

Kerendia® (finerenone)
Effective 09/01/2022

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Kerendia® (finerenone) is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan and currently receiving treatment with requested medication, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes mellitus
2. Documentation of concurrent therapy with an ACE-I or ARB
3. Paid claims or physician documented inadequate response or adverse reaction to ONE or contraindication to ALL of the following:
 - a. Farxiga® (dapagliflozin)
 - b. Invokana® (canagliflozin)
 - c. Jardiance® (empagliflozin)
 - d. Steglatro® (ertugliflozin)
4. Quantity limit of 1 tablet/day



Continuation of Therapy

Reauthorizations requires physician documentation of continuation of therapy and positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

References

1. Kerendia[®] (finerenone) [prescribing information]. Whippany (NJ): Bayer HealthCare Pharmaceuticals Inc.; 2021 Jul.
2. FDA Approves Drug to Reduce Risk of Serious Kidney and Heart Complications in Adults with Chronic Kidney Disease Associated with Type 2 Diabetes [press release on the internet]. FDA; 2021 Jul 9 [cited 2021 Aug 28]. Available from: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-approves-drug-reduce-risk-serious-kidney-and-heart-complications-adults-chronic-kidney-disease>.
3. Garber AJ, Abrahamson MJ, Barzilay JI, Blonde L, Bloomgarden ZT, Handelsman Y et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm – 2020. *Endocrine Practice*. 2020 Jan;26(1):107-139.
4. American Diabetes Association. Summary of Revisions: Standards of Medical Care in Diabetes-2021. *Diabetes Care* 2021 Jan; 44(Supplement 1): S4-S6.
5. Bakris GL, Agarwal R, Anker SD, Pitt B, Ruilope LM, Nowack C et al. Design and Baseline Characteristics of the Finerenone in Reducing Kidney Failure and Disease Progression in Diabetic Kidney Disease Trial. *Am J Nephrol*. 2019;50(5):333-344.
6. Perkovic V, Badve S, Bakris GL. Treatment of diabetic kidney disease. Basow DS (Ed). *UpToDate* [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Aug 28]. Available from: <http://www.utdol.com/utd/index.do>.
7. Farxiga[®] (dapagliflozin) [prescribing information]. Wilmington (DE): AstraZeneca Pharmaceuticals Inc.; 2021 Apr.
8. Invokana[®] (canagliflozin) [prescribing information]. Titusville (NJ): Janssen Pharmaceuticals Inc.; 2020 Aug.
9. Boehringer Ingelheim. EMPA-KIDNEY (The Study of Heart and Kidney Protection With Empagliflozin). In: *ClinicalTrials.gov* [Internet]. National Library of Medicine (US). 2021 [cited 2021 Nov 03]. Available from: <https://clinicaltrials.gov/ct2/show/NCT03594110?term=EMPA-KIDNEY&draw=2&rank=1>
10. Bayer. Study to Evaluate the Efficacy (Effect on Disease) and Safety of Finerenone on Morbidity (Events Indicating Disease Worsening) & Mortality (Death Rate) in Participants With Heart Failure and Left Ventricular Ejection Fraction (Proportion of Blood Expelled Per Heart Stroke) Greater or Equal to 40% (FINEARTS-HF). In: *ClinicalTrials.gov* [Internet]. National Library of Medicine (US). 2021 [cited 2021 Nov 03]. Available from: <https://www.clinicaltrials.gov/ct2/show/NCT04435626>
11. Bayer. Efficacy and Safety of Finerenone in Subjects With Type 2 Diabetes Mellitus and the Clinical Diagnosis of Diabetic Kidney Disease (FIGARO-DKD). In: *ClinicalTrials.gov* [Internet]. National Library of Medicine (US). 2021 [cited 2021 Nov 03]. Available from: <https://www.clinicaltrials.gov/ct2/show/NCT02545049?term=FIGARO-DKD&draw=2&rank=3>

Review History

07/20/2022 – Created criteria to match Masshealth for July P&T. Effective 9/01/22.



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