JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS137
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	Subject **Kerendia**	*Revision Date*	10/20/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Kerendia

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I. POLICY

Kerendia (finerenone) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Kerendia** may be approved for patients meeting all the following:
   1. Patient is 18 years of age or older
   2. Documented diagnosis of diabetes mellitus type 2
   3. Documented diagnosis of chronic kidney disease (CKD) with one of the following:
      a. persistent high albuminuria (Urine Albumin-to-Creatinine Ratio [UACR] 30 to 300 mg/g), estimated glomerular filtration rate (eGFR) 25 to 60 mL/min/1.73 m², and presence of diabetic retinopathy
      b. persistent very high albuminuria (UACR ≥300 mg/g) and eGFR 25 to 75 mL/min/1.73 m²
   4. Documentation of both of the following:
      a. Patient has a serum potassium ≤4.8 mmol/L
      b. Patient is currently receiving a maximum tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) unless their use is contraindicated

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial therapy may be approved for 12 months
B. Continuation of therapy may be approved in 12-month intervals with documentation showing all of the following:
   1. Reduction in eGFR decline and disease progression

IV. EXCLUSIONS

A. Kerendia will not be approved for the following:
   1. Patients that are less than 18 years of age
   2. Patients with severe hepatic impairment (Child Pugh C)
   3. Patients with adrenal insufficiency
   4. Patients receiving concurrent treatment with strong CYP3A4 inhibitors
   5. Any indications or uses that are not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Kerendia [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; July 2021.
2. Bakris GL, Agarwal R, Anker SD, Pitt B, Ruilope LM, Rossing P, Kolkhof P, Nowack C, Schloemer P, Joseph A, Filippatos G; FIDELIO-DKD Investigators. Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes. N Engl J Med. 2020 Dec 3;383(23):2219-2229.
3. Filippatos G, Anker SD, Agarwal R, Pitt B, Ruilope LM, Rossing P, Kolkhof P, Schloemer P, Tornus I, Joseph A, Bakris GL; FIDELIO-DKD Investigators. Finerenone and Cardiovascular Outcomes in Patients With Chronic Kidney Disease and Type 2 Diabetes. Circulation. 2021 Feb 9;143(6):540-552.

VI. APPROVALS

Signature on file at JHHC

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