

AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Kerendia[®] (finerenone)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Quantity Limit: 30 tablets per 30 days (all strengths)

Kerendia[®] Initial Dosing Recommendations:

eGFR (mL/min/1.73m ²)	Starting Dose
≥ 60	20 mg once daily
≥ 25 to < 60	10 mg once daily
< 25	Not Recommended

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Treatment of Chronic Kidney Disease Associated with Type 2 Diabetes			
Dose Adjustment Based on Current Serum Potassium Concentration and 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.

Treatment of Heart Failure with LVEF ≥ 40%				
Dose Adjustment Based on Current Serum Potassium Concentration and Current Kerendia® Dose				
		10 mg once daily	20 mg once daily	40mg once daily
Current Serum Potassium (mEq/L)	< 5	Increase the dose to 20 mg once daily*	Maintain 20 mg once daily if eGFR < 60 mL/min/1.73 m ² at initiation. Otherwise increase the dose to 40 mg once daily*	Maintain 40 mg once daily.
	≥ 5 to < 5.5	Maintain current dose.		
	≥ 5.5 to < 6	Withhold Kerendia. Restart at 10 mg once daily when serum potassium < 5.5.	Decrease to 10 mg once daily.	Decrease to 20 mg once daily.
	≥ 6	Withhold Kerendia. Restart at 10 mg once daily when serum potassium < 5.5 mEq/L.**		

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

**If repeated serum potassium measurements are ≥5.5, restart Kerendia at 10 mg once daily when serum potassium < 5.

CLINICAL CRITERIA: Check below all that apply. **All criteria must be met for approval.** To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Diagnosis: Chronic Kidney Disease Associated with Type 2 Diabetes

Initial Authorization: 6 months

- Member is 18 years of age or older and has a diagnosis of chronic kidney disease associated with type 2 diabetes

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- ❑ Must submit lab test results documenting **BOTH** of the following obtained within the past 60 days
 - ❑ Member's current eGFR is > 25 mL/minute/1.73 m²
 - ❑ Member's current Urinary Albumin-to -Creatinine Ratio (UACR) is ≥ 30 mg/g
- ❑ Member's current serum potassium is ≤ 5 mEq/L along with **BOTH** of the following (**submit current lab documentation obtained within the past 60 days**):
 - ❑ Therapy will **NOT** be initiated if serum potassium > 5 mEq/L
 - ❑ Initiation with increased serum potassium monitoring during the first 4 weeks will be performed if serum potassium is > 4.8 to 5 mEq/L
- ❑ Member is established on treatment with maximally tolerated dose of angiotensin-converting enzyme inhibitor (ACE) or angiotensin receptor blocker (ARB) medication and will continue to take along with Kerendia[®] (finerenone) (**verified by chart notes and/or pharmacy paid claims**)
- ❑ Member is established on standard therapy for treatment of type 2 diabetes (**verified by chart notes and/or pharmacy paid claims**)
- ❑ Member is established on treatment with, or has a contraindication, or intolerance to, at least **ONE** sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (e.g., Farxiga[®], Jardiance[®]) (**verified by chart notes and/or pharmacy paid claims**)
- ❑ Member does **NOT** have a diagnosis of adrenal insufficiency or a diagnosis of known significant non-diabetic renal disease, including clinically relevant renal artery stenosis
- ❑ Member is **NOT** receiving simultaneous treatment with strong CYP3A4 inhibitors
- ❑ For initial therapy, members will be dosed as follows:
 - ❑ eGFR ≥ 60 mL/minute/1.73 m²: starting dose will be 20 mg once daily
 - ❑ eGFR ≥ 25 to < 60 mL/minute/1.73 m²: starting dose will be 10 mg once daily

❑ **Diagnosis: Chronic Kidney Disease Associated with Type 2 Diabetes**

Reauthorization: 12 months.

- ❑ Member continues to receive treatment with **ALL** the following unless contraindicated or not tolerated (**must submit documentation of therapy contraindication or intolerance if applicable**):
 - ❑ Maximally tolerated dose of angiotensin-converting enzyme inhibitor (ACE) or angiotensin receptor blocker (ARB) medication
 - ❑ SGLT2 inhibitor medication
 - ❑ Standard therapy for treatment of type 2 diabetes (unless member is using an SGLT2 inhibitor as monotherapy)
- ❑ Member's current eGFR is > 25 mL/minute/1.73 m² (**submit current lab documentation**)
- ❑ Member has had a positive clinical response to therapy, such as decrease in Urinary Albumin-to-creatinine Ratio (UACR) from baseline level, improvement or stabilization of eGFR from baseline level, stabilization of kidney function; etc. (**submit current lab or medical chart note documentation**)

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- ❑ Member's current serum potassium level does **NOT** exceed 5.5 mEq/L (**submit current lab documentation**)
- ❑ Provider attests Kerendia[®] will be withheld if serum potassium is > 5.5 mEq/L and will consider restarting therapy when serum potassium normalizes (≤ 5.0 mEq/L)

❑ **Diagnosis: Heart Failure with LVEF $\geq 40\%$**

Initial Authorization: 6 months

- ❑ Member is 18 years of age or older
- ❑ Member has a left ventricular ejection fraction $\geq 40\%$ (**submit current documentation**)
- ❑ Member must have **BOTH** of the following (**submit documentation**):
 - ❑ Evidence of structural or functional heart disease
 - ❑ Symptomatic heart failure (NYHA class II-IV)
- ❑ Member is established on treatment with, or has a contraindication, or intolerance to, at least **ONE** sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with heart failure (e.g., Farxiga[®], Jardiance[®]) (**verified by chart notes and/or pharmacy paid claims**)
- ❑ Member must be on standard background medical therapy for HFmrEF or HFpEF, if appropriate (e.g. SGLT2 inhibitors, loop diuretics, ACE inhibitors, angiotensin receptor blockers) (**verified by chart notes and/or pharmacy paid claims**)
- ❑ Member will **NOT** take Kerendia concomitantly with another mineralocorticoid receptor antagonist (e.g. spironolactone, eplerenone) (**verified by chart notes and/or pharmacy paid claims**)
- ❑ Provider must submit lab work from the past 60 days showing **BOTH** of the following:
 - ❑ Member's current eGFR is > 25 mL/minute/1.73 m²
 - ❑ Member's current serum potassium is < 5 mEq/L
- ❑ Member's starting dose is appropriate for their current eGFR and serum potassium, and provider agrees to follow FDA labeled dosing regimen (based on lab work obtained 4 weeks after initiating treatment)
- ❑ Member is **NOT** receiving simultaneous treatment with strong CYP3A4 inhibitors
- ❑ Member does **NOT** have a history of adrenal insufficiency

❑ **Diagnosis: Heart Failure with LVEF $\geq 40\%$**

Reauthorization: 12 months.

- ❑ Member has symptomatic heart failure (NYHA class II-IV) with LVEF $\geq 40\%$ that requires continued treatment (**submit documentation**)
- ❑ Member must be on standard background medical therapy for heart failure, if appropriate (e.g. SGLT2 inhibitors, diuretics, ACE inhibitors, angiotensin receptor blockers) (**verified by chart notes and/or pharmacy paid claims**)

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- ❑ Member has had a positive clinical response to therapy, such as fewer unplanned hospital visits or urgent care visits for heart failure, improvement in NYHA functional class, improvement in quality of life (**submit current medical chart note documentation**)
- ❑ Member will **NOT** take Kerendia concomitantly with another mineralocorticoid receptor antagonist (e.g. spironolactone, eplerenone) (**verified by chart notes and/or pharmacy paid claims**)
- ❑ Provider must submit current lab work showing **ALL** the following:
 - ❑ Member's current eGFR is $> 25 \text{ mL/minute/1.73 m}^2$
 - ❑ Member's current serum potassium is $< 6 \text{ mEq/L}$
 - ❑ Member's current dose of Kerendia is appropriate based on lab work

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****