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| **Clinical Policy Title:** | finerenone |
| **Policy Number:** | RxA.699 |
| **Drug(s) Applied:** | Kerendia® |
| **Original Policy Date:** | 08/18/2021 |
| **Last Review Date:** | 11/20/2023 |
| **Line of Business Policy Applies to:** | All lines of business (except Medicare) |

## Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

**I. Initial Approval Criteria**

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

1. Diagnosis of chronic kidney disease associated with type 2 diabetes;
2. Prescribed by or in consultation with a nephrologist or an endocrinologist;
3. Member meets all of the following (a, b, and c)
   a. eGFR of ≥25 mL/min/1.73 $m^2$;
   b. Urine albumin-to-creatinine ratio ≥ 30 mg/g;
   c. Serum potassium ≤4.8 mEq/L
4. Member is currently taking an ACE or ARB inhibitor at maximally tolerated doses for more than 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. CKD associated with Type 2 Diabetes** (must meet all):

1. Member is currently receiving medication, excluding manufacturer samples;

**Approval Duration**

**All Lines of Business (except Medicare):** 12 months

**References**

1. IPD Analytics RxInsights_New Drug Review_ Kerendia®_08 2021. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Kerendia. Accessed April 26, 2022.

| Review/Revision History | Review/Revision Date | P&T Approval Date |
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| Policy established. | 08/19/2021 | 09/14/2021 |
| Policy was reviewed:<br>1. Dosing Information, Dosing Regimen, finerenone | 04/26/2022 | 07/18/2022 |

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| (Kerendia®): Updated to include dosing information for eGFR (mL/min/1.73m$^2$) < 25 for indication CKD associated with T2D.<br>2. Initial Approval Criteria, I.A.4:<br>a. updated to remove “or stage 2,3, or 4 CKD”.<br>b. and updated to include: Urine albumin-to-creatinine ratio ≥ 30 mg/g.<br>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.<br>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".<br>5. Appendix B, Drug Name: Updated to include therapeutic alternatives:<br>a. captopril<br>b. enalapril (Vasotec®, Epaned®)<br>c. fosinopril<br>d. lisinopril (Zestril®, Qbrelis®)<br>e. perindopril<br>f. quinapril (Accupril®)<br>g. ramipril (Altace®)<br>h. trandolapril<br>i. candesartan (Atacand®)<br>j. losartan (Cozaar®)<br>k. telmisartan (Micardis®)<br>l. valsartan (Diovan®)<br>6. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. | | |

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| 7. References were reviewed and updated. | | |
| Policy was reviewed. | 11/20/2023 | 11/20/2023 |