SmartPA Criteria Proposal

Drug/Drug Class:	Kerendia Clinical Edit
First Implementation Date:	TBD
Proposed Date:	December 16, 2021
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒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 10-01-2020 to 9-30-2021				
Drug	**Claims**	**Cost per tablet**	**Cost per month**	**Cost per year**
KERENDIA 10 MG TABLET	1	$18.97	$569.10	$6,924.05
KERENDIA 20 MG TABLET	0			

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **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 ≥ 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:		Progress Notes:	
MedWatch Form:		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.; July 2021.
- IPD Analytics. Renal: Chronic Kidney Disease. Available at: https://secure.ipdanalytics.com/. Accessed November 2021.
- KDIGO 2012 Clinical Practice Guidelines for the Evaluation and Management of Chronic Kidney Disease. Kidney Int Suppl. 2013;3(1). Available at: https://kdigo.org/guidelines/ckd-evaluation-and-management/. Accessed November 2021.
- de Boer IH, Caramori ML, Chan JCN, et al. Executive summary of the 2020 KDIGO Diabetes Management in CKD Guideline: evidence-based advances in monitoring and treatment. Kidney Int 2020; 98:839–848. Available at: https://kdigo.org/wp-content/uploads/2018/03/KDIGO-Diabetes-in-CKD-GL-Exec-Summary.pdf. Accessed November 2021.

- 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.
- 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.