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 m² 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 m^2
  - ❑ 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 contradiction, 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 m^2: starting dose will be 20 mg once daily
  - ❑ eGFR ≥ 25 to < 60 mL/minute/1.73 m^2: 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 m^2 **(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 ≥ 40%

Initial Authorization: 6 months

- ❑ Member is 18 years of age or older
- ❑ Member has a left ventricular ejection fraction ≥ 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 must have tried and failed **ONE** of the following sodium glucose co-transporter-2 (SGLT2) inhibitors unless contraindicated or has history of intolerance **(verified by chart notes and/or pharmacy paid claims)**:
  - ❑ Brand Farxiga (dapagliflozin)
  - ❑ Jardiance (empagliflozin)
- ❑ 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 m^2
  - ❑ 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 ≥ 40%

Reauthorization: 12 months.

- ❑ Member has symptomatic heart failure (NYHA class II-IV) with LVEF ≥ 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 mL/minute/1.73 m^2
  - Member's current serum potassium is < 6 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.****