ALASKA MEDICAID
Prior Authorization Criteria

# Kerendia®
# (finerenone)

## FDA INDICATIONS AND USAGE[1]

Kerendia® is a non-steroidal mineralocorticoid receptor antagonist (MRA) 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).

## APPROVAL CRITERIA[1,2,3,4]

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with a cardiologist or nephrologist **AND**;
3. Patient has the diagnosis of chronic kidney disease and type 2 diabetes **AND**;
4. Patient is currently taking a maximally tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or has a contraindication to both drug classes **AND**;
5. Chart notes have been submitted with baseline labs showing all of the following:
   a) Estimated glomerular filtration rate ≥ 25 mL/min/1.73 m2 and < 75 mL/min/1.73 m2
   b) Urine albumin-to-creatinine ratio ≥ 30 mg/g
   c) Serum potassium level ≤ 5.0 mEq/L.

## DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Patient is taking strong CYP3A4 inhibitors concomitantly **OR;**
3. Patient has adrenal insufficiency **OR;**
4. Patient has severe hepatic impairment (Child Pugh C).

## CAUTIONS[1]

- Patients with decreased kidney function and higher baseline potassium levels are at increased risk. Monitor serum potassium levels and adjust dose as needed.
- Patients should avoid concomitant use of grapefruit or grapefruit juice.
- May cause hyperkalemia, hypotension, and hyponatremia.

## DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 6 months if:
  - Patient has disease improvement and/or stabilization OR improvement in the slope of decline (based on UACR or eGFR) and the patient has not developed hyperkalemia.

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**QUANTITY LIMIT**

- 30 tablets per 30 days (10mg and 20mg strengths)

**REFERENCES / FOOTNOTES:**

1. Kerendia®. Prescribing Information. Whippany, NJ; Bayer; July 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215341s000lbl.pdf. Accessed September 22, 2021.
2. Efficacy and safety of finerenone in in subjects with type 2 diabetes and diabetic kidney disease (FIDELIO-DKD). Available at: https://clinicaltrials.gov/ct2/show/NCT02540993. Accessed September 23, 2021.
3. Bakris GL, Agarwal R, Anker SD, et al. Effect of finerenone on chronic kidney disease outcomes in type 2 diabetes. N Engl J Med. 2020; 383(23): 2219-2229. DOI: 10.1056/NEJMoa2025845.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney Int. 2020 Oct;98(4S):S1-S115.