SmartPA Criteria Proposal

Drug/Drug Class:	Direct Renin Inhibitors and Combinations PDL Edit
First Implementation Date:	April 9, 2008
Proposed Date:	October 17, 2023
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 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:

Preferred Agents	Non-Preferred Agents
• Aliskiren • Tekturna HCT®	• Tekturna®

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: 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:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

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

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: “Direct Renin Inhibitors and Combinations”, UMKC-DIC; June 2023
- Evidence-Based Medicine and Fiscal Analysis: “Direct Renin Inhibitors and Combination Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; July 2021.
- Mann J and Hilgers KF. Renin-angiotensin system inhibition in the treatment of hypertension. *UpToDate.* https://www.uptodate.com/contents/renin-angiotensin-system-inhibition-in-the-treatment-of-hypertension?search=tekturna&source=search_result&selectedTitle=2~122&usage_type=default&display_rank=1. May 2022.
- USPDI, Micromedex; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.