

**CHARTER
DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

I. AUTHORITY

The National Defense Authorization Act (NDAA) for Fiscal Year 2000, Public Law 106-65, October 5, 1999, Section (Sec.) 701, amended Chapter 55 of Title 10, United States Code, by inserting after Sect. 1074f a new section, 1074g, entitled “Pharmacy Benefits Program.” Under Sec. 1074 g (b), the Secretary of Defense is required to establish a Pharmacy and Therapeutics (P&T) Committee for the purpose of developing a uniform formulary of pharmaceutical agents, review such formulary on a periodic basis, and make additional recommendations regarding the formulary as the Committee determines necessary and appropriate. The Committee shall function under procedures established by the Secretary under regulations promulgated to implement this section.

II. DEPARTMENT OF DEFENSE P&T COMMITTEE

A. GENERAL PROVISIONS

The Department of Defense (DoD) P&T Committee (henceforth, P&T Committee) is responsible for development and maintenance of a uniform formulary. It consists of government members whose primary mission is to uniformly, consistently, and equitably provide appropriate drug therapy to meet patients’ clinical needs in an effective and efficient manner. The P&T Committee focuses its attention on actions that will encourage the safe and effective use of pharmaceutical agents that will provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending.

B. PROCEDURES

The uniform formulary shall assure the availability of pharmaceutical agents in the complete range of therapeutic classes. The selection for inclusion on the uniform formulary of particular pharmaceutical agents shall be based on the relative clinical effectiveness and relative cost effectiveness of the agents in each therapeutic class of pharmaceutical agents.

1. Clinical Effectiveness: The P&T Committee shall presume a pharmaceutical agent in a therapeutic class is clinically effective and should be included on the uniform formulary. This presumption shall exist unless the P&T Committee finds by majority of those voting that the agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical

outcomes over other drugs included on the uniform formulary in that therapeutic class. If the P&T Committee makes such finding, the P&T Committee may recommend that the pharmaceutical agent be placed in the non-formulary tier (Tier 3) or not covered tier (Tier 4) of the uniform formulary.

2. **Cost Effectiveness:** The P&T Committee, in evaluating the cost effectiveness of pharmaceutical agents, shall evaluate the cost of agents in a therapeutic class in relation to the safety, effectiveness, and clinical outcomes of the other agents in the class. If the P&T Committee determines by majority of those voting that a pharmaceutical agent in a therapeutic class is not cost effective in relation to the safety, effectiveness, and clinical outcomes of such agent, the P&T Committee may recommend that the agent be placed in the non-formulary tier (Tier 3) or not covered tier (Tier 4) of the uniform formulary.
3. **Basic Core Formulary:** The Basic Core Formulary (BCF) is a sub-set of the approved uniform formulary and applies only to Military Medical Treatment Facilities (MTFs). The BCF is the minimum formulary that must be available at all MTFs. Pharmaceutical agents recommended for approval for the uniform formulary may also be recommended for inclusion on the BCF.
4. **Extended Core Formulary:** The Extended Core Formulary (ECF) is a sub-set of the approved uniform formulary, and applies only to MTFs. The ECF is a list of medications that may be on an MTF formulary, if providers at that MTF require agents from that therapeutic class for the scope of care that is provided at the MTF beyond primary care. Pharmaceutical agents recommended for approval for the uniform formulary may also be recommended for inclusion on the ECF.
5. All recommendations shall be by majority of the voting members participating.

C. DUTIES OF THE DoD P&T COMMITTEE

1. Periodically conduct therapeutic drug class reviews and reviews of The Food and Drug Administration-newly approved (innovator) drugs that are appropriate for the TRICARE pharmacy benefit and over-the-counter drugs.
2. Consider the relative safety, effectiveness, cost and other pertinent factors in recommending pharmaceutical agents to be included on the uniform formulary, BCF, and ECF, and those pharmaceutical agents recommended for non-formulary (Tier 3) or not covered (Tier 4) status.
3. Recommend an implementation period and medical necessity criteria for all pharmaceutical agents recommended for non-formulary (Tier 3) status.

4. Recommend an implementation period for those pharmaceutical agents recommended for not covered (Tier 4) status.
5. Identify drugs that are candidates for prior authorization and recommend prior authorization criteria and an implementation period that would be applied across the Military Health System (MHS).
6. Identify drugs that are candidates for quantity limits and recommend quantity limits that would be applied across the MHS.
7. Evaluate requests from local MTF P&T Committees for changes to the uniform formulary, BCF and ECF, quantity limits, prior authorizations, and medical necessity criteria, and utilize standardized processes for handling such requests.
8. Consider medical readiness implications pertaining to BCF, ECF, prior authorization, medical necessity criteria and quantity limit issues.
9. Review MHS pharmacy utilization and cost data.
10. Review and approve the contracting strategies and evaluation factors for DoD and joint Department of Veterans Affairs (VA)/DoD pharmaceutical procurement contracting initiatives, and prospectively identify circumstances where it would be medically necessary to use a non-contracted drug in lieu of a contracted drug.
11. Evaluate drugs for inclusion on the Select Maintenance Drug List for the Expanded MTF/Mail Order Pharmacy Initiative.
12. Review and recommend pre-authorization of drugs from manufacturers that are non-compliant with Section 703 of NDAA for Fiscal Year 2008.
13. Consider other matters related to the uniform formulary, MHS drug distribution system, MHS GENESIS-specific requirements, and issues involving the safe and effective use of pharmaceutical agents within the MHS.

D. MEMBERSHIP

The P&T Committee members must have expertise in identifying the medical and pharmaceutical needs of the populations serviced throughout the MHS. The P&T Committee will have 20 voting members and additional non-voting members as outlined below.

1. Voting Members

- a. Chief, Clinical Support Division, Medical Affairs, Defense Health Agency (DHA)
 - b. Chief, Pharmacy Operations Division, Healthcare Operations, DHA
 - c. Chief, Formulary Management Branch, Pharmacy Operations Division, Healthcare Operations, DHA (recorder)
 - d. Physician Representative TRICARE Health Plan, Healthcare Operations
 - e. The Army, Navy, and Air Force service representative Internal Medicine specialty consultants or designees
 - f. One Army, Navy, Air Force or DHA Pediatric specialty consultant or designees (Active Duty or Government Civilian employee)
 - g. One Army, Navy, Air Force or DHA Family Medicine specialty consultant or designee (Active Duty or Government Civilian employee)
 - h. One Army, Navy, Air Force or DHA Obstetrics/Gynecology specialty consultant or designees (Active Duty or Government Civilian employee)
 - i. The Army, Navy, and Air Force service representative Pharmacy consultants
 - j. One physician or pharmacist from the United States Coast Guard
 - k. One (each) provider at large from the Army, Navy, Air Force and DHA (Active Duty or Government Civilian employee)
 - l. One Army, Navy, Air Force or DHA Oncology specialty consultant or designee (Active Duty or Government Civilian employee)
 - m. One Army, Navy, Air Force or DHA Oncology pharmacist (Active Duty or Government Civilian employee)
2. Non-Voting Members
 - a. Representative(s) from the DHA Office of General Counsel
 - b. One physician or pharmacist from the VA

- c. Representative(s) from the DHA Managed Care Contracting Division
 - d. Representative(s) from the Defense Logistics Agency
 - e. Contracting Officer's Representative(s) from the TRICARE Pharmacy Program purchased care contract(s), which include the TRICARE retail network and/or TRICARE Mail Order Pharmacy points of service.
3. Each voting member and non-voting member may have a designated alternate who can represent the member, including voting (if representing a voting member), at P&T Committee meetings in the event the member cannot attend.
 4. Additional subject matter experts may be requested to participate as required to address specific drugs and/or therapeutic classes under review.
 5. The DoD P&T Committee will meet at least quarterly, as scheduled by the Chair. Meetings will be scheduled far enough in advance to facilitate appropriate scheduling and notice of Beneficiary Advisory Panel (BAP) meetings.
 6. The Chair will be the Chief, Clinical Support Division, Medical Affairs, DHA (or designee).
 7. The TRICARE Health Plan representative is included to provide insight on network provider issues. He/she shall be the Senior TRICARE Health Plan Medical Director (or designee).

E. SUPPORTING AGENCY

The DHA will provide administrative and related support, including the funding of members' travel to P&T Committee meetings.

III. **AGENDA AND ROUTING OF MINUTES**

The agenda will be provided to the P&T Committee members no later than seven days prior to the meeting date. P&T Committee meeting minutes will be forwarded to the Chair of the P&T Committee, and the Chief, Pharmacy Operations Division, Healthcare Operations, DHA, no later than 21 days after the meeting. The BAP will be provided an opportunity to comment on the P&T Committee's uniform formulary recommendations concerning: 1) placement of pharmaceutical agents on the uniform formulary or not covered (Tier 4) status; 2) any applicable implementation periods; and 3) prior authorization requirements. The P&T Committee minutes, including the Committee's

recommendations, along with the comments of the BAP, will then be forwarded to the Director, DHA for final decision.

IV. OWNER

The Chair of the P&T Committee shall be accountable to the Director, DHA, for the performance of the P&T Committee.

V. DURATION OF CHARTER

The Director, DHA, will review this charter every five years from the date of approval.

VI. DATE CHARTER IS FILED

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RONALD J. PLACE
LTG, MC, USA
Director