

Pharmacy and Therapeutics Committee  
*Guidance Document Regarding New Generic Drug Policy  
for the Preferred Drug List*

***Introduction***

The Virginia Medicaid Pharmacy and Therapeutics (P&T) Committee, in its meeting on April 17, 2007, requested the development of a Guidance Document to address the management of generic drugs in classes subject to the Preferred Drug List (PDL). Of interest to the Committee was clarifying the conditions in which a new generic drug would be adopted as “preferred” on the PDL; particularly when immediate action is warranted and there are 30 days or more until the next scheduled P&T Committee meeting. The intent was to create a default policy for the management of new generics while maintaining the primary methods of reviewing new generics as a regular part of the P&T Committee meeting agenda. Optimally, the P&T Committee will review pending generics and act upon all new generics during annual drug class reviews. A motion was made and unanimously approved to create a Guidance Document to develop a policy to address this issue.

One recommendation was to utilize price points as a method of determining when generic drugs should be considered for preferred status on the PDL. In addition, the Committee’s discussion included the potential removal of brand name drugs from preferred status when therapeutically equivalent generic drugs are more cost effective. This Guidance Document outlines current policies and proposed guidelines for the future management of new generics in drug classes subject to the PDL.

***Objective***

**The goal of the policy is to achieve more timely capture of cost savings that result from the market introduction of less expensive, therapeutically equivalent generics in PDL-eligible drug classes.**

Guidelines will be developed to allow the Department to take interim actions, in the absence of a P&T Committee discussion, which are in the best financial interest of the Commonwealth. The policy will not address clinical issues where health and safety concerns are present because all drugs involved are therapeutically equivalent. This policy recognizes that the PDL is mature and the most significant changes now relate to the introduction new generics in established PDL-eligible drug classes.

***Current New Drug Policies***

Since its inception, the P&T Committee has adhered to policies for reviewing new drugs in therapeutic classes subject to the PDL as well as a specific new generic drug policy (See “Preferred Drug List Generic Policy” and “Process for Reviewing New Drugs” at the following link: [http://www.dmas.virginia.gov/pharm-p&t\\_committee.htm](http://www.dmas.virginia.gov/pharm-p&t_committee.htm)). Under the current policy, as the Food and Drug Administration (FDA) approves a new drug product in a class previously reviewed and deemed “PDL-eligible” by the P&T Committee, the drug is immediately considered non-preferred and requires prior authorization. Further determination of the drug’s status is typically conducted by the P&T Committee at its next meeting; however, current guidelines allow the Department’s Director to change new generics to preferred, in consultation with the P&T Committee Chair, if he chooses, where drugs are therapeutically equivalent and cost information warrants this change. This process includes a review of supplemental rebate contracts to ensure there are no conflicts as well as appropriate notification to P&T Committee members and public stakeholders.

Item 302 S.2.b (Chapter 847) of the 2007 General Assembly Appropriations Act requires that the P&T Committee schedule meetings at least quarterly to review any drug in a class subject to the PDL that is newly approved by the FDA, provided there is at least thirty (30) days notice of approval prior to the quarterly meeting. First Health Services Corporation (FHSC) monitors all new drugs (brand and generic) in PDL-eligible classes introduced in the market through weekly updates from First DataBank (FDB) and notifies the

Department of changes. A drug will be considered eligible for P&T Committee review if it meets one of the following criteria:

- A “new brand” drug defined by the FDA as having the new drug application (NDA) approved which indicates that the product may be marketed in the United States
- A “new brand of an established generic” and has met the FDA definition above of “new brand”
- A “First Generic” on the monthly FDA update of “Generic Drug Approvals”. First Generics are those drug products that have not previously been approved as generic drug products and are new to the marketplace.

Drugs that meet these criteria are included on the agenda of the next P&T Committee meeting for review, regardless of whether an annual review is conducted for the respective drug class. New, non-branded generic drugs within a drug class previously evaluated by the P&T Committee are deemed the same PDL status (preferred or non-preferred) as the existing generic drugs in the related class and therefore, will be addressed at the next annual review of the class.

FHSC makes recommendations for the PDL status of the drug based on the determination of its potential “cost advantage”. The "cost advantage" is currently determined by the final net cost, which is the cost to the Commonwealth net of all federal (CMS) and supplemental rebates. When comparing the final net cost of the generic to the brand, the lesser cost determines which drug presents the greatest “cost advantage”. At the point the cost difference of the generic is neutral or in the best interest of the Department, a recommendation is made to change the status of the generic to preferred along with the brand. With the P&T Committee’s next annual review of the class, it may also be recommended to change the brand to non-preferred.

*The new generic drug policy will be integrated with existing policies to clarify interim actions in the absence of a P&T Committee discussion.*

### ***Recommendations for Future Management of New Generic Drugs on PDL***

The following changes or clarifications are recommended to the current new drug policies when brand drug A is preferred and a new generic of drug A is released to the market or scheduled for release to the market:

#### **Procedural Change/ Clarification**

1. A “new generic watch list” will be established and updated on an ongoing basis with all new generics in PDL-eligible classes as they enter the market or are anticipated (with FDA-approval). This will include both first time generics as well as multi- source generics that affect the marketplace. On a quarterly basis, the “new generic watch list” will be sent via e-mail to the Department, P&T Committee Chair and another P&T Committee member. This document will contain the PDL class name; the generic and brand names; the current PDL status of both the brand and generic; information on Federal Upper Limit (FUL) or Maximum Allowable Cost (MAC) price, if they exist; summary of financial comparison; number of manufacturers; recommendations for PDL action; and other pertinent information. Also sent quarterly will be an updated PDL criteria showing all brands and generics as well as their PDL status. A generic watch list or update will be sent on an ad-hoc basis if pricing changes dictate that more immediate review and action are required by the Department.
2. Within two weeks of the new generic drug’s pricing information being posted to First DataBank, Virginia Medicaid’s drug database, FHSC will evaluate the financial impact; the final net cost (drug cost minus all rebates) of preferred brand A will be compared to the final net cost of generic A. This pricing evaluation of new generic drugs will include consideration of the current FUL and MAC pricing, if they exist. *The publishing of the generic price on FDB is an indication that the generic is widely available in the market.* This information will be included on generic watch list and sent on a quarterly or ad hoc basis to the Department, P&T Committee Chair, and another P&T Committee member.

3. All supplemental rebate contract addendums proposed by manufacturers must be thoroughly reviewed to ensure there are no provisions in conflict with this policy.
4. The PDL Quicklist and criteria will be updated and posted to the DMAS and FHSC web sites within a week of any decisions made by the Department's Director, who may consult with the P&T Committee Chair or another member of the P&T Committee, outside of a P&T Committee meeting.

#### **Decision-Making Changes/ Clarification**

1. FHSC will advise of the product with the best cost advantage to the Department. At the time the generic and brand drugs are equivalent in final net cost, FHSC will recommend to the Department that the generic drug become preferred and the brand drug non-preferred. *This is recommended because the generic typically begins to be reimbursed at the MAC or FUL once the generic price becomes equivalent to the brand; these pricing methodologies commonly create the lowest price.* FHSC will consider the financial impact on supplemental rebate collections before recommending a brand agent be removed from preferred status on the PDL. The final decision is made by the Department's Director who may consult with the P&T Committee Chair or another Committee member.
2. If there is a need for immediate action, the Department's Director may consult with the P&T Committee Chair or another Committee member to determine the status of new generics in PDL eligible classes. Immediate action will be necessary if there are 30 days or greater until the next P&T Committee meeting and there is widespread market availability of the new generic. FHSC's recommendations, based on the guidelines above, will be provided for consideration of the drug status. DMAS staff will develop a "decision brief" summarizing the relevant information. Unless there are exceptional circumstances, the guidelines will be applied automatically (systems change to prior authorization requirements) with the approval by the Department's Director. Any actions taken outside of P&T Committee meetings by the Director will be communicated to members via email messages and during their next scheduled meeting.
3. Any decision to change the status of the preferred brand to non-preferred outside of P&T Committee meetings will also be made by the Department's Director in consultation with the P&T Committee Chair or another Committee member. DMAS staff will develop a "decision brief" summarizing the relevant information. Any actions taken by the Department's Director in consultation with the P&T Committee Chair or another Committee member, outside of P&T Committee meetings, will be communicated to members via email messages and during their next scheduled meeting. In addition, the brand drug manufacturer will be notified of the change.
4. All new generics to be reviewed by the P&T Committee will be included on the agenda of its next meeting. FHSC will present an updated "generic watch list" to review market information and recommendations for new generics. The clinical discussion of the new generic drugs will occur in the public meeting; there should be little discussion as these drugs are therapeutically equivalent to the brand already established on the PDL. During the confidential session of the meeting, all of the financial information for each new generic along with the current PDL status of the related brand and generic products will be reviewed. The Committee will determine the PDL status of the brand and generic drug products as with current practices.

#### ***Review by the P&T Committee***

All other components of existing new drug policies will remain and these new actions will be integrated into these policies to clarify interim actions in the absence of a P&T Committee discussion. The revised policy will be reviewed by the P&T Committee during an upcoming meeting and published on the DMAS web site. Information on these policy changes may also be included in the next *Medicaid Memorandum* to medical and pharmacy providers that addresses PDL updates.