BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

KERENDIA® (finerenone) oral
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for **KERENDIA** (finerenone)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by an Endocrinologist or Nephrologist, or in consultation with an Endocrinologist or Nephrologist

Indication
- Chronic Kidney Disease associated with type 2 diabetes where use is to reduce risk of sustained estimated glomerular filtration rate decline, end stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure

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- Heart failure (New York Heart Association class II–IV) with left ventricular ejection fraction (LVEF) greater than or equal to 40 percent where use is to reduce risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits

Age Requirement

- 18 years of age or older

Baseline Clinical Evaluation

- **Chronic Kidney Disease associated with type 2 diabetes:**
  - Serum potassium is less than or equal to 5 mEq/L
  - Estimated glomerular filtration rate is greater than or equal to 25 mL/min/1.73 m²
  - Urine albumin to creatinine ratio is greater than or equal to 30 mg/g
- **Heart failure (New York Heart Association class II–IV) with left ventricular ejection fraction greater than or equal to 40 percent:**
  - Serum potassium is less than or equal to 5 mEq/L
  - Estimated glomerular filtration rate is greater than or equal to 25 mL/min/1.73 m²
  - N terminal prohormone B type natriuretic peptide (NT proBNP) greater than or equal to 300 pg/mL (BNP greater than or equal to 100 pg/mL) in sinus rhythm
  - If in atrial fibrillation: NT proBNP greater than or equal to 900 pg/mL (BNP greater than or equal to 300 pg/mL)
  - Structural heart abnormalities based on any local imaging measurement within the last 12 months, defined by at least **ONE** of the following:
    1. Left atrial diameter (LAD) greater than or equal to 3.8 cm
    2. Left atrial area (LAA) greater than or equal to 20 cm²
    3. Left atrial volume index (LAVI) greater than 30 mL/m²
    4. Left ventricular mass index (LVMI) greater than or equal to 115 g/m² (male) or 95 g/m² (female)
    5. Septal thickness or posterior wall thickness greater than or equal to 1.1 cm

Alternative Therapies

- Failure (trial for at least three months duration), contraindication, intolerance to **ALL** of the following:
  - Angiotensin converting enzyme inhibitor (e.g., lisinopril, enalapril, others) OR angiotensin receptor blocker (e.g., candesartan, losartan, others)
  - **For Heart failure NYHA class II–IV with LVEF 40 percent or greater only:**
    1. Spironolactone
    2. Eplerenone

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the U.S. Food and Drug Administration (FDA) (see Definitions section)

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Safety

- **NO** contraindications such as:
  - Concomitant use with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir, clarithromycin)
  - Adrenal insufficiency
- No concomitant use with strong or moderate CYP3A4 inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifampin, bosentan, efavirenz, nafcillin, rifabutin, rifapentine, others)
- Does not have severe hepatic impairment (Child Pugh Class C)

Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualifications

- Continues to be seen by a physician specializing in or is in consultation with an Endocrinologist or Nephrologist

Clinical Response

- Condition has not worsened while on therapy defined as **ANY** of the following:
  - Decline in eGFR of greater than or equal to 40 percent
  - Kidney failure (on chronic dialysis, required kidney transplantation, or sustained decrease in estimated glomerular filtration rate to less than 15 mL/min/1.73 m²)
  - Nonfatal myocardial infarction
  - Hospitalization for heart failure
  - Significant unacceptable adverse drug reactions that may exclude continued use

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

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Safety

- **NO** new contraindications or significant adverse drug effects that may exclude continued use:
  - Contraindications listed in initial therapy criteria
  - Significant adverse effect such as hyperkalemia
  - Worsening of renal function in heart failure
- **NO** concomitant use with:
  - Strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir, clarithromycin)
  - Strong or moderate CYP3A4 inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifampin, bosentan, efavirenz, nafcillin, rifabutin, rifapentine, others)
- Does not have an eGFR less than 25 mL/min/1.73m2
- Does not have severe hepatic impairment (Child Pugh Class C)

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use from above criteria

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

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 Non-Cancer Medications

2. Off-Label Use of Cancer Medications

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). Kerendia (finerenone) is also indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥ 40%.

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.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Chronic kidney disease (CKD):
Presence of kidney damage (detected as urinary albumin excretion of 30 mg/day or more, or equivalent) or decreased kidney function (estimated glomerular filtration rate [eGFR] <60 mL/min/1.73 m^2) for three or more months, regardless of the cause

Diabetic kidney disease (DKD):
A clinical diagnosis based upon the presence of albuminuria, decreased estimated glomerular filtration rate (eGFR), or both, inpatients with diabetes (i.e., CKD in diabetes)

Moderately increased albuminuria: 30 to 300 mg/g or mg/day

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Severely increased albuminuria: >300 mg/g or mg/day

Chronic Kidney Disease classification based upon Glomerular Filtration Rate and Albuminuria		
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		
	A1	A2	A3
GFR category	< 30 mg/g	30-300 mg/g	> 300 mg/g
G1: ≥ 90 mL/min/1.73 m^2	1 if CKD	1	2
G2: 60-90 mL/min/1.73 m^2	1 if CKD	1	2
G3a: 45-59 mL/min/1.73 m^2	1	2	3
G3b: 30-44 mL/min/1.73 m^2	2	3	3
G4: 15-29 mL/min/1.73 m^2	3	3	4+
G5: < 15 mL/min/1.73 m^2	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:

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El Sayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 10. Cardiovascular disease and risk management: Standards of Care in Diabetes—2023. Diabetes Care 2023 Jan;46(Suppl. 1): S158–S190. Accessed July 10, 2024. Re-evaluated June 17, 2025.

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