SmartPA Criteria Proposal

Drug/Drug Class:	ACE Inhibitors and ACE Inhibitors/Diuretic Combinations PDL Edit
First Implementation Date:	March 12, 2003
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: Angiotensin-converting-enzyme-inhibitors (ACEIs) block the activation of the renin-aldosterone system, which is a mediator of blood pressure. In addition to their effects on blood pressure, ACEIs are also thought to have beneficial ventricular effects following myocardial infarction (MI), in patients with heart failure, and in preventing the progression of diabetic nephropathy. Professional associations, such as the American Heart Association, and the American Diabetes Association, as well as cardiology specialists, recommend ACEIs as the standard of care for patients with recent MI, in patients at high risk for cardiovascular events, and in patients with diabetic nephropathy. ACEIs have been shown to be efficacious when used alone or in combination with diuretics. These fixed-dose combinations of diuretics and ACEIs are approved for the management of hypertension but are not indicated as initial therapy.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Benazepril • Benazepril/HCTZ • Enalapril Tabs • Enalapril/HCTZ • Fosinopril • Lisinopril • Lisinopril/HCTZ • Quinapril • Ramipril	• Accupril® • Accuretic® • Altace® • Captopril • Captopril/HCTZ • Enalapril Soln • Epaned® • Fosinopril/HCTZ • Lotensin® • Lotensin HCT® • Moexipril • Perindopril • Prinivil® • Qbrelis® • Quinapril/HCTZ • Trandolapril

	• Vaseretic® • Vasotec® • Zestoretic® • Zestril®

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: ACE Inhibitors and ACE Inhibitors/Diuretic Combinations
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 4 or more preferred agents:
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For ~~**Epaned or**~~ **Enalapril solution** ~~**or Qbrelis**~~: Clinical Consultant Review for participants aged 10 years or older
- **For Qbrelis:**
  - **Documented compliance to current therapy OR**
  - **Reason of medical necessity as to why enalapril solution cannot be utilized**

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
ACEON 2 MG	PERINDOPRIL	2 tablets per day
ACEON 4 MG	PERINDOPRIL	2 tablets per day
ACEON 8 MG	PERINDOPRIL	1 tablet per day
ALTACE 1.25 MG	RAMIPRIL	1 tablet per day
ALTACE 10 MG	RAMIPRIL	2 tablets per day
ALTACE 2.5 MG	RAMIPRIL	1 tablet per day
ALTACE 5 MG	RAMIPRIL	1 tablet per day
UNIVASC 15 MG	MOEXIPRIL	2 tablets per day
UNIVASC 7.5 MG	MOEXIPRIL	1 tablet per day
ZESTORETIC 10 MG/12.5 MG	LISINOPRIL/HCTZ	1 tablet per day
ZESTORETIC 20 MG/12.5 MG	LISINOPRIL/HCTZ	4 tablets per day
ZESTORETIC 20 MG/25 MG	LISINOPRIL/HCTZ	2 tablets per day

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: “Angiotensin Converting Enzyme Inhibitors (ACEI) and Diuretic Combinations)”, UMKC-DIC; April 2023.
- Evidence-Based Medicine and Fiscal Analysis: “Angiotensin Converting Enzyme Inhibitor Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; July 2021.
- Evidence-Based Medicine and Fiscal Analysis: “Angiotensin Converting Enzyme Inhibitor/Diuretic Combination Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; July 2021.
- Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension. 2018;71(6):e13-e115.
- USPDI, Micromedex; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.