

## Kerendia™ (finerenone) – New drug approval

- On July 9, 2021, the FDA announced the approval of Bayer's Kerendia (finerenone), to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).
- Diabetes is the leading cause of CKD in the U.S. CKD can sometimes progress to kidney failure and they are at increased risk of heart disease.
- Kerendia is a nonsteroidal mineralocorticoid receptor antagonist. Mineralocorticoid receptor overactivation is thought to contribute to fibrosis and inflammation.
- The efficacy of Kerendia was established in FIDELIO-DKD, a randomized, double-blind, placebo-controlled study in 5,674 adult patients with CKD associated with T2D. Patients were randomized to receive Kerendia or placebo and were followed for a median of 2.6 years. The primary composite endpoint was the incidence of a sustained decline in eGFR of  $\geq 40\%$ , kidney failure (defined as chronic dialysis, kidney transplantation, or a sustained decrease in eGFR to  $< 15$  mL/min/1.73 m<sup>2</sup>), or renal death.
  - Kerendia reduced the incidence of the primary composite endpoint (hazard ratio [HR] 0.82, 95% CI: 0.73, 0.93,  $p = 0.001$ ). The event rate (100 patient year) was 7.6 and 9.1 for Kerendia and placebo, respectively.
  - Kerendia also reduced the incidence of the composite endpoint of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or hospitalization for heart failure (HR 0.86, 95% CI: 0.75, 0.99,  $p = 0.034$ ).
- Kerendia is contraindicated in patients:
  - Who are receiving concomitant treatment with strong CYP3A4 inhibitors
  - With adrenal insufficiency
- A warning and precaution for Kerendia is hyperkalemia.
- The most common adverse reactions ( $\geq 1\%$  and more frequently than placebo) with Kerendia use were hyperkalemia, hypotension, and hyponatremia.
- The recommended starting dose of Kerendia is based on eGFR and is presented in the table below. The target daily dose of Kerendia is 20 mg.
  - Prior to initiation of Kerendia, measure serum potassium levels and eGFR. Treatment should not be initiated if serum potassium is  $> 5.0$  mEq/L.

eGFR (mL/min/1.73m <sup>2</sup> )	Starting dose
$\geq 60$	20 mg once daily
$\geq 25$ to $< 60$	10 mg once daily
$< 25$	Not recommended

- Bayer plans to launch Kerendia beginning the end of July 2021. Kerendia will be available as a 10 mg and 20 mg tablet.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](https://www.optum.com).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2021 Optum, Inc. All rights reserved.