

# SENTARA HEALTH PLANS

## 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 1-800-750-9692. 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 Sentara #: \_\_\_\_\_ 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 <sup>2</sup> )	Starting Dose
≥ 60	20 mg once daily
≥ 25 to < 60	10 mg once daily
< 25	Not Recommended

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<b>Treatment of Chronic Kidney Disease Associated with Type 2 Diabetes</b>			
<b>Dose Adjustment Based on Current Serum Potassium Concentration and Current Kerendia® Dose</b>			
		<b>10 mg once daily</b>	<b>20 mg once daily</b>
<b>Current Serum Potassium (mEq/L)</b>	<b>≤ 4.8</b>	Increase the dose to 20 mg once daily*	Maintain 20 mg once daily
	<b>&gt; 4.8 – 5.5</b>	Maintain 10 mg once daily	Maintain 20 mg once daily
	<b>&gt; 5.5</b>	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.

<b>Treatment of Heart Failure with LVEF ≥ 40%</b>				
<b>Dose Adjustment Based on Current Serum Potassium Concentration and Current Kerendia® Dose</b>				
		<b>10 mg once daily</b>	<b>20 mg once daily</b>	<b>40mg once daily</b>
<b>Current Serum Potassium (mEq/L)</b>	<b>&lt; 5</b>	Increase the dose to 20 mg once daily*	Maintain 20 mg once daily if eGFR < 60 mL/min/1.73 m <sup>2</sup> at initiation. Otherwise increase the dose to 40 mg once daily*	Maintain 40 mg once daily.
	<b>≥ 5 to &lt; 5.5</b>	Maintain current dose.		
	<b>≥ 5.5 to &lt; 6</b>	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.
	<b>≥ 6</b>	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<sup>2</sup>
  - ❑ Member's current Urinary Albumin-to -Creatinine Ratio (UACR) is  $\geq 30$  mg/g
- ❑ Member's current serum potassium is  $\leq 5$  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  $\geq 60$  mL/minute/1.73 m<sup>2</sup>: starting dose will be 20 mg once daily
  - ❑ eGFR  $\geq 25$  to  $< 60$  mL/minute/1.73 m<sup>2</sup>: 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<sup>2</sup> (**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 ( $\leq$  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 m<sup>2</sup>
  - 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 mL/minute/1.73 m<sup>2</sup>
  - 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.\****