



HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

DEC 22 2004

MEMORANDUM FOR SURGEON GENERAL OF THE ARMY  
SURGEON GENERAL OF THE NAVY  
SURGEON GENERAL OF THE AIR FORCE

SUBJECT: TRICARE Pharmacy Benefit Program Formulary Management

- References: (a) 10 U.S.C. 1074g  
(b) 32 C.F.R. 199.21  
(c) Assistant Secretary of Defense (Health Affairs) Policy Memorandum 98-034, "Policy for Basic Core Formulary and Committed Use Requirements Contracts," April 27, 1998  
(d) Assistant Secretary of Defense (Health Affairs) Policy Memorandum 98-025, "Policy for Implementation of the DoD Pharmacy and Therapeutics Committee," March 23, 1998  
(e) Assistant Secretary of Defense (Health Affairs) Policy Memorandum, "Policy for Dispensing Prescriptions in Outpatient Military Pharmacies," December 8, 1999

Effective January 1, 2005, references (c), (d) and (e) are canceled and replaced by this policy.

The Department of Defense was directed by reference (a) to establish an effective, efficient, integrated pharmacy benefits program for the Military Health System, to include a Uniform Formulary of pharmaceutical agents. This statutory requirement was implemented by reference (b), establishing the TRICARE Pharmacy Benefits Program and formulary management for pharmaceutical agents dispensed through military treatment facility (MTF) pharmacies, the TRICARE Mail Order Pharmacy Program, and the TRICARE Retail Pharmacy Program. Formulary management in the Military Health System is accomplished by the DoD Pharmacy and Therapeutics Committee through the Uniform Formulary, the Basic Core Formulary, and the Extended Core Formulary. Formulary management by the Services and individual MTFs is limited to the circumstances described in this policy.

### **Uniform Formulary**

Formulary management for the Department of Defense is the responsibility of the Director, TRICARE Management Activity. Decisions regarding the TRICARE Uniform Formulary will be based on the Director's review of the determinations and

**HA POLICY: 04-032**

recommendations of the DoD Pharmacy and Therapeutics (P&T) Committee, as well as comments and recommendations of the Beneficiary Advisory Panel, in making final decisions regarding which pharmaceutical agents in a therapeutic class should be designated for formulary or non-formulary status. The DoD P&T Committee will consider the relative clinical effectiveness and relative cost effectiveness of pharmaceutical agents in a therapeutic class in recommending the selection of agents for the DoD Uniform Formulary (UF).

Pharmaceutical agents selected for the UF will be classified as generic or formulary for the purpose of determining the appropriate cost share. Pharmaceutical agents not selected for the UF are non-formulary, and will be cost-shared as such in retail pharmacies and the TRICARE Mail Order Program (TMOP). In accordance with reference (b), non-formulary pharmaceutical agents are excluded from MTF formularies. MTFs may make non-formulary agents available to covered beneficiaries only for prescriptions approved through the non-formulary special order process that validates the medical necessity for use of the non-formulary agent in lieu of a pharmaceutical agent that is on the MTF formulary. The non-formulary special order process may only be used for prescriptions written by MTF providers or for prescriptions written by a civilian provider to whom the patient was referred by the MTF.

### **Basic Core Formulary**

The Basic Core Formulary (BCF) is a subset of the pharmaceutical agents that are included on the UF. The BCF contains the minimum set of pharmaceutical agents that each MTF pharmacy must have on its formulary to support the primary care scope of practice for Primary Care Manager (PCM) enrollment sites. Pharmacies at these sites are full service MTF pharmacies. Limited service MTF pharmacies (e.g., specialty pharmacies within an MTF and/or pharmacies servicing **only** active duty) are not required to include the entire BCF on their formularies, but may limit their formularies to those BCF agents appropriate to the needs of the patients they serve. The BCF applies only to MTF formularies and does not affect the TRICARE Mail Order Pharmacy Program or the TRICARE Retail Pharmacy Program.

In creating the BCF, the DoD P&T Committee may identify a subset of UF agents in each therapeutic class that provide greater value than other UF agents in the class based upon an additional determination of the relative clinical effectiveness and relative cost effectiveness of the UF agents. A pharmaceutical agent will be included on the BCF if it meets the following conditions: (1) the pharmaceutical agent is classified as generic or formulary on the UF; (2) the pharmaceutical agent is in a therapeutic class that supports the primary care scope of practice for Primary Care enrollment sites; and (3) the pharmaceutical agent is determined to provide greater value than other UF agents in that therapeutic class because of the DoD P&T Committee's determination of the relative clinical effectiveness and relative cost effectiveness of the agent.

**HA POLICY: 04-032**

The DoD P&T Committee may recommend one or more of the agents for inclusion on the BCF. Pharmaceutical agents are recommended for inclusion on the BCF because they offer a significant clinical advantage and/or cost effectiveness advantage over other pharmaceutical agents within a therapeutic class. Individual MTFs must have all BCF pharmaceutical agents on their formulary, and the Services have no authority to direct otherwise. In addition to the required BCF pharmaceutical agents, MTF formularies may include one or more of the remaining pharmaceutical agents listed on the uniform formulary within that therapeutic class.

### **Extended Core Formulary**

The Extended Core Formulary (ECF) generally includes pharmaceutical agents within therapeutic classes that are used to support more specialized scopes of practice than the pharmaceutical agents on the BCF. Individual MTFs are not required to have any pharmaceutical agents on their formulary except those on the BCF. However, individual MTFs whose scope of health care services exceed the scope of practice for Primary Care Manager enrollment sites may have formularies beyond the mandatory BCF, based on local requirements as determined by the MTF's P&T Committee. The ECF is a subset of the pharmaceutical agents in therapeutic classes other than classes covered by the BCF that each MTF pharmacy must have on its formulary. An MTF formulary is not required to include any of the therapeutic classes that are included on the ECF. However, if an MTF formulary does include a therapeutic class from the ECF, the MTF formulary must include all of the pharmaceutical agents that are on the ECF within that therapeutic class. The ECF applies only to MTF formularies and does not affect the TRICARE Mail Order Pharmacy Program or the TRICARE Retail Pharmacy Program.

The DoD P&T Committee determines which therapeutic classes are included on the ECF. In creating the ECF, the DoD P&T Committee may designate a subset of UF agents in each therapeutic class that provide greater value than other UF agents in the class based upon an additional determination of the relative clinical effectiveness and relative cost effectiveness of the UF agents. A pharmaceutical agent will be included on the ECF if it meets the following conditions: (1) the pharmaceutical agent is classified as generic or formulary on the UF; (2) the pharmaceutical agent is in a therapeutic class that supports a scope of practice that exceeds the scope of practice for Primary Care enrollment sites; and (3) the pharmaceutical agent is determined to provide greater value than other UF agents in that therapeutic class because of the DoD P&T Committee's determination of the relative clinical effectiveness and relative cost effectiveness of the agent.

The DoD P&T Committee may recommend one or more of the agents for inclusion on the ECF. Pharmaceutical agents are recommended for inclusion on the ECF because they offer a significant clinical advantage and/or cost effectiveness advantage

over other pharmaceutical agents within a therapeutic class. Individual MTFs must have all ECF pharmaceutical agents within a therapeutic class on their formulary if the MTF P&T Committee has determined that class is necessary to support the MTF's scope of practice. In addition to the designated ECF agents, MTF formularies may include one or more of the remaining pharmaceutical agents listed on the uniform formulary within that therapeutic class.

### **MTF Formularies**

Although the UF, BCF and ECF determine much of the content of MTF formularies, the MTF Commander, based on the recommendation of the MTF P&T Committee, still makes some decisions regarding the content of the MTF formulary for outpatient pharmaceutical services as outlined below and illustrated in Appendix A. The MTF Commander, based on the recommendation of the MTF P&T Committee, retains decision authority pertaining to MTF formulary management of pharmaceuticals used solely for inpatient services.

An MTF formulary at a full service MTF pharmacy must include all the pharmaceutical agents that are included on the BCF. In order to meet the clinical needs of its patient population, the MTF formulary may also include additional pharmaceutical agents that are not included on the BCF, as long as the additional pharmaceutical agent is included on the UF.

The MTF decides which therapeutic classes from the ECF are to be included on the MTF formulary. If an MTF formulary includes a therapeutic class from the ECF, the MTF formulary must include all the pharmaceutical agents that are on the ECF within that therapeutic class. In order to meet the clinical needs of its patient population, the MTF formulary may also include additional pharmaceutical agents that are not included on the ECF, as long as the additional pharmaceutical agents are included on the UF.

An MTF formulary cannot include a pharmaceutical agent that is classified as non-formulary in regard to the UF. Although not a beneficiary entitlement, non-formulary pharmaceutical agents may be made available to eligible covered beneficiaries through MTF pharmacies for prescriptions approved through the non-formulary special order process that validates the medical necessity for use of the non-formulary pharmaceutical agent in lieu of a pharmaceutical agent that is on the MTF formulary.

A hypothetical example in Appendix A illustrates how the UF, BCF and ECF may affect the content of an MTF formulary.

### **Transition to the Uniform Formulary**

A new Charter, superseding reference (d), has been issued for the DoD Pharmacy and Therapeutics Committee. The Committee shall meet at least quarterly to review therapeutic classes of pharmaceutical agents and make recommendations concerning which pharmaceutical agents should be on the Uniform Formulary, the BCF, and the ECF. The committee will review the classes in a methodical but expeditious manner. During the transition period from our previous methodology of formulary management involving only the MTFs and the TRICARE Mail Order Pharmacy Program, previous decisions by the DoD Pharmacy and Therapeutics Committee authorized by references (c) and (d), or committed use requirements contracts executed by DoD or jointly by DoD and VA, shall continue in effect. As therapeutic classes are reviewed under the new formulary management process and pharmaceutical agents are designated for formulary/non-formulary status, this policy shall apply.

It is anticipated that the DoD Pharmacy and Therapeutics Committee will begin its process of reviewing therapeutic classes for the Uniform Formulary during the second quarter of FY 2005. Specific information regarding the therapeutic classes to be reviewed at Committee meetings will be posted to the DoD Pharmacoeconomic Center (PEC) website [http://www.pec.ha.osd.mil/PT\\_Committee.htm](http://www.pec.ha.osd.mil/PT_Committee.htm). Manufacturers will be encouraged to submit their most favorable pricing data through a Uniform Formulary Blanket Purchase Agreement (BPA) offer. Additional information on the Uniform Formulary BPA process and procedures for the submission of such offers can be found at the DoD PEC web site.

### **Administration of the Uniform Formulary**

The Services and MTF Commanders are responsible for ensuring compliance with TRICARE Uniform Formulary policy and formulary management determinations, including compliance with the terms of any national contracts executed by DoD or jointly by DoD and VA. As therapeutic classes are reviewed, any existing pharmaceutical contracts, blanket purchase agreements, or voluntary incentive agreements that are inconsistent with the statutory requirements of the TRICARE Pharmacy Benefits Program will be addressed at the time the class is reviewed. The Services and MTF Commanders will assure that local prescriber or pharmacy industry initiatives to supplant or circumvent national contracts, agreements, or TRICARE Uniform Formulary decisions do not occur.

As therapeutic classes are reviewed and specific pharmaceutical agents are classified as formulary or non-formulary, a decision will also be made as to the effective date of change from formulary to non-formulary. Under reference (b), the effective date may be no more than 180 days from the date of the decision, but may be less, and will apply in all pharmacy service venues.

**HA POLICY: 04-032**

This policy will allow DoD to comply with the statutory and regulatory requirement for an effective, efficient, integrated pharmacy benefits program for the Military Health System.

  
William Winkenwerder, Jr., MD

**HA POLICY: 04-032**

## Appendix A

A hypothetical example involving two fictitious therapeutic classes illustrates how the Uniform Formulary (UF), Basic Core Formulary (BCF) and Extended Core Formulary (ECF) affect the content of an MTF formulary.

Therapeutic classes X and Y each contain five pharmaceutical agents. Class X is on the BCF. Class Y is on the ECF. The formulary status of the pharmaceutical agents in each of the classes is illustrated in Table 1.

Table 1. Formulary Status of Pharmaceutical Agents

Therapeutic Class	Agents on UF	Non-formulary agents	Agents on BCF	Agents on ECF
X	A,B,C, D	E	A and B	None
Y	G,H,I, J	K	None	G and H

Given the formulary status of the pharmaceutical agents in Table 1, the MTF formulary:

- Must include agents A and B, and it may include agents C and/or D.
- Must include agents G and H if therapeutic class Y is included on the MTF formulary. If G and H are on the MTF formulary, it may also include agents I and/or J.
- MTF formulary cannot include agents E or K.