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).

To reduce the risk of cardiovascular death, hospitalization for heart failure (HF), and urgent HF visits in adult patients with HF with left ventricular ejection fraction (LVEF) ≥40%.

POLICY

Criteria for Initial Approval

Chronic Kidney Disease (CKD) and Type 2 Diabetes Mellitus (T2DM)

The requested drug will be covered with prior authorization when all of 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 18 years of age or older

4. 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
5. The member meets **ALL** 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
    c. A serum potassium level ≤5 mEq/L
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**

Heart Failure (HF)
The requested drug will be covered with prior authorization when all of the following criteria are met:
1. The member has a diagnosis of heart failure (HF)
2. The member has a left ventricular ejection fraction (LVEF) ≥40%
3. The member is 18 years of age or older
4. The member meets **BOTH** of the following criteria:
    a. An eGFR ≥25 ml/min/1.73m^2
    b. A serum potassium level ≤5 mEq/L
5. The member is stable and at goal with a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with heart failure OR the member has a history of failure, contraindication, or intolerance to SGLT2 inhibitors

Approval will be for **12 months**

Continuation of Therapy
Chronic Kidney Disease (CKD) and Type 2 Diabetes Mellitus (T2DM)
The requested drug will be covered with prior authorization when all of the following criteria are met:
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 has a serum potassium level ≤5.5 mEq/L

Approval will be for **12 months**

Heart Failure (HF)
The requested drug will be covered with prior authorization when all of the following criteria are met:
1. The member is experiencing clinical improvement with the requested agent
2. The member is stable and at goal with a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with heart failure OR the member has a history of failure, contraindication, or intolerance to SGLT2 inhibitors
3. The member has a serum potassium level ≤5.5 mEq/L

Approval will be for **12 months**

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

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

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.

The 2022 American College of Cardiology/American Heart Association/Heart Failure Society of America (AHA/ACC/HFSA) HF Guideline recommends MRAs (class 2b recommendation, weak) in patients with symptomatic HFpEF with LVEF ≥ 50% and in patients with HFmrEF with LVEF 41% to 49% behind. Additional treatment recommendations for both symptomatic HFpEF and HFmrEF include diuretics for edema and/or congestion symptoms (class 1 recommendation, strong), SGLT2 inhibitors (class 2a recommendation, moderate), angiotensin receptor-neprilysin inhibitors (ARNI) (class 2b recommendation, weak), and ARBs (class 2b recommendation, weak). The American College of Cardiology (ACC) Expert Decision Pathway for HFpEF recommends dapagliflozin or empagliflozin for all patients with HFpEF to reduce CV death and hospitalization for heart failure as well as improve health status unless contraindicated. Among patients with LVEF <55% to 60%, use of an MRA, ARNI, or ARB may be considered.

The Finerenone Trial to Investigate Efficacy and Safety Superior to Placebo in Patients with Heart Failure (FINEARTS-HF) was a randomized, double-blind, placebo-controlled, international trial in adult patients with heart failure and a LVEF of 40% or greater. Approximately 14% of patients were taking a sodium glucose co-transporter-2 (SGLT-2) inhibitor at baseline. Overall, the primary outcome of a composite of total worsening heart failure events and death from cardiovascular causes occurred at a significantly lower rate compared to placebo.

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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POLICY HISTORY

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