BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 8/19/2021
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

KERENDIA® (finerenone) oral

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

KERENDIA® (finerenone) oral

Criteria:

- **Criteria for initial therapy:** Kerendia (finerenone) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist or Nephrologist

2. Individual is 18 years of age or older

3. A confirmed diagnosis of Chronic kidney disease (CKD) associated with type 2 diabetes (T2D) used to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure

4. Individual is treated with **ALL** of the following:
    a. Angiotensin converting enzyme inhibitor (e.g., lisinopril, enalapril, others) **OR** angiotensin receptor blocker (e.g., candesartan, losartan, others)
    b. Other standard of care treatment for diabetes

5. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
    a. Serum potassium is less than 4.8 mEq/L
    b. **ONE** of the following:
        i. Urine albumin to creatinine ratio (UACR) is greater than or equal to 30 but less than 300 mg/g and eGFR is greater than or equal to 25 but less than 60 mL/min/1.73m^2 and there is medical record documentation of diabetic retinopathy
        ii. UACR is greater than or equal to 300 but less than or equal to 5,000 mg/g and eGFR is greater than or equal to 25 but less than 75 mL/min/1.73m^2

6. For eGFR greater than or equal to 45 mL/min/1.73m^2 there is a documented failure, contraindication or intolerance to **ONE** of the following sodium-glucose co-transporter 2 (SGLT2) inhibitors:
    a. Invokana (canagliflozin)
    b. Farxiga (dapagliflozin)
    c. Jardiance (empagliflozin)

7. There are **NO** FDA-label contraindications, such as:
    a. Concomitant use with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir, clarithromycin)
    b. Patients with adrenal insufficiency

8. There are no significant interacting drugs

9. There are **NONE** of the following:
    a. Chronic heart failure with reduced ejection fraction and persistent symptoms (New York Heart Association Class II, III, & IV)
    b. Non-diabetic kidney disease

c. eGFR less than 25 mL/min/1.73m^2
d. Severe hepatic impairment (Child-Pugh Class C)
e. Hemoglobin A1c greater than 12%
f. Uncontrolled blood pressure

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Kerendia (finerenone) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist or Nephrologist

2. Individual's condition has not worsened while on therapy
    a. Worsening is defined as **ANY** of the following:
        i. A decline in eGFR of greater than or equal to 40%
        ii. Kidney failure defined as on chronic dialysis, required kidney transplantation or a sustained decrease in eGFR to less than 15 mL/min/1.73m^2
        iii. Experienced a nonfatal myocardial infarction
        iv. Hospitalized for heart failure
        v. Evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Hyperkalemia

5. There are no significant interacting drugs

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of a Non-cancer Medications**

2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

KERENDIA® (finerenone) oral

Description:

Kerendia (finerenone) is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained estimated glomerular filtration rate (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).

Finerenone is a nonsteroidal, selective antagonist of the mineralocorticoid receptor (MR), which is activated by aldosterone and cortisol and regulates gene transcription. Finerenone blocks MR mediated sodium reabsorption and MR overactivation in both epithelial (e.g., kidney) and nonepithelial (e.g., heart, and blood vessels) tissues. MR overactivation is thought to contribute to fibrosis and inflammation. Finerenone has a high potency and selectivity for the MR and has no relevant affinity for androgen, progesterone, estrogen, and glucocorticoid receptors.

In meta-analyses of the cardiovascular disease (CVD) outcome trials for dapagliflozin, canagliflozin, and empagliflozin compared with placebo there was a reduction in the risk of major adverse cardiovascular (CV) events and a composite outcome of CV death or hospitalization for heart failure. The clinical benefit of the SGLT2 inhibitors in reducing the risk of major CV events of myocardial infarction, stroke, and CV death was limited to those patients with established atherosclerotic CVD, with no benefit in those with multiple risk factors for CVD. In contrast to the findings for major adverse CV events, the meta-analyses showed a reduction in hospitalization for heart failure with use of sodium-glucose co-transporter 2 (SGLT2) inhibitors regardless of the presence of established atherosclerotic CVD or heart failure at baseline.

In a meta-analysis of the CVD outcome trials for dapagliflozin, canagliflozin, and empagliflozin, there was a reduction in the progression of diabetic kidney disease (DKD), with a similar effect observed in patients with established atherosclerotic CVD or multiple risk factors for CVD. DKD is a major cause of CKD and is the most common cause of end-stage kidney disease.

SGLT2 inhibitors reduce the risk of kidney disease progression and end-stage renal disease in patients with diabetic kidney disease, regardless of the degree of proteinuria. Patients with severely increased albuminuria (albumin-to-creatinine ratio ≥300 mg/g) are at higher risk for kidney disease progression and end-stage renal disease and therefore derive a greater absolute benefit from therapy with SGLT2 inhibitors.

SGLT2 inhibitors can have a role in patients with urine to creatinine ratio (UACR) greater than 300 mg/g and an eGFR of less than 90 mL/min/1.73m^2. However, dapagliflozin and empagliflozin should not be used for eGFR less than 45 mL/min/1.73m^2 and canagliflozin should not be used for eGFR less than 30 mL/min/1.73m^2.

Use of SGLT2 inhibitors should be avoided in patients with frequent bacterial urinary tract infections or genitourinary yeast infections, low bone density and high risk for falls and fractures, foot ulceration, and factors predisposing to diabetic ketoacidosis (DKA; e.g., pancreatic insufficiency, drug or alcohol abuse disorder) because of increased risk while using these agents.

KERENDIA® (finerenone) oral

Definitions:

Chronic Kidney Disease classification based upon Glomerular Filtration Rate and Albuminuris		
GFR Stages	GFR (mL/min/1.73m^2)	Terms
G1	≥ 90	Normal or high
G2	60-89	Mildly decreased
G3a	45-59	Mildly to moderately decreased
G3b	30-44	Moderately to severely decreased
G4	15-29	Severely decreased
G5	< 15	Kidney failure (if treated with dialysis: G5D)
Albuminuria Stages	Albumin Excretion Rate (AER mg/day)	
A1	< 30	Normal to mildly increased
A2	30-300	Moderately increased
A3	> 300	Severely increased

Staging of patients who meet the definition of Chronic Kidney Disease			
	Persistent albuminuria category		
GFR category	A1	A2	A3
G1	1 if CKD	1	2
G2	1 if CKD	1	2
G3a	1	2	3
G3b	2	3	3
G4	3	3	4+
G5	4+	4+	4+
GFR and albuminuria grid to reflect the risk of progression by intensity of coloring (green, yellow, orange, red, deep red). The numbers in the boxes are a guide to the frequency of monitoring (number of times per year).			

Resources:

Kerendia (finerenone) product information, revised by Bayer Healthcare Pharmaceuticals, Inc. 07-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on July 30,2021.

Mottl AK, Tuttle KR, Barkis GL. Diabetic kidney disease: Manifestations, evaluation, and diagnosis. In: UpToDate, Glassock RJ, Nathan DM, Forman JP (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on August 09, 2021.

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Perkociv V, Badve SV, Barkis GL. Treatment of diabetic kidney disease. In: UpToDate, Glassock RJ, Nathan DM, Forman JP (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on August 09, 2021.

DeSantis A. Sodium-glucose co-transporter 2 inhibitors for the treatment of hyperglycemia in type 2 diabetes mellitus. In: UpToDate, Nathan DM, Mulder JE (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on August 10, 2021.

Bakris GL, Agarwal R, Anker SD, et al.: Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes. NEJM 2020 Dec 3; 383 (23): 2219-2229. DOI: 10.1056/NEJMoa2025845. Accessed August 09, 2021.