Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Kerendia (finerenone)**

Effective: September 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Kerendia (finerenone) is indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with CKD associated with type 2 diabetes. Kerendia is also indicated 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%.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Kerendia (finerenone) when **ALL** the following criteria are met:

Chronic Kidney Disease associated with Type 2 Diabetes

1. Patient is 18 years of age or older

AND

2. Patient has type 2 diabetes (T2D)

AND

3. Patient has chronic kidney disease (CKD)

AND

4. The patient is currently taking, or has had trial and failure, inadequate response, intolerance, or contraindication to at least ONE medication in the following classes:
    a. Angiotensin-converting enzyme inhibitor (ACEi)
    b. Angiotensin II receptor blocker (ARB)

AND

5. The patient is currently taking, or has had trial and failure, inadequate response, intolerance, or contraindication to a sodium-glucose cotransporter 2 (SGLT2) inhibitor

Heart Failure with Left Ventricular Ejection Fraction (LVEF) ≥ 40%

1. Patient is 18 years of age or older

AND

2. Patient has heart failure with left ventricular ejection fraction (LVEF) ≥ 40%

AND

3. The patient has had trial and failure, inadequate response, intolerance, or contraindication to both spironolactone and eplerenone

AND

4. The patient is currently taking, or has had trial and failure, inadequate response, intolerance, or contraindication to a sodium-glucose cotransporter 2 (SGLT2) inhibitor

Limitations

1. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

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4. Pitt B, Filippatos G, Agarwal R, et al; FIGARO-DKD Investigators. Cardiovascular Events with Finerenone in Kidney Disease and Type 2 Diabetes. N Engl J Med. 2021 Dec 9;385(24):2252-2263. doi: 10.1056/NEJMoa2110956.
5. KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney Int. 2022 Nov;102(5S):S1-S127. doi: 10.1016/j.kint.2022.06.008. PMID: 36272764.
6. Heerspink HJL, Stefánsson BV, Correa-Rotter R et al; DAPA-CKD Trial Committees and Investigators. Dapagliflozin in patients with chronic kidney disease. N Engl J Med. 2020;383(15):1436-1446. doi: 10.1056/NEJMoa2024816.
7. Wanner C, Inzucchi SE, Lachin JM, Fitchett D, von Eynatten M, Mattheus M, Johansen OE, Woerle HJ, Broedl UC, Zinman B; EMPA-REG OUTCOME Investigators. Empagliflozin and Progression of Kidney Disease in Type 2 Diabetes. N Engl J Med. 2016 Jul 28;375(4):323-34. doi: 10.1056/NEJMoa1515920.
8. Sridhar VS, Liu H, Cherney DZI. Finerenone-A New Frontier in Renin-Angiotensin-Aldosterone System Inhibition in Diabetic Kidney Disease. Am J Kidney Dis. 2021 Aug;78(2):309-311. doi: 10.1053/j.ajkd.2021.02.324.
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Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 8, 2023: No changes
- August 13, 2024: No changes
- August 12, 2025: Effective September 1, 2025, added coverage criteria for Kerendia's supplemental indication in heart failure with left ventricular ejection fraction (LVEF) ≥ 40%.
- August 11, 2026: Minor wording updates. Administrative update to remove Carelink from Medical Necessity Guideline template. (eff 9/1/26)

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.