Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCEND072.1025	**ENDOCRINE & METABOLIC DRUGS** **KERENDIA®** (finerenone tablet)
Effective Date: 1/1/2026	**Review/Revised Date**: 03/23, 3/24, 02/25, 10/25 (NN)
Original Effective Date: 04/22	**P&T Committee Meeting Date**: 02/22, 04/23, 04/24, 04/25, 10/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit

REQUIRED MEDICAL INFORMATION:
All the following must be met:
1. For Chronic Kidney Disease associated with Type 2 diabetes:
    a. Patient has a diagnosis of chronic kidney disease associated with type 2 diabetes mellitus
    b. Member has tried and failed, or has a contraindication or intolerance to, a maximally tolerated Angiotensin Converting Enzyme inhibitor (such as lisinopril) or Angiotensin Receptor Blocker (such as losartan)
2. For Heart Failure:
    a. Patient has a diagnosis of heart failure with left ventricular ejection fraction (LVEF) greater than or equal to 40%
    b. Patient has been treated with diuretics within 30 days prior to start of requested therapy

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTIONS: N/A

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COVERAGE DURATION:
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

QUANTITY LIMIT:
One tablet per day

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Finerenone is a selective non-steroidal mineralocorticoid receptor antagonist which works by blocking mineralocorticoid-mediated sodium reabsorption and over activation in epithelial (kidney) and non-epithelial (heart, blood vessels) tissues.

FDA APPROVED INDICATIONS:
- To reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2DM)
- To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥ 40%.

POSITION STATEMENT:
Diabetes is the leading cause of chronic kidney disease (CKD) worldwide. CKD is diagnosed by the persistent presence of elevated urinary albuminuria, low estimated glomerular filtration rate (eGFR), or other manifestations of kidney damage. Patients with concomitant type 2 diabetes (T2DM) and CKD are at risk for long-term

complications including retinopathy and neuropathy; risks of kidney failure with the need for dialysis or transplantation; and cardiovascular complications including ischemia, arrhythmia, and heart failure.

Current guidelines for the management of CKD in patients with T2DM, include the American Diabetes Association (ADA) Standards of Care 2025 and Kidney Disease Improving Global Outcomes (KDIGO) 2024.

The 2025 ADA guidelines recommend the use of angiotensin-converting enzyme inhibitors (ACEi) or angiotensin II receptor blockers (ARBs), and sodium-glucose cotransporter-2 (SGLT-2) inhibitors as first-line drug therapy for patients with T2DM and CKD. A nonsteroidal mineralocorticoid receptor antagonist (MRA) is recommended as additional risk-based therapy to reduce chronic kidney disease progression and cardiovascular events in people with chronic kidney disease and albuminuria who are on maximally tolerated ACEi or ARB therapy. Finerenone is currently the only FDA approved nonsteroidal MRA with which has shown cardiovascular and kidney benefits.

The 2024 KDIGO guidelines similarly recommend the use of a nonsteroidal MRA in patients with T2DM and CKD with persistent albuminuria despite maximally tolerated ACEi/ARB therapy. The choice of nonsteroidal MRA should be based on those agents with proven kidney and cardiovascular benefits in this patient population such as finerenone.

REFERENCE/RESOURCES:

1. Kerendia (finerenone) prescribing information. Bayer HealthCare Pharmaceuticals, Inc. July 2021.
2. Finerenone In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically. Accessed February 5, 2025
3. Finerenone In: Lexi-Drugs Online [Internet database]. Hudson, OH: Lexi-Comp, Inc. Updated periodically. Accessed February 5, 2025
4. American Diabetes Association Standards of Medical Care in Diabetes- 2023. Diabetes Care 2025;48(1):S1.
5. Kidney Disease Improving Global Outcomes (KDIGO) 2024 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. *Kidney International* 2024 April;105(4S):S117-314.