Pharmacy

Medical Necessity Criteria for Renin-Angiotensin Antihypertensive Agents

Background

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, combinations of ARBs with direct rennin inhibitors. After evaluating the relative clinical and cost effectiveness of the RAAs at its February 2011 meeting the DoD P&T Committee recommended that the following medications listed below be designated as non-formulary. This recommendation was approved by the Director, TMA on 9 May 2011. The following is the current list of non-formulary medications in this class:

- Aliskiren/amlodipine (Tekamlo)
- Olmesartan/amlodipine/Hctz (Tribenzor)

Effective Date: 13 Jul7 2011

Patients currently using a nonformulary agent may wish to ask their doctor to consider a formulary alternative.

Special Notes:

1. Active duty cost share always $0 in all points of service for all three tiers; Active duty cost share always $0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. 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.
3. Prior authorization criteria may apply to some non-preferred formulary agents.

Medical Necessity Criteria for Renin-Angiotensin Antihypertensive Agents

The non-formulary cost share for Tribenzor may be reduced to the formulary cost share IF one or more of the following criteria are met:

1. Use of ALL of the above formulary alternatives is contraindicated.
2. The patient has experienced significant adverse effects with ALL of the above formulary alternatives.

The non-formulary cost share for Tekamlo may be reduced to the formulary cost share IF the following criteria is met:

1. Use of ALL of the above formulary alternatives is contraindicated.

Medical necessity Criteria approved through the DoD P&T Committee process February 2011. For more information, please see the DoD P&T Committee minutes.

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US Family Health Plan Pharmacy Program Medical Necessity Form for **Tribenzor** (olmesartan - amlodipine - HCTZ)

5643

This form applies to the US Family Health Plan Mail Order Pharmacy and the US Family Health Plan Retail Pharmacy programs. This form must be completed and signed by the prescriber.

- Tekamlo and Tribenzor are non-formulary. All other commercially-available Angiotensin II Receptor Blocker agents, also called ARBs, and Direct Renin Inhibitor agents are formulary. In addition, the following formulary agents are the preferred agents and will not require prior authorization: losartan and losartan-HTCZ [Cozaar and Hyzaar], Diovan and Diovan HCT, Exforge and Exforge HCT, Micardis and Micardis HCT, and Twynsta. The other formulary agents listed below are non-preferred and might require prior authorization. **Tekamlo and Tribenzor are non-formulary, but available to most beneficiaries at the nonformulary cost share.**
- You do NOT need to complete this form in order for non-Active duty beneficiaries (spouses, dependents, and retirees) to obtain non-formulary products at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of a non-formulary product is medically necessary. If a non-formulary product is determined to be medically necessary, non-Active duty beneficiaries may obtain it at the formulary cost share.

MAIL ORDER and RETAIL	• The provider may **call**: **1-877-880-7007** or the completed form may be **faxed** to:**1-617-562-5296** • The patient may attach the completed form to the prescription and mail it to: ATTN: Pharmacy, 77 Warren St, Brighton, MA 02135

Step 1 **Please complete patient and physician information** (please print):

Patient Name: _____ Physician Name: _____

Address: _____ Address: _____

_____ _____

Sponsor ID # _____ Phone #: _____

Date of Birth: Secure Fax #:

Step 2 **Please explain why the patient cannot use the formulary medications. Circle a reason code if applicable. You MUST supply a specific written clinical explanation as to why all of the formulary medications would be unacceptable.**

Formulary Medications	Reason	Clinical Explanation
Preferred formulary medications *(do not require prior authorization):* • Losartan and losartan HCTZ [Cozaar/Hyzaar] • Diovan and Diovan HCT • Exforge and Exforge HCT • Micardis and Micardis HCT • Twynsta		
Non-preferred formulary medications *(might require prior authorization):* • Amturnide • Atacand and Atacand HCT • Avapro and Avalide • Azor • Benicar and Benicar HCT • Edarbi • Tekturna and Tekturna HCT • Teveten and Teveten HCT • Valturna	1 2	

Acceptable clinical reason for not using a formulary products:

1. Use of the formulary agents contraindicated.
2. The patient previously responded to a non-formulary agent and changing to a formulary agent would incur unacceptable risk.

Step 3 **I certify the above is correct and accurate to the best of my knowledge.** Please sign and date:

_____ _____

Prescriber Signature Date

Implemented: 13 July 2011