Drug/Drug Class: Kerendia Clinical Edit
First Implementation Date: April 28, 2022
Revised Date: N/A
Prepared for: MO HealthNet
Prepared by: MO HealthNet/Conduent
Criteria Status: ☒ 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:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Date Range FFS 10-01-2020 to 9-30-2021</th>
<th>Claims</th>
<th>Cost per tablet</th>
<th>Cost per month</th>
<th>Cost per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>KERENDIA 10 MG TABLET</td>
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<td>1</td>
<td>$18.97</td>
<td>$569.10</td>
<td>$6,924.05</td>
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Type of Criteria: ☒ Appropriate Indications

Data Sources: ☒ 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

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
<th>Other:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

Disposition of Edit

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

Default Approval Period

3 months

References