Original Effective Date: 11/01/2021
Current Effective Date: 08/23/2023
Last P&T Approval/Version: 07/26/2023
Next Review Due By: 07/2024
Policy Number: C21829-A

Kerendia (finerenone)

PRODUCTS AFFECTED

Kerendia (finerenone)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. CHRONIC KIDNEY DISEASE ASSOCIATED WITH TYPE 2 DIABETES
   1. Documentation of diagnosis of type 2 diabetes
      AND
   2. Documentation of diagnosis of chronic kidney disease (CKD)
      AND
   3. Prescriber attests member is currently receiving standard of care background therapy, including

a maximum tolerated labeled dose of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB), unless member has a documented FDA labeled contraindication to those therapies
AND

4. Documentation member's serum potassium level is ≤ 5.0mEq/L (lab value within last 30 days) AND member's eGFR (ml/min/1.73m^2) is ≥ 25 ml/min/1.73m^2 (lab value within last 30 days) [DOCUMENTATION REQUIRED]
   AND
5. Documentation of an inadequate response (3-month trial), serious side effects, or contraindication to one PDL/formulary preferred SGLT2 inhibitor
   AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Kerendia (finerenone) include: Concomitant use with strong CYP3A4 inhibitors and patients with adrenal insufficiency, concomitant use with strong or moderate CYP3A4 inducers]

CONTINUATION OF THERAPY:

A. CHRONIC KIDNEY DISEASE ASSOCIATED WITH TYPE 2 DIABETES

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by stabilization of eGFR or decline of eGFR <40% from pre-treatment baseline
   AND
4. Prescriber attests to or the clinical reviewer has found that the member has not progressed to end stage renal disease (ESRD) requiring dialysis
   AND
5. Prescriber attests a recent review of member's current medication has been completed and there is no concomitant use of strong CYP3A4 inhibitors or strong or moderate CYP3A4 inducers (a contraindication)

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified nephrologist or endocrinologist. [If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Target dose of 20 mg once daily, based on eGFR and serum potassium thresholds.

Maximum Quantity Limits –20 mg once daily, 30 tablets/30 days

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Non-steroidal Mineralocorticoid Receptor Antagonists

FDA-APPROVED USES:
Kerendia (finerenone) 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)

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Dose adjustment based on current serum potassium concentration and current dose:

		Current Kerendia Dose	
		10 mg once daily	**20 mg once daily**
Current Serum Potassium (mEq/L)	**≤ 4.8**	Increase the dose to 20 mg once daily.*	Maintain 20 mg once daily.
	> 4.8 – 5.5	Maintain 10 mg once daily.	Maintain 20 mg once daily.
	> 5.5	Withhold Kerendia. Consider restarting at 10 mg once daily when serum potassium ≤ 5.0 mEq/L.	Withhold Kerendia. Restart at 10 mg once daily when serum potassium ≤ 5.0 mEq/L.

* If eGFR has decreased by more than 30% compared to previous measurement, maintain 10 mg dose.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Chronic kidney disease (CKD) currently affects 15% of all U.S. adults, or an estimated 37 million people. High blood pressure and diabetes are the main causes of CKD, with approximately 50% of CKD patients also having a diagnosis of diabetes or cardiovascular disease (CVD). The Centers for Disease Control and Prevention (CDC) shows that CKD is more common in people ≥65 years of age, females, and people from minority groups (e.g., Blacks, Native Americans, and Hispanics). The estimated prevalence of diagnosed T2D in the U.S. adult population is 8.5% (i.e., 22 million people). Among U.S. adults 18 years of age or older with diabetes, the prevalence of CKD (stages 1–4) is 37%. Therefore, there is a potential population of approximately 8 million people with T2D with CKD in the United States. There is currently no cure for CKD, but treatment can help slow progression.
Both Kidney Disease Improving Global Outcomes (KDIGO) and the American Diabetes Association (ADA) recommend an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) as first-line therapy to prevent progression of renal disease and cardiovascular complications.

SGLT2 inhibitors can be added to treatment in patients with T2D, CKD, and eGFR ≥30mL/min/1.73 m2 , including those who have met their glycemic targets

Kerendia was approved based on the results of the Phase 3, randomized, double-blind, placebo-controlled FIDELIO-DKD (NCT02540993) clinical trial, in which 5734 adult patients (5674 for statistical analysis) with CKD and T2D were randomized 1:1 to receive finerenone or placebo.
FIDELIO-DKD consisted of a run-in period (4 to 16 weeks), screening (≤2 weeks), and double-blind treatment period. At the trial's conclusion, patients receiving Kerendia had been followed for a median of 2.2 years.
The primary composite outcome of kidney failure, sustained decrease of ≥40% in eGFR from baseline, or death from renal causes was significantly lower in the finerenone group (17.8%) versus the placebo group (21.1%). Patients who received finerenone also had a lower relative risk of key secondary outcome events (death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for heart failure), occurring in 13% of patients in finerenone group and 14.8% of patients in the placebo group. To follow up on these secondary cardiovascular outcomes, Kerendia is also being studied in the Phase 3 FIGARO-DKD trial (NCT02545049).
FIGARO-DKD is investigating the drug's efficacy and safety versus placebo in addition to an ACE inhibitor or ARB in the reduction of cardiovascular morbidity and mortality in an additional 7437 patients with CKD and T2D. The primary endpoint is time to first occurrence of the composite endpoint of cardiovascular death and nonfatal cardiovascular events (myocardial infarction, stroke, or hospitalization for heart failure). Compared with FIDELIO-DKD, FIGARO-DKD includes more patients at earlier stages of CKD. Combined, both Phase 3 studies will have enrolled approximately 13,000 patients with CKD and T2D

Safety
In FIDELIO-DKD, serious adverse events occurred in 32% of patients receiving finerenone and 34% patients receiving placebo, leading to 7% and 6% of patients, respectively, to permanently discontinue therapy. Hyperkalemia led to permanent discontinuation of therapy in 2.3% of patients receiving finerenone and was the most frequently reported adverse reaction (18.3%) in the study overall. Other adverse reactions included hypotension (4.8%) and hyponatremia (1.4%)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Kerendia (finerenone) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Kerendia (finerenone) include: Concomitant use with strong CYP3A4 inhibitors and patients with adrenal insufficiency, concomitant use with strong or moderate CYP3A4 inducers.

OTHER SPECIAL CONSIDERATIONS:
For patients who are unable to swallow whole tablets, Kerendia may be crushed and mixed with water or soft foods such as applesauce immediately prior to use and administered orally.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Kerendia TABS 10MG
Kerendia TABS 20MG

REFERENCES

1. Kerendia (finerenone) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; September 2022
2. Bakris GL, Agarwal R, Anker SD, et al; FIDELIO-DKD Investigators. Effect of finerenone on chronic kidney disease outcomes in type 2 diabetes. N Engl JMed. 2020;383(23):2219-2229. doi:10.1056/NEJMoa2025845
3. Centers for Disease Control and Prevention. Chronic kidney disease basics. Updated February 7, 2020. Accessed July 30, 2021. https://www.cdc.gov/kidneydisease/basics.html
4. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes – 2023. Diabetes Care 2023; 46 (Suppl. 1): S140-S157. https://doi.org/10.2337/dc23-S009

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Age Restrictions Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q3 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy FDA Approved Uses Other Special Consideration	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file