
POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

Subsection

- 1.0 Statement of Policy
- 2.0 Mission Statement
- 3.0 Hospital Formulary
- 4.0 Additions or Deletions to the Hospital Formulary
- 5.0 Restricted Drugs
- 6.0 Non-Formulary Medications
- 7.0 Drug Product Selection
- 8.0 Drug Product Quality Reporting System

Revised 5/95, 9/98, 6/01, 9/04

POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

1.0 Statement of Policy

The Pharmacy and Therapeutics Committee is a standing committee of the Medical Executive Committee and serves as the official organizational liaison between the medical staff and the Department of Pharmacy Services. The Committee serves both an advisory and an educational role within the institution to assist in formulating policies and developing educational programs on all matters relating to the evaluation, selection, and use of pharmacological products.

Reviewed 5/95, 6/01; Revised 9/98, 7/05, 10/08

2.0 Mission Statement

Because of the number of drugs available and complexities surrounding their safe and effective use, University of Washington Medical Center, Harborview Medical Center and the Seattle Cancer Care Alliance must have an organized program for maximizing rational drug therapy. The Pharmacy and Therapeutic Committee is the organizational keystone of such a program.

2.1 Administrative Structure

The Pharmacy and Therapeutics (P & T) Committee is an advisory group of the medical staff and is the organizational liaison between the medical staff and the pharmacy department. It is responsible for recommending policy to the medical staff and the hospital administration on matters related to the therapeutic use of drugs.

2.2 The general purpose of the P & T Committee is to ensure the safe and effective use of drugs at University of Washington Medical Center, Harborview Medical Center, University of Washington Physicians Network and the Seattle Cancer Care Alliance.

2.2.1 Advisory - The committee recommends professional policies regarding evaluation, selection, and therapeutic use of drugs.

2.2.2 Educational - The committee recommends programs designed to meet the needs of the professional staff for complete current knowledge of drugs and drug use.

2.3 Organization and Operation

The P & T Committee is composed of at least three physicians, one pharmacist, one nurse, and one hospital administrator. The chairperson is chosen among

POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

the physician members. A pharmacist is designated as secretary. All are voting members except the administrator. All members must disclose any real or potential conflict(s) of interest. This disclosure statement must be completed and submitted at the time of appointment to the Pharmacy & Therapeutics committee or any of its subcommittees or work groups, and resubmitted annually.

2.4 Responsibilities of the Secretary of the P & T Committee include:

2.4.1 Preparation of the committee agenda.

2.4.2 Provision of background information on items of discussion.

2.4.3 Discussion of implications of committee recommendations on medication distribution, economics, personnel, patient safety, and rational therapy.

2.4.4 Communication of P & T decisions to medical, nursing and pharmacy staff via email.

2.4.5 Recording and distribution of minutes.

2.4.6 Maintenance and correspondence files and conducting correspondence for committee.

2.5 P & T Committee Meetings

The P & T Committee meets regularly, on the third Tues of each month from 4-5 pm with location alternating between UWMC and HMC. Meetings can be cancelled with 30 days notice, however; the committee must convene at least six times per year. Persons requesting additions or deletions to the formulary are required to attend the respective meeting to speak to the request and address question that may arise. An agenda and supplementary material will be distributed prior to the meeting for appropriate review.

2.6 Functions

The responsibilities of individuals performing the pharmacy and therapeutic function include the development of a formulary that is reviewed for currentness at stated intervals, the review of all untoward drug reactions, the review of the medication use process.

POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

- 2.7 Responsibilities of the Pharmacy and Therapeutics Committee
 - 2.7.1 The medication formulary.
 - 2.7.1.a To develop a formulary of drugs accepted for safe use within the medical centers and provide for its constant revision. The selection of items to be included in the formulary will be based on objective evaluation of their relative therapeutic merits, safety, and cost. The committee will minimize duplication of the same basic drug type, drug entity, or drug product.
 - 2.7.2 Provide guidance to multidisciplinary groups on safe medication use practices.
 - 2.7.3 To advise the professional staff in all matters pertaining to the use of drugs.
 - 2.7.4 To establish guidelines for the restricted use of selected medication when applicable.
 - 2.7.5 To establish guidelines for non-formulary requests.
 - 2.7.6 To establish guidelines for exemptions from the non-formulary states of certain drugs for specialty services when necessary.
 - 2.7.7 To educate the hospital's professional staff on matters related to drug use.
 - 2.7.8 To study problems related to the distribution and administration of medications including medication incidents.
 - 2.7.9 To maintain an Adverse Drug Reaction reporting program and to review adverse drug reactions occurring in the hospital.
 - 2.7.10 To suggest drug classes for medication utilization evaluation (MUE) and to develop guidelines for those MUE's.
 - 2.7.11 To establish policy and procedures for Medical Service Representative activities specifically concerning displays and the use of sample medications.

POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

- 2.7.12 To establish a comprehensive policy on the use of investigational drugs (JCAHO requires that pharmacy be responsible for proper labeling, storage, and distribution of investigational drugs).

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3.0 Medication Formulary

- 3.1 The Medication Formulary consists of a listing of all pharmaceutical products which are available for use within UWMC/HMC/SCCA.
- 3.2 A continually revised listing of all pharmaceuticals selected by the P & T Committee shall be maintained by the Pharmacy and incorporated into the Medication Formulary.
- 3.3 The Medication Formulary will include the following:
- 3.3.1 An alphabetical index of the available products by generic name.
 - 3.3.2 An pharmacological index of available products, arranged by therapeutic category consistent with the American Hospital Formulary Services numbering system.
 - 3.3.3 The specific dosage forms of each drug entity stocked in the Pharmacy.
 - 3.3.4 Policy and procedures regarding the dispensing of drugs as well as other essential information to promote rational and economic drug utilization within UWMC/HMC/SCCA.
 - 3.3.4.a The ordering of a Formulary Drug or item.
 - 3.3.4.b Restricted Formulary Drugs Policy and Procedures.
 - 3.3.4.c Non-Formulary Drugs (Special Orders).
 - 3.3.4.d Procedures for Additions or Deletions to the formulary.
 - 3.3.4.e Use of Investigational Drugs.
 - 3.3.4.f Self Administered Medication Program.
 - 3.3.5 Phone numbers to obtain information.

POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

- 3.4 The electronic medication formulary will be updated monthly and printed copies will be redistributed annually.
- 3.5 Additions or deletions will be published in a quarterly newsletter and will become effective as per Section 12, Subsection 4 (for additions), and as per Section 9, Subsection 25 (for deletions).
- 3.6 Copies of the UWMC/HMC/SCCA medication formulary will be provided to each clinic, nursing unit, and E.R.
- 3.7 The Purchasing Assistant Director, in collaboration with the Inpatient and Outpatient managers, will monitor the formulary on a quarterly basis for removal of obsolete products or products with minimal use.
 - 3.7.1 A list of drugs proposed for deletion will be sent to the Secretary of the P & T Committee for consideration by the Committee.
 - 3.7.2 Once approved for deletion, the products will be removed from the formulary and from the shelves for credit from the manufacturer, as per Section 9, Subsection 25.

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POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

4.0 Additions or Deletions to UWMC/HMC Formulary

4.1 Statement of Policy

Request for additions or deletions of drugs to the hospital formulary must be submitted in writing to the Secretary of the Pharmacy & Therapeutics Committee by an attending physician. Members of the committee may also submit items for addition, deletion, or a change in formulary status.

4.2 Procedures

- 4.2.1 Changes to the formulary will be considered by submitting a properly completed "Request for Addition to Formulary" form to the P & T Committee, through the Secretary of the P & T Committee.
- 4.2.2 FDA approved pharmaceuticals, biologicals, or pharmaceutical device may be considered for formulary addition. Non FDA approved products, non compendial products, or investigational entities, shall not be considered for formulary status and should be handled as investigational new drugs. (See Section 15)
- 4.2.3 Requests will be considered at regularly scheduled meetings of the P & T Committee.
- 4.2.4 The physician initiating the request must attend the committee meeting when his or her request is evaluated.
- 4.2.5 The request will be worked up in a standard monograph form by a staff pharmacist or pharmacy resident.
- 4.2.6 P & T drug monographs will be distributed to members of the committee and the original requester prior to the P & T Committee meeting.
- 4.2.7 Requests for changes to the formulary will be presented at the P & T Committee meeting for action. Actions on requests will be consistent with the mission of the P & T Committee to provide the medical staff with the most effective and safe therapeutic agents, assure rational drug use, and provide therapeutically effective and economical treatment for the patient.

POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

- 4.2.8 All P & T drug addition decisions will take effect on the first of the month following the P & T meeting. This will allow time for the clinical staff, purchasing and drug information to distribute the information, become informed and have the product available. Also see section 9, subsection 25 regarding deletions from Medical Center's Formulary.

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POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

5.0 Restricted Drugs

5.1 Statement of Policy

- 5.1.1 A restricted drug is a therapeutic agent added to the formulary by the P & T Committee under the "Restricted Drug Category".
- 5.1.2 The "Restricted Drug Category" consists of drugs which may have a limited scope of applicability in diagnosis or therapy, or have unique toxicity potential or hazard liability, or lack unique properties which would provide any demonstrable advantage over existing formulary products, although under specific circumstances the drug may be a useful alternative to an existing formulary agent.
- 5.1.3 Restricted drug use is controlled by the P & T Committee. The P & T Committee may restrict a drug by:
 - 5.1.3.1 Requiring specialty service approval prior to pharmacy dispensing (Level I Restriction) or
 - 5.1.3.2 Limiting its use to one or more individual specialists, specialty services, or diagnoses (Level II Restriction).
- 5.1.4 Pharmacy personnel shall be responsible for the acquisition, storage, distribution and inventory of restricted formulary drugs, and will work in concert with the designated specialty group to maintain the compliance of the "Restricted Drug Category".
- 5.1.5 Restricted formulary or non-formulary agents used in clinical trials approved by the University of Washington Human Subjects Review Committee are exempt from the Policy requirements when used for study subjects.

5.2 Procedure to Obtain Release of a Restricted Drug

5.2.1 Level I Restricted Drugs

- 5.2.1.1 Pharmacist informs prescribing physician of agent's restricted use and requirement for subspecialty service approval. Prescribing physician is responsible for requesting approval from designated subspecialty service.

POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

- 5.2.1.2 Subspecialty service representative approves agent, recommends an alternative agent(s), or denies use of the restricted agent (In the latter case, an appeal may be made to the subspecialty service attending by the patient's attending physician.)
 - 5.2.1.3 Subspecialty service representative calls pharmacy and gives verbal approval for use of the restricted agent. The representative must identify himself/herself, give service they are representing and name of patient drug is to be used on.
 - 5.2.1.4 Pharmacy notes on the computerized medical record that the subspecialty service authorized release of the restricted drug.
 - 5.2.1.5 It is the responsibility of the subspecialty service from whom permission is required to have a representative available at all times for consultation. This task generally falls to the fellow or senior resident on the service. In situations where the permission-granting authority cannot be reached by the patient's physician in a reasonable period of time, the attending physician on the subspecialty service may be asked for approval.
- 5.2.2 Level II Restricted Drugs
- 5.2.2.1 Pharmacist informs any unauthorized prescribers of the agent's restricted status and alternative formulary products available for use.
 - 5.2.2.2 If the drug is determined to be absolutely necessary for a condition not explicitly covered by the restriction, then the pharmacy may release the restricted agent to the patient.
 - 5.2.2.3 When a Level II restricted drug is released to the patient, the pharmacy will note the rationale for the exception on the computerized medical record.

POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

6.0 Non-Formulary Medications

6.1 Policy

This policy defines the process for non-formulary medication usage. Pharmacy is responsible for the acquisition, storage, distribution, inventory, and monitoring usage of non-formulary drugs.

6.2 Procedures

6.2.1 When a non-formulary medication is ordered for use in a patient, the pharmacist will contact the prescriber to determine the rationale for the request, and whether a formulary medication would meet the patient's needs. If the prescriber and the pharmacist determine that the non-formulary medication is necessary, the pharmacist will initiate the non-formulary request form.

6.2.2 Once completed, the non-formulary drug request form will be forwarded to pharmacy purchasing for acquisition of the product. Non-formulary products are not routinely stocked, and thus there will be a delay in the delivery of the drug to the patient.

6.2.1.1 Pharmacy purchasing will obtain the smallest package size sufficient to meet the patient's needs.

6.2.2.2 Pharmacy purchasing will provide the relevant cost data to the pharmacist or billing technician as appropriate.

6.2.3 The Outcomes and Cost Management Pharmacist will review usage reports for non-formulary medications, and present to the Pharmacy and Therapeutics Committee as part of the monograph and DUE process.

6.2.3 Pharmacy will provide additional information about the drug product via electronic formulary (Efacts)

POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

7.0 Drug Product Selection

- 7.1 The Department of Pharmacy Services will select the vendor for drug entities admitted to the formulary by the Pharmacy and Therapeutics Committee.
- 7.2 Vendor selection will be based on vendor quality issues, vendor's ability to supply, packaging, breadth of product line, approved NDA, returned goods policy, direct vs. wholesaler distribution, nonperformance coverage, product quality, and cost.
- 7.2.1 Competitive bids will be sought on multisource or multivendor products (see Purchasing, Section 9, Subsection 2.0).
- 7.2.2 Invitations to bid may include in its requirements from manufacturers:
- 7.2.2.a Submission of bioavailability data.
- 7.2.2.b Sample of packaging.
- 7.2.2.c Return-goods policy.
- 7.2.2.d Evidence of compliance with current good manufacturing practices.
- 7.3 The Pharmacy will be able to add or delete new dosage forms after the drug entity has been approved by the P & T Committee.
- 7.3.1 When possible, all of a drug's individual dosage forms will be purchased from the same manufacturer to assure predictable drug response or patient acceptance, safety and/or education.

Exceptions: Different dosage forms of a drug may be purchased from different manufacturers when points in 7.3.1 are not applicable: eg. IV drug purchase from one manufacturer and oral drug from another manufacturer.

POLICIES AND PROCEDURES

Section 12: Pharmacy & Therapeutics Committee Drug Product Selection

8.0 Drug Product Quality Reporting System

Drug product or supply defects will be reported to purchasing personnel in the Pharmacy and, when appropriate, to the FDA and the vendor or manufacturer of the affected product. The FDA is notified thru the Medwatch Medical Products Reporting Program.

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