



SmartPA Criteria Proposal

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| Drug/Drug Class: | Kerendia Clinical Edit |
| First Implementation Date: | April 28, 2022 |
| Revised Date: | April 27, 2023 |
| Prepared for: | MO HealthNet |
| Prepared by: | MO HealthNet/Conduent |
| Criteria Status: | <input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria |

Executive Summary

Purpose: Ensure appropriate utilization and control of Kerendia® (finerenone).

Why Issue Selected: Kerendia® (finerenone) was approved by the FDA on July 9, 2021, to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). CKD is defined as abnormalities of kidney structure or function, present for at least 3 months, with implications for health. CKD is classified into stages, ranging from Stage 1 (early disease) to Stage 5 (end-stage disease with complete kidney failure). 37 million (15%) adults in the United States (U.S.) have been diagnosed with CKD; approximately 8 million of which have Stage 1-4 CKD in addition to T2D. Kerendia is a nonsteroidal, selective mineralocorticoid receptor antagonist (MRA). Kerendia has a high potency and selectivity for the mineralocorticoid receptor (MR) and has no relevant affinity for androgen, progesterone, estrogen, and glucocorticoid receptors. MR overactivation is thought to contribute to fibrosis and inflammation in the kidneys and cardiovascular system. MR selectivity differentiates Kerendia from other available aldosterone antagonists (i.e., spironolactone or eplerenone) and may result in lower incidence of adverse effects.

Due to the specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Kerendia.

| Program-Specific Information: | Date Range FFS 10-01-2021 to 9-30-2022 | | | |
|-------------------------------|--|--------|-------------|---------------------|
| | Drug | Claims | Spend | Avg Spend per Claim |
| | KERENDIA 10 MG TABLET | 33 | \$20,013.12 | \$606.46 |
| | KERENDIA 20 MG TABLET | 4 | \$2,285.48 | \$571.37 |

Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Clinical Edit

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Kerendia® (finerenone)
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

- Documentation of compliance to previous Kerendia therapy (90/120 days) **OR**
- Participant is aged \geq 18 years **AND**
- Documented diagnosis of CKD stage 1-4 **AND**
- Documented diagnosis of type 2 diabetes **AND**
- Documented therapy with ACE-inhibitor (ACEI) or angiotensin receptor blocker (ARB) for 60 of the past 90 days **AND**
- Documented adequate therapeutic trial of 2 sodium-glucose co-transporter 2 (SGLT2) inhibitors

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is currently pregnant
- Diagnosis of adrenal insufficiency
- Diagnosis of CKD stage 5 or end stage renal disease
- Claim is for more than 1 tablet per day

Required Documentation

Laboratory Results:
MedWatch Form:

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Progress Notes:
Other:

| |
|---|
| |
| X |

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

3 months

References

- Kerendia® (finerenone) [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; September 2022.
- IPD Analytics. Renal: Chronic Kidney Disease. Available at: <https://secure.ipdanalytics.com/>. Accessed March 2023.
- KDIGO 2022 Clinical Practice Guidelines for the Evaluation and Management of Chronic Kidney Disease. Kidney Int Suppl. 2022 Nov;102(5S):S1-S127. Available at: [https://www.kidney-international.org/article/S0085-2538\(22\)00507-5/fulltext](https://www.kidney-international.org/article/S0085-2538(22)00507-5/fulltext). Accessed October 2022.
- Bakris GL, Agarwal R, Anker SD, et al., on behalf of the FIDELIO-DKD Investigators. Effect of finerenone on chronic kidney disease outcomes in type 2 diabetes. N Engl J Med 2020; 383:2219-29. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMoa2025845>. Accessed November 2021.

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- Agarwal R, Kolkhof P, Bakris G, et al. Steroidal and non-steroidal mineralcorticoid receptor antagonists in cardiorenal medicine. Eur H J 2021; 42:152-161. Available at: <https://academic.oup.com/eurheartj/article/42/2/152/5936792>. Accessed November 2021.
- ClinicalTrials.gov. U.S. National Library of Medicine. Available at: <https://www.clinicaltrials.gov/ct2/home>. Accessed November 2021.
- IPD Analytics. New Drug Review: Kerendia (finerenone). August 2021.