Kerendia (finerenone)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

To reduce the risk of estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular (CV) death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) and type 2 diabetes mellitus (T2DM).

POLICY

Criteria for Initial Approval

The requested drug will be covered with prior authorization when the following criteria are met:

1. The member has a diagnosis of chronic kidney disease (CKD)
2. The member has a history of type 2 diabetes mellitus (T2DM)
3. The member is currently receiving a maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) OR the member has experienced an intolerance, allergy or contraindication to an ACEi or ARB.
4. The member meets both of the following criteria:
    a. Urinary albumin-to-creatinine ratio (UACR) ≥30 mg/g (≥3 mg/mmol)
    b. An eGFR ≥25 ml/min/1.73m^2
5. The requested drug will be used to reduce the risk of any of the following:

a. Sustained eGFR decline
b. End-stage kidney disease
c. Cardiovascular death
d. Non-fatal myocardial infarction
e. Hospitalization for heart failure

6. The member is stable and at goal with a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease OR the member has a history of failure, contraindication, or intolerance to SGLT2 inhibitors.

Approval will be for **12 months**

Continuation of Therapy

1. The member is experiencing clinical improvement with the requested agent
2. The member is currently receiving a maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) OR the member has experienced an intolerance, allergy or contraindication to an ACEi or ARB.
3. The member is stable and at goal with a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease OR the member has a history of failure, contraindication, or intolerance to SGLT2 inhibitors.
4. The member is not experiencing signs or symptoms of hyperkalemia

Approval will be for **12 months**

Kerendia (finerenone) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

30 tablets per 30 days

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

CLINICAL RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. 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).

The American Diabetes Association (ADA) Standards of Medical Care in Diabetes and the Kidney Disease Improving Global Outcomes (KDIGO) published a consensus report recommending treatment with an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) in patients with diabetes, hypertension and albuminuria. For patients with T2D and CKD in particular, recommendations consist of early initiation of metformin and furthermore the addition of sodium-glucose cotransporter 2 (SGLT2) inhibitors to delay progression of CKD and reduce cardiovascular risk. More recently, a nonsteroidal, mineralocorticoid receptor antagonist (ns-MRA) with proven kidney and cardiovascular benefit

is recommended for patients with T2D, an estimated glomerular filtration rate (eGFR) ≥ 25 ml/min/1.73m^2, a normal serum potassium, and albuminuria despite maximum tolerated dose of an ACEi or ARB.
Kerendia (finerenone) is a selective, ns-MRA with kidney and cardiovascular benefits described in two phase 3 studies of patients with T2D and kidney disease. The Finerenone in Reducing Kidney Failure and Disease Progression in Diabetic Kidney Disease (FIDELIO-DKD) study was a randomized, double-blind placebo-controlled multicenter study in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). At baseline, 99.8% of patients in the FIDELIO-DKD study were treated with an ACE inhibitor or ARB and 97% were on an antidiabetic agent. A total of 14 patients were not receiving an ACE inhibitor or ARB at baseline, and 7 patients received treatment with both an ACE inhibitor and an angiotensin-receptor blocker. Overall, the primary kidney end point (sustained decline in eGFR of ≥ 40%, kidney failure or renal death) was reduced with finerenone compared to placebo. In Finerenone in Reducing Cardiovascular Mortality and Morbidity in Diabetic Kidney Disease (FIGARO-DKD), background therapy was comparable to the FIDELIO-DKD population. FIGARO-DKD demonstrated that the primary composite cardiovascular end point (cardiovascular death, non-fatal myocardial infarction, a non-fatal stroke, or hospitalization for heart failure) was reduced with finerenone compared to placebo.

Therefore, coverage for Kerendia will be considered in patients who are receiving concomitant therapy with, have experienced an intolerance to or have a contraindication to an ACEi or ARB and an SGLT2 inhibitor.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

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- 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.
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- KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. *Kidney International.* 2022;102(5S).

POLICY HISTORY

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