Drug/Drug Class: Direct Renin Inhibitors and Combinations PDL Edit

First Implementation Date: April 9, 2008

Revised Date: January 6, 2022

Prepared For: MO HealthNet

Prepared By: MO HealthNet/Conduent

Criteria Status: ☒ Existing Criteria
☐ Revision of Existing Criteria
☐ New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Direct renin inhibitors directly target the renin-angiotensin-aldosterone system (RAAS) at the point of activation by inhibiting renin and blocking the conversion of angiotensinogen to angiotensin I, leading to decreased plasma renin activity. Tekturna® (aliskiren) is the only approved product in this therapeutic class. During Tekturna therapy the effects of increased renin levels are blocked, so that plasma renin activity, (inactive) angiotensin I, and (active) angiotensin II are all reduced. Angiotensin II, a powerful vasoconstrictor, also inhibits renin release, thus providing a negative feedback to the RAAS system. Aliskiren is metabolized by CYP3A4. Drug interactions have been noted with co-administration of Avapro, Lipitor, ketoconazole, and furosemide. Tekturna offers an alternative in the treatment of hypertension, but at this time doesn’t offer an advantage over the proven efficacy of existing angiotensin converting enzyme (ACE) inhibitor and angiotensin receptor blocker (ARB) classes.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

<table>
<thead>
<tr>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Aliskiren</td>
<td>• Tekturna®</td>
</tr>
<tr>
<td>• Tekturna HCT®</td>
<td></td>
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</tbody>
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Type of Criteria: ☒ Preferred Drug List
☐ Increased risk of ADE
☐ Appropriate Indications
☐ Clinical Edit

Data Sources: ☒ Only Administrative Databases
☐ Databases + Prescriber-Supplied

Setting & Population:

- Drug class for review: Direct Renin Inhibitors and Combinations
- Age range: All appropriate MO HealthNet participants
Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 1 or more Angiotensin Receptor Blocker (ARB) agents
- Failure to achieve desired therapeutic outcomes with trial on 1 or more preferred agents
  - Documented trial period for preferred agents OR
  - Documented ADE/ADR to preferred agents

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:  
MedWatch Form:  
Progress Notes:  
Other:  

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

Default Approval Period

1 year

References

2. Evidence-Based Medicine Analysis: "Direct Renin Inhibitors and Combinations", UMKC-DIC; July 2021.
3. USPDI, Micromedex; 2021.
4. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.