Commercial/Healthcare Exchange PA Criteria
Effective: September 14, 2021

Prior Authorization: Kerendia

Products Affected: Kerendia (finerenone) film coated tablet

Medication Description: 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.

Covered Uses: To reduce the progression of chronic kidney disease and decrease the risk for associated cardiovascular complications in patients with Type 2 diabetes mellitus and chronic kidney disease

Exclusion Criteria:
1. Concomitant use with strong CYP3A4 inhibitors
2. Adrenal insufficiency

Required Medical Information:
1. Diagnosis
2. Medical history and labs

Age Restrictions: 18 years of age and older

Prescriber Restrictions: None

Coverage Duration: 12 months

Other Criteria:

I. Initial Approval Criteria

1. Patient has a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D); AND
2. Patient meets one of the following:
    A. Patient is currently receiving a maximally tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB); OR
    B. According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy; AND
3. At baseline (prior to initiation of Kerendia), patient meets all of the following:

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A. Estimated glomerular filtration rate ≥ 25 mL/min/1.73m^2 and <75 mL/min/1.73m^2; AND
B. Urine albumin-to-creatinine ratio (URAC) ≥ 30 mg/g; AND
C. Serum potassium level ≤ 5.0 mEq/L

II. Continuation Therapy:

1. Patient is having positive response to therapy
2. Patient is not experiencing toxicity from therapy

Quantity Limit: 30 tablets per 30 days

References:

1. Kerendia ™ [prescribing information]. Whippany, NJ. Bayer Healthcare Pharmaceuticals Inc. Updated 7/2021. Accessed August 16, 2021.
2. Kerendia ™ . IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated August 12, 2021. Accessed August 16, 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/14/2021

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