
[HEALTH PLAN MAILING ADDRESS]

Patient: [PATIENT FULL NAME]
Subscriber ID: [#XXXXXXXXXX]
[Subscriber Group ID: #XXXXXXXXXXXX]

Re: Request for KERENDIA® (finerenone)

Dear [NAME OF CONTACT AT PAYER],

I am writing on behalf of my patient, [NAME OF PATIENT], to request that [PAYER COMPANY NAME] approve coverage for KERENDIA, [INDICATION].

This letter documents the medical necessity for use of KERENDIA for my patient and provides information about [NAME OF PATIENT]'s medical history and treatment, relevant test results, American Diabetes Association (ADA) Guideline recommendations for use, and a copy of the KERENDIA Prescribing Information.

[NAME OF PATIENT] is [a/an] [AGE]-year-old [male/female] with a diagnosis of [PATIENT DIAGNOSIS] as of [DATE OF DIAGNOSIS]. [NAME OF PATIENT] has been in my care for [PATIENT DIAGNOSIS] since [DATE]. [Provide a brief discussion of patient's relevant medical history, condition/symptoms, diagnostic test results, and therapy to date, including other treatments attempted and results. If this patient has previously taken or is currently taking KERENDIA, include duration of therapy].

Further, this treatment approach is aligned with the 2022 ADA Standards of Care that include 2 Grade A recommendations for the use of KERENDIA for patients like mine who have CKD associated with T2D[2,3]:

- Recommendation 10.44: For patients with T2D and CKD treated with maximum tolerated doses of angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, addition of KERENDIA should be considered to improve cardiovascular (CV) outcomes and reduce the risk of CKD progression
- Recommendation 11.3c: In patients with CKD who are at an increased risk for cardiovascular events or CKD progression or are unable to use a sodium-glucose cotransporter 2 inhibitor, a nonsteroidal mineralocorticoid receptor antagonist (KERENDIA) is recommended to reduce CKD progression and CV events

Based on the above information, KERENDIA is indicated and medically necessary for [NAME OF PATIENT]'s treatment.

If you have any questions, please contact me at [PHYSICIAN TELEPHONE NUMBER].

Thank you in advance for your immediate attention to this request.

Sincerely,
[PRESCRIBER NAME AND SIGNATURE]

References: 1. American Diabetes Association. Addendum. Accessed June 13, 2022. https://diabetesjournals.org/care/article/doi/10.2337/dc22-ad09/147059/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.

Medical and Tiering Exceptions (cont'd)

Requesting a Tiering Exception

Coverage scenario Your patient's plan covers KERENDIA® (finerenone) in a non-preferred tier that has a higher co-pay or co-insurance.

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. By submitting a tiering exception request letter that outlines the reasons why treatment is necessary to meet the medical needs of your patient, the health plan may grant approval for your patient to pay the lowest branded co-pay in place for the plan.

This exception may be especially helpful for patients who may not be eligible to participate in savings programs and may need assistance covering their drug costs.

Under this scenario, a letter of medical necessity may also be submitted along with the tiering exception request letter to describe why KERENDIA is medically necessary and further support this request.

Sample Tiering Exception Request Letter

IMPORTANT SAFETY INFORMATION (cont'd)

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.]

To download these sample letters and other PA support resources, visit www.KerendiaHCP.com/accessresources.

Navigating the Appeals Process

Appealing a Coverage Denial

Coverage scenario A PA request for KERENDIA® (finerenone) coverage was submitted to your patient's health plan, but the request was denied.

If a 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.

Resubmitting the request through an appeal **is a crucial step to ensuring that your patient has access** to KERENDIA. There are various ways to approach the appeals process, including:

Requesting a Peer-to-Peer Review

Peer-to-peer (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.

P2P Reviews May Enable KERENDIA Coverage Even When PAs and Medical Exceptions Are Denied

A doctor's persuasive explanation of their medical decision in a P2P review may be more compelling than formal written requests.[2]

To contact the health plan regarding a P2P review request, follow the guidance provided on the denial notice.

HCP, healthcare provider.

Navigating the Appeals Process (cont'd)

Submitting a Letter of Appeal

A **Letter of Appeal** can be submitted via fax or mail to formally request reconsideration of a PA denial. The letter can be tailored to address the reason(s) provided for the denial and supported with accompanying evidence as needed or as requested by the patient's health plan.

Download a **Sample Letter of Appeal** and other PA support resources at www.KerendiaHCP.com/accessresources.

Note: Depending on the health plan, there may be an option to submit an e-appeal through CoverMyMeds.

Sample Letter of Appeal

IMPORTANT SAFETY INFORMATION (cont'd)

Sample Letter of Appeal 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]

Reference Number: [Denial Reference Number / Appeal Number]

Dear [NAME OF MEDICAL OR PHARMACY DIRECTOR],

I am writing on behalf of my patient, [INSERT PATIENT NAME], to request an appeal by a Medical Advisor of the above-mentioned denial for coverage of KERENDIA. Based on the letter of denial, it is my understanding KERENDIA has been denied for the following reason(s):

[INSERT DENIAL REASON FROM THE DENIAL LETTER]

Based on my medical expertise, I ask that you reconsider this decision. KERENDIA 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).[1] It is my professional medical opinion that KERENDIA is appropriate and necessary to treat the diagnosis of [DIAGNOSIS AND ICD-10 CODE]. I believe that [INSERT PATIENT NAME] would benefit from KERENDIA for the following reason(s):

- [SUMMARY OF MEDICAL HISTORY AND RELEVANT POINTS]
- [PAST DRUG AND TREATMENT HISTORY, INCLUDING ADVERSE EVENTS]
- [PREVIOUS OR CURRENT TREATMENT WITH KERENDIA AND DURATION OF THERAPY]
- [MOST RECENT CLINICAL SYMPTOMS]

In summary, I believe that the presented and attached documentation reinforces my choice of KERENDIA for the treatment of [INSERT PATIENT NAME] and supports the request for treatment approval. Furthermore, this treatment approach is aligned with the 2022 ADA Standards of Care which include 2 Grade A recommendations for the use of KERENDIA for patients like mine who have CKD associated with T2D[2,3]:

- Recommendation 10.44: For patients with T2D and CKD treated with maximum tolerated doses of angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, addition of KERENDIA should be considered to improve cardiovascular outcomes and reduce the risk of CKD progression
- Recommendation 11.3c: In patients with CKD who are at an increased risk for cardiovascular events or CKD progression or are unable to use a sodium-glucose cotransporter 2 inhibitor, a nonsteroidal mineralocorticoid receptor antagonist KERENDIA is recommended to reduce CKD progression and CV events

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

Sincerely,

[PRESCRIBER NAME AND SIGNATURE]

References: 1. KERENDIA [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2022. 2. American Diabetes Association Professional Practice Committee. Addendum. 10. Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes—2022. Diabetes Care 2022;45(Suppl. 1): S144–S174. Diabetes Care 1 September 2022; 45 (9): 2178–2181.

- **To further support your appeal letter, include recommendations 10.43 and 11.5d (level of evidence: A) from the 2024 American Diabetes Association (ADA) Standards of Care**, which support the use of KERENDIA® (finerenone) in appropriate patients with CKD associated with T2D.[3] Please click here to view 10.43 and here to view 11.5d.

Access Support for Providers and Patients

covermymeds®

Bayer works with CoverMyMeds to provide **prior authorization and appeals support** for your practice to help get your patients access to KERENDIA® (finerenone).

Your practice can submit PA requests and appeals, speak with a payer expert by phone or through chat, and sign up for live demos of the CoverMyMeds platform.

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

BLINKRx

Bayer works with BlinkRx, a **digital pharmacy** that may help your patients save time and money on their KERENDIA prescription. BlinkRx **automatically applies savings for eligible patients through the $0 Copay Program (no copay card needed),*** offers low prices on all prescriptions, and will have the prescription delivered to their home with no delivery charge.

For additional support or to submit prescriptions by phone or fax, contact BlinkRx:

PHONE 1 (866) 839-0766

FAX 1 (866) 585-4631

Self Pay Through BlinkRx

If your patient does not have insurance, their insurance plan does not cover KERENDIA, or they cannot afford their plan's copay, they can choose to pay for their prescription without going through their insurance. KERENDIA is available for **$99 per month through BlinkRx**. Call 1-866-839-0766 or visit www.BlinkRx.com to learn more. Terms and conditions apply.

E-prescribe KERENDIA to BlinkRx US Boise, Idaho.

Please remind your patients that they **must respond** to the call/text from BlinkRx to receive their KERENDIA prescription.

*Patients are eligible if they are commercially insured and may pay as little as $0 per month. Benefit limitations apply. Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. Full terms and conditions apply. Visit **www.KERENDIAcopay.com** for more information.

BlinkRx is not affiliated with the KERENDIA Patient Support Program.

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$0 KERENDIA Copay Savings Card

Your eligible commercial patients may pay as little as $0 per month with the KERENDIA Copay Savings Card.*

*Patients are eligible if they are commercially insured and may pay as little as $0 per month. Benefit limitations apply. Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. Full terms and conditions apply. Visit **www.KERENDIAcopay.com** for more information.

30-day Free Trial Offer

New patients can get up to 30 days of KERENDIA at no cost through the KERENDIA Free Trial Offer.† A 30-day free trial voucher is available to new patients, depending on their insurance.

†Terms and Conditions apply. Visit **www.KERENDIAfreetrial.com** for more information or call 1-888-KERENDIA.

Bayer US Patient Assistance Foundation

If your patients cannot afford their prescription medication, Bayer may be able to help. Patients can call **1-866-2BUSPAF (228-7723)** or visit **www.patientassistance.bayer.us** to learn more.

Bayer US Patient Assistance Foundation

To learn more about financial assistance options offered by Bayer, your patients can call **1-888-537-3634** or visit **www.kerendia.com/savingsandsupport**.

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.

References: 1. Data on file. Bayer. **2.** American Medical Association. 7 prior authorization terms that drive every doctor to distraction. Accessed March 15, 2024. https://www.ama-assn.org/practice-management/prior-authorization/7-prior-authorization-terms-drive-every-doctor-distraction **3.** American Diabetes Association. Standards of care in diabetes–2024. *Diabetes Care*. 2024;47(suppl 1):S1-S321.

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