



Kerendia (finerenone) Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
4/1/2023

Date of Origin

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Kerendia® (finerenone) Tablets	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)		1

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

CLINICAL RATIONALE

Overview	<p>Type 2 diabetes is the leading cause of chronic kidney disease (CKD) worldwide. International guidelines for the management of CKD in patients with type 2 diabetes recommend control of hypertension and hyperglycemia, as well as the use of a renin-angiotensin system (RAS) blocker (an angiotensin-converting-enzyme [ACE] inhibitor or angiotensin-receptor blocker [ARB]) and, more recently, a sodium-glucose cotransporter 2 (SGLT2) inhibitor.(2) The International Society of Nephrology Kidney Disease Improving Global Outcomes (KDIGO) guidelines recommend ACEIs or ARBs for slowing the progression of CKD in patients with diabetes, with the dose titrated to the highest approved dose that is tolerated. In addition, the KDIGO guidelines also state that glycemic management for patients with type 2 diabetes and CKD should include first-line treatment with metformin and a sodium-glucose cotransporter-2 (SGLT2) inhibitor, with further drug therapy as needed for glycemic control, (unless pretreatment eGFR less than 20 ml/min). SGLT2 inhibitors have a large effect on reducing CKD progression that appears to be independent of eGFR. Even when glycemic targets are achieved on metformin, an SGLT2 inhibitor should be added for their beneficial effects. The KDIGO guidelines recommend that the selection of an SGLT2 inhibitor should prioritize agents with documented kidney or cardiovascular benefits and take eGFR into account.(8) Of these, canagliflozin and dapagliflozin have obtained FDA approval for reducing the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death and hospitalization for heart failure in adults with CKD at risk of progression.(4-6) Nonetheless, despite recommended treatment, a risk of CKD progression remains. Evidence supports a pathophysiological role for overactivation of the mineralocorticoid receptor in cardiorenal diseases, including CKD and diabetes, through inflammation and fibrosis that lead to progressive kidney and cardiovascular dysfunction.(2)</p> <p>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.(1)</p>
Efficacy	The FIDELIO-DKD and FIGARO-DKD studies were randomized, double-blind, placebo-controlled, multicenter studies in adult patients with chronic kidney disease (CKD)

	<p>associated with type 2 diabetes. Both trials excluded patients with known significant non-diabetic kidney disease. All patients were to have a serum potassium less than or equal to 4.8 mEq/L at screening and be receiving standard of care background therapy, including a maximum tolerated labeled dose of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker. Patients with a clinical diagnosis of chronic heart failure with reduced ejection fraction and persistent symptoms (New York Heart Association class II to IV) were excluded. The starting dose of Kerendia was based on screening eGFR. The dose of Kerendia could be titrated during the study, with a target dose of 20 mg daily. The FIDELIO-DKD patients were followed for 2.6 years and the FIGARO-DKD patients were followed for 3.4 years.(1)</p> <p>At baseline, 99.8% of patients were treated with an ACEi or ARB. Approximately 97% were on an antidiabetic agent (insulin [64.1%], biguanides [44%], glucagon-like peptide-1 [GLP-1] receptor agonists [7%], sodium-glucose cotransporter 2 [SGLT2] inhibitors [5%]), 74% were on a statin, and 57% were on an antiplatelet agent. In the FIGARO-DKD study, background therapies were similar to the FIDELIO-DKD study.(1)</p> <p>In the FIDELIO-DKD trial, Kerendia reduced the incidence of the primary composite endpoint of a sustained decline in eGFR of greater than or equal to 40%, kidney failure, or renal death (HR 0.82, 95% CI 0.73-0.93, p=0.001). The treatment effect reflected a reduction in a sustained decline in eGFR of greater than or equal to 40% and progression to kidney failure. Kerendia also reduced the incidence of the composite endpoint of cardiovascular (CV) death, non-fatal myocardial infarction (MI), and non-fatal stroke or hospitalization for heart failure (HR 0.86, 95% CI 0.75-0.99, p=0.034). The treatment effect reflected a reduction in CV death, non-fatal MI, and hospitalization for heart failure. In the FIGARO-DKD study, Kerendia reduced the incidence of the primary composite endpoint of CV death, non-fatal MI, non-fatal stroke or hospitalization for heart failure (HR 0.87, 95% CI 0.76-0.98, p = 0.026). The treatment effect was mainly driven by an effect on hospitalization for heart failure, though CV death also contributed to the treatment effect.(1)</p> <p>At the time of this writing, there are two sodium-glucose co-transporter 2 (SGLT-2) inhibitors that are indicated to reduce the risk of kidney disease: Farxiga (dapagliflozin) and the Invokana (canagliflozin) family (Invokana, Invokamet, and Invokamet XR). While an official recommendation for Kerendia is not evident, we recognize the longer time in therapy these SGLT-2 inhibitors have. Thus, we require use of these SGLT-2 inhibitors or FDA contraindication/intolerance/hypersensitivity to same before approving use of Kerendia.(4-6)</p> <p>In the 2022 edition of the American Diabetes Association’s Standards of Medical Care in Diabetes, a recommendation was made for patients with chronic kidney disease who are at increased risk for cardiovascular events or chronic kidney disease progression or are unable to use a sodium-glucose cotransporter 2 inhibitor. In these patients, a nonsteroidal mineralocorticoid receptor antagonist (finerenone) is recommended to reduce chronic kidney disease progression and cardiovascular events.(7) The International Society of Nephrology Kidney Disease Improving Global Outcomes (KDIGO) guidelines recommend a nonsteroidal mineralocorticoid receptor antagonist (finerenone) with proven kidney or cardiovascular benefit for patients with type 2 diabetes, an eGFR greater than or equal to 25 ml/min per 1.73 m², normal serum potassium concentration, and albuminuria (greater than or equal to 30 mg/g [greater than or equal to 3 mg/mmol]) despite maximum tolerated dose of renin-angiotensin system (RAS) blocker. (8)</p>
Safety	<p>Kerendia is contraindicated in patients concomitantly using strong CYP34 inhibitors and in patients with adrenal insufficiency. Treatment with Kerendia should not be initiated if serum potassium is greater than 5 mEq/L. Initiation of treatment with Kerendia is not recommended if estimated glomerular filtration rate (eGFR) is less than 25 mL/min/1.73m².(1)</p>

REFERENCES

Number	Reference
1	Kerendia Prescribing information. Bayer Healthcare Pharmaceuticals Inc. September 2022.
2	Bakris GL, Agarwal R, Anker SD, et al. "Effects of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes". N Engl J Med 2020; 383:2219-2229. Available at: https://www.nejm.org/doi/pdf/10.1056/NEJMoa2025845?articleTools=true
3	KDIGO 2020 Clinical Practice Guidelines for Diabetes Management in Chronic Kidney Disease. Supplement to Kidney International. Vol 98, Issue 4S, October 2020. Available at: https://kdigo.org/wp-content/uploads/2020/10/KDIGO-2020-Diabetes-in-CKD-GL.pdf. Reference no Longer used.
4	Farxiga Prescribing information. AstraZeneca. July 2022.
5	Invokana Prescribing information. Janssen Pharmaceuticals, Inc. August 2020.
6	Invokamet, Invokamet XR Prescribing information. Janssen Pharmaceuticals, Inc. August 2020.
7	American Diabetes Association Professional Practice Committee. "Chronic Kidney Disease and Risk Management: Standards of Medical care in Diabetes-2022." Diabetes Care 2022; 45(Suppl. 1): S175+-S184. Available at: https://diabetesjournals.org/care/issue/45/Supplement_1
8	KDIGO 2022 Clinical Practice Guidelines for Diabetes Management in Chronic Kidney Disease. Supplement to Kidney International. Vol 102, Issue 5S, November 2022. Available at: https://www.kidney-international.org/article/S0085-2538(22)00507-5/fulltext .

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Preferred Status	Effective Date
Kerendia	finerenone tab	10 MG ; 20 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date
Kerendia	Finerenone Tab	10 MG	30	TABS	30	Days				
Kerendia	Finerenone Tab	20 MG	30	TABS	30	Days				

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Kerendia	finerenone tab	10 MG ; 20 MG	Commercial ; HIM ; ResultsRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Kerendia	Finerenone Tab	10 MG	Commercial ; HIM ; ResultsRx
Kerendia	Finerenone Tab	20 MG	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> ONE of the following: <ol style="list-style-type: none"> The requested agent is eligible for continuation of therapy AND ONE of the following: <div data-bbox="477 1675 1174 1751" data-label="Text" style="border: 1px solid black; padding: 5px; margin: 10px auto; width: fit-content;"> <p style="text-align: center;">Agents Eligible for Continuation of Therapy</p> <p style="text-align: center;">All target agents are eligible for continuation of therapy</p> </div> Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days OR

Module	Clinical Criteria for Approval
	<p>2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed OR</p> <p>B. The patient has a diagnosis of CKD associated with type 2 diabetes and BOTH of the following:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient will be using an agent containing an angiotensin-receptor enzyme inhibitor (ACEi) (e.g., lisinopril, captopril) or an agent containing an angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan) at a maximally tolerated dose in combination with the requested agent OR B. The patient has an intolerance or hypersensitivity to an agent containing an angiotensin-receptor enzyme inhibitor (ACEi) AND an agent containing an angiotensin II receptor blocker (ARB) OR C. The patient has an FDA labeled contraindication to ALL agents containing an angiotensin-receptor enzyme inhibitor (ACEi) AND ALL agents containing an angiotensin II receptor blocker (ARB) AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient will be using an agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin) in combination with the requested agent OR B. The patient has an intolerance or hypersensitivity to an agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin) OR C. The patient has an FDA labeled contraindication to ALL agents containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin) OR D. The patient has chronic kidney disease and is at increased risk for cardiovascular events or chronic kidney disease progression OR <p>C. The patient has another FDA approved indication for the requested agent and route of administration OR</p> <p>D. The patient has another indication that is supported in compendia for the requested agent and route of administration AND</p> <ol style="list-style-type: none"> 2. The patient's serum potassium is less than or equal to 5.0 mEq/L AND 3. The patient's estimated glomerular filtration rate (eGFR) is greater than or equal to 25 mL/min/1.73m² AND 4. The patient's urine albumin-to-creatinine ratio (UACR) is greater than or equal to 30 mg/g AND 5. ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication AND 6. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence</p> <p>Length of Approval: 4 months</p> <p>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria section below.</p> <p>Renewal Evaluation</p>

Module	Clinical Criteria for Approval
	<p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process AND 2. The patient has had clinical benefit with the requested agent AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval: 12 months</p> <p>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria section below.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. ALL of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) is greater than the program quantity limit AND B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit OR 3. ALL of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) is greater than the program quantity limit AND B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication AND C. The prescriber has provided information in support of therapy with a higher dose for the requested indication <p>Length of Approval: Initial: 4 months; Renewal: 12 months</p>