

Clinical Policy Title:	finerenone
Policy Number:	RxA.699
Drug(s) Applied:	Kerendia®
Original Policy Date:	08/18/2021
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Heart failure (must meet all):

1. Diagnosis of heart failure with left ventricular ejection fraction (LVEF) $\geq 40\%$;
2. Member meets all of the following (a, b, and c):
 - a. eGFR of ≥ 25 mL/min/1.73 m²;
 - b. Urine albumin-to-creatinine ratio ≥ 30 mg/g;
 - c. Serum potassium ≤ 4.8 mEq/L;
3. Member is currently taking an ACE inhibitor or ARB for at least 30 days, unless contraindicated or clinically significant side effects are experienced;
4. Member is currently taking an SGL2 inhibitor for at least 30 days, unless contraindicated or clinically significant side effects are experienced.

B. CKD associated with Type 2 Diabetes (must meet all):

1. Diagnosis of chronic kidney disease associated with type 2 diabetes;
2. Member meets all of the following (a, b, and c)
 - a. eGFR of ≥ 25 mL/min/1.73 m²;
 - b. Urine albumin-to-creatinine ratio ≥ 30 mg/g;
 - c. Serum potassium ≤ 4.8 mEq/L
3. Member is currently taking an ACE inhibitor or ARB for at least 30 days, unless contraindicated or clinically significant side effects are experienced.
4. Member is currently taking an SGL2 inhibitor for at least 30 days, unless contraindicated or clinically significant side effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indication in Section I (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met been initial approval criteria.

Approval Duration

All Lines of Business (except Medicare): 12 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

References

1. IPD Analytics RxInsights_New Drug Review_ Kerendia®_08 2021. Available at: <https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Kerendia>. Accessed March 24, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/19/2021	09/14/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Dosing Information, Dosing Regimen, finerenone (Kerendia®): Updated to include dosing information for eGFR (mL/min/1.73m²) < 25 for indication CKD associated with T2D. 2. Initial Approval Criteria, I.A.4: <ol style="list-style-type: none"> a. updated to remove “or stage 2,3, or 4 CKD”. b. and updated to include: Urine albumin-to-creatinine ratio ≥ 30 mg/g. 3. Initial Approval Criteria, I.A.5: Updated combination therapy criteria from Member is on concurrent therapy with an ACE inhibitor or ARB to Member is on concurrent therapy with an ACE inhibitor or ARB at maximally tolerated doses for ≥ 4 weeks, unless contraindicated or clinically significant side effects are experienced. 4. Initial Approval Criteria, I.A.7: Updated to remove prior trial and failure criteria "Member has tried and failed both SGLT2 inhibitors: Farxiga, Invokana". 5. Appendix B, Drug Name: Updated to include therapeutic alternatives: <ol style="list-style-type: none"> a. captopril b. enalapril (Vasotec®, Epaned®) c. fosinopril d. lisinopril (Zestril®, Qbrelis®) e. perindopril f. quinapril (Accupril®) g. ramipril (Altace®) h. trandolapril 	04/26/2022	07/18/2022

<ul style="list-style-type: none"> i. candesartan (Atacand®) j. losartan (Cozaar®) k. telmisartan (Micardis®) l. valsartan (Diovan®) <p>6. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C.</p> <p>7. References were reviewed and updated.</p>		
<p>Policy was reviewed.</p>	<p>11/20/2023</p>	<p>11/20/2023</p>
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> 1. Removed prescriber criteria. 2. Updated continuation of therapy language. 	<p>03/24/2025</p>	<p>04/10/2025</p>
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> 1. Added heart failure indication to Policy with criteria. 	<p>8/1/2025</p>	<p>N/A</p>
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> 1. Trial and failure of SGLT2 inhibitor added to CKD indication. 	<p>09/10/2025</p>	<p>12/11/2025</p>