

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

I. AUTHORITY

Section 1074g of Title 10, United States Code requires the Secretary of War 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 uniform formulary as the P&T Committee determines necessary and appropriate. The P&T Committee functions under procedures established by the Secretary under Part 199.21 of Title 32, Code of Federal Regulations.

II. P&T COMMITTEE

A. General Provisions:

The P&T Committee is responsible for development and maintenance of a uniform formulary of pharmaceutical agents. It consists of government members, majority physicians, to include representatives of the uniformed services facilities and representatives of providers in facilities of the uniformed services, 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 DoW, including consideration of better care, healthier people, and smarter spending.

B. Procedures:

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

1. **Clinical Effectiveness:** It is presumed a pharmaceutical agent in a therapeutic class is clinically effective and should be included on the uniform formulary unless the P&T Committee finds by majority of those voting that the pharmaceutical agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over other pharmaceutical agents included on the uniform formulary in that therapeutic class. This determination is based on the collective professional judgment of the P&T Committee and consideration of pertinent information from a variety of sources determined by the P&T Committee to be relevant and reliable. If the P&T Committee makes such determination, the P&T Committee may recommend that the pharmaceutical agent be placed in the non-formulary tier (Tier 3) or be partially or completely excluded from the uniform formulary (not covered).

2. **Cost Effectiveness:** The P&T Committee, in evaluating the cost effectiveness of pharmaceutical agents, evaluates the cost of pharmaceutical agents in a therapeutic class in relation to the safety, effectiveness, and clinical outcomes of the other pharmaceutical 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 pharmaceutical agent, the P&T Committee may recommend that the agent be placed in the non-formulary tier (Tier 3) or be partially or completely excluded from the uniform formulary (not covered).
 - a. When the P&T Committee determines a pharmaceutical agent to be non-formulary (Tier 3), it is generally not available in Military Medical Treatment Facilities (MTFs) or in the retail point of service unless there is a valid medical necessity. Non-formulary pharmaceutical agents are available in the mail order program.
3. **Basic Core Formulary (BCF):** The BCF is a sub-set of the uniform formulary and is a mandatory component of formularies at all full-service MTFs. The BCF contains a minimum set of pharmaceutical agents that each full-service MTF pharmacy must have on its formulary to support the primary care scope of practice for Primary Care enrollment sites. Limited-service MTF pharmacies are not required to include the entire BCF but may limit their formularies to those BCF agents appropriate to the needs of the patients they serve.
4. **Extended Core Formulary (ECF):** The ECF is a sub-set of the uniform formulary. The ECF is a list of pharmaceutical agents 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.
5. While the BCF and ECF remain in regulation, Defense Health Agency (DHA) policy requires MTFs to follow the full uniform formulary.
6. All uniform formulary recommendations are a majority of the voting P&T Committee members participating.

C. Duties of the DoW P&T Committee:

1. Conduct therapeutic drug class reviews, reviews of Food and Drug Administration-newly approved (innovator) drugs, and certain over-the-counter drugs.
2. Evaluate the relative clinical effectiveness of pharmaceutical agents within a therapeutic class by considering information about their safety, effectiveness and clinical outcome.
3. Evaluate the relative cost effectiveness of pharmaceutical agents in relation to the safety, effectiveness, and clinical outcomes of the other pharmaceutical agents in the class.
4. Recommend the status of pharmaceutical agents be changed from formulary to the non-formulary (Tier 3) of the uniform formulary.

5. Recommend partial or complete exclusion from the uniform formulary any pharmaceutical agent that provides very little or no clinical effectiveness.
6. Recommend an implementation period and/or medical necessity criteria for all pharmaceutical agents recommended for non-formulary (Tier 3) or partially or completely excluded from the uniform formulary.
7. Recommend preferential status to any non-generic pharmaceutical agent of the uniform formulary by treating it for purposes of cost-sharing as a generic product.
8. Identify pharmaceutical agents that require prior authorization and establish prior authorization criteria for the pharmaceutical agent.
9. Identify pharmaceutical agents that require quantity limits and recommend quantity limits.
10. 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.
11. Consider medical readiness implications pertaining to prior authorization, medical necessity criteria, and quantity limit issues.
12. Review Military Health System (MHS) pharmacy utilization and cost data.
13. Review and approve the contracting strategies and evaluation factors for DoW and Department of Veterans Affairs (VA)/DoW 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.
14. Evaluate pharmaceutical agents for inclusion on the TRICARE Maintenance Drug List for the Expanded MTF/Mail Order Pharmacy Initiative.
15. Review and recommend pre-authorization of drugs from manufacturers that are non-compliant with pricing standards for the retail pharmacy program under Sec. 703 of NDAA for Fiscal Year 2008.
16. 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.
17. Recommend criteria for use (CFU) for medications that are ordered and dispensed from MTFs (i.e., both MTF employed healthcare providers and MTF pharmacy). CFU may include automatic therapeutic substitution protocols for all new patients or new and current patients.

D. Membership:

The P&T Committee members must have expertise in treating the medical needs of the populations served through such entities of the MHS and in the range of pharmaceutical and biological medicines available for treating such populations. The P&T Committee will have 20 voting members and additional non-voting members as outlined below.

1. Voting Members
 - a. Physicians:
 - i. Chief, Clinical Support Division, Medical Affairs, DHA

- ii. Physician Representative TRICARE Health Plan
 - iii. The Army, Navy, and Air Force Service representative Internal Medicine specialty consultants or designees
 - iv. One Army, Navy, Air Force or DHA Pediatric specialty consultant or designees (active duty or government civilian employee)
 - v. One Army, Navy, Air Force or DHA Family Medicine specialty consultant or designee (active duty or government civilian employee)
 - vi. One Army, Navy, Air Force or DHA Obstetrics/Gynecology specialty consultant or designees (active duty or government civilian employee)
 - vii. One physician or pharmacist from the United States Coast Guard
 - viii. One (each) provider at large from the Army, Navy, Air Force and DHA (active duty or government civilian employee)
 - ix. One Army, Navy, Air Force or DHA Oncology specialty consultant or designee (active duty or government civilian employee)
- b. Pharmacy:
- i. Chief, Pharmacy Operations Division, Healthcare Operations, DHA
 - ii. Chief, Formulary Management Branch, Pharmacy Operations Division, Healthcare Operations, DHA (recorder)
 - iii. The Army, Navy, and Air Force service representative Pharmacy consultants. This can be delegated to the DHA Pharmacy Consultants (DPC)
 - iv. 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 (OGC)
 - 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 private sector 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. When possible, additional subject matter experts will be consulted in preparation for the P&T meeting to address specific drugs and/or therapeutic classes under review.
5. The DoW 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

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).
8. P&T members:
 - a. May not have any direct financial interest in any pharmaceutical company.
 - b. Must submit an OGE 450 Confidential Financial Disclosure Report and Non-Disclosure Agreement annually.
 - c. May not individually meet with any pharmaceutical company representatives for any product under review by the DoW P&T.

E. Supporting Agency

The DHA will provide administrative and related support, including the funding of travel to P&T Committee meetings for the voting members and DHA OGC representatives.

III. AGENDA AND ROUTING OF MINUTES

The agenda and supporting clinical documents are provided to the P&T Committee members no later than seven days prior to the meeting date. P&T Committee meeting minutes are 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 for review and forwarding to leadership. The BAP is 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 partially or completely excluded from the uniform formulary; 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, are then be forwarded to the Director, DHA or designee for final decision.

IV. OWNER

The Chair of the P&T Committee is 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

David J. Smith, M.D.
Acting Director
Defense Health Agency