

## Uniform Formulary Medical Necessity Criteria for Renin-Angiotensin Antihypertensive Agents (RAAs) - Angiotensin Converting Enzyme (ACE) Inhibitors

**Drug Class** - Renin-Angiotensin Antihypertensives (RAAs). The class includes several subclasses of medications that have been reviewed separately by the DoD P&T Committee at previous meetings, as well as new FDA-approved medications that affect the renin-angiotensin system. The RAAs class is comprised of the following:

- Angiotensin receptor blockers (ARBs)
- Angiotensin converting enzyme inhibitors (ACE inhibitors)
- Combinations of ARBs or ACE inhibitors with thiazide diuretics
- Combinations of ARBs or ACE inhibitors with calcium channel blockers (CCBs)
- Direct renin inhibitors.
- Combinations of direct renin inhibitors with thiazide diuretics

The Angiotensin Converting Enzyme (ACE) inhibitor class includes ten drugs, perindopril (Aceon), ramipril (Altace), moexipril (Univasc), benazepril, captopril, enalapril, fosinopril, lisinopril, Mavik and quinapril.

**Background** - After evaluating the relative clinical and cost effectiveness of the ACE inhibitors, the DoD P&T Committee recommended that the following medications be designated as non-formulary: Accupril (quinapril), Aceon (perindopril), Altace (ramipril), and Univasc (moexipril). This recommendation has been approved by the Director, TMA. As of April 2008 (February 2008 P&T meeting), quinapril was changed from non-formulary (Tier 3) to formulary generic (Tier 1) status under the DoD P&T Committee's expedited review process. The following is the current list of non-formulary medications in this class:

- Aceon (perindopril)
- Uniretic (moexipril/HCTZ)
- Univasc (moexipril)

**Effective Date:** 15 Feb 2006

Patients currently using a non-formulary ACE inhibitor may wish to ask their doctor to consider a formulary alternative.

### Uniform Formulary Status, Copays, and Therapeutic Alternatives for ACE Inhibitors\*, \*\* .

Uniform Formulary Status	Medication	Military Treatment Facilities (MTFs) (up to a 90 day supply)	TMOP (up to a 90 day supply)	Retail Network (up to a 30-day supply)
Non-Formulary (Tier 3)	Aceon Uniretic Univasc	Not available**	\$22	\$22
Formulary: Brand Name (Tier 2)	Mavik	\$0	\$9	\$9
Formulary: Generic (Tier 1)	benazepril, captopril***, enalapril, fosinopril, lisinopril quinapril ramipril	\$0	\$3	\$3

1 Active duty copay always \$0 in all points of service for all three tiers; active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary.

\*\* MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.

\*\*\*Captopril is a short-acting ACE inhibitor that may require dosing three or four times daily; the other ACE inhibitors are long-acting and can be dosed once or twice a day. Patients are not required to have tried captopril..

### **Medical Necessity Criteria for ACE Inhibitors**

The \$22 non-formulary copay for the non-formulary ACE inhibitors (Aceon, Univasc or Unirectic) may be reduced to the \$9 formulary copay IF one or more of the following criteria are met:

1. Use of ALL of the formulary long-acting ACE inhibitors (benazepril, enalapril, fosinopril, lisinopril, Mavik, quinapril and ramipril) is contraindicated.
2. The patient has experienced significant adverse effects from ALL of the formulary long-acting ACE inhibitors (benazepril, enalapril, fosinopril, lisinopril, Mavik, quinapril and ramipril) that are not expected to occur with the non-formulary ACE inhibitor.
3. Use of ALL of the formulary long-acting ACE inhibitors (benazepril, enalapril, fosinopril, lisinopril, Mavik, quinapril and ramipril) has resulted in therapeutic failure.
4. The patient is stabilized on a non-formulary ACE inhibitor (Aceon, Univasc or Unirectic), is clinically fragile (multiple comorbidities), and changing to a formulary ACE inhibitor would incur an unacceptable risk to the patient (e.g., destabilization, abrupt worsening of symptoms).

Criteria recommended by the DoD Pharmacy & Therapeutics Committee at the August 2005 meeting & approved by the Director, TMA on 13 October 2005; amended under the DoD P&T Committee's expedited review process. For more information, please see DoD P&T Committee minutes.