

**Preferred Drug List (PDL)
Process for Reviewing New Drugs
Approved by the Food and Drug Administration**

Item 326 #2c of the 2005 General Assembly Conference Committee Report requires that the Pharmacy and Therapeutics (P&T) Committee schedule meetings at least quarterly to review any drug in a class subject to the Preferred Drug List (PDL) that is newly approved by the Food and Drug Administration (FDA), provided there is at least thirty (30) days notice of approval prior to the quarterly meeting. As the FDA approves new drug products, the following process will be utilized to review for inclusion on the PDL:

- 1) If the new drug product belongs in a class of drugs that has been previously reviewed by the P&T Committee, the drug will immediately be classified as non-preferred and will require prior authorization in order to be dispensed. Further determination of the status of the drug will be conducted by the P&T Committee.
- 2) First Health Services Corporation will be responsible for informing DMAS of any new drug products and providing relevant clinical information. A drug will be considered eligible for review if it meets one of the following criteria:
 - It is 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. Once the new brand drug name appears on the FDA web site as approved it will be eligible for review.
 - It is a “new brand of an established generic” and has met the FDA definition above of “new brand”.
 - It is deemed 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.
- 3) New, non-branded generic drugs within an established generic drug class that has been previously evaluated by the P&T Committee will not be reviewed. These new generics will be deemed the same PDL status (preferred or non-preferred) as the existing generic drugs in the related class.
- 4) Product line extensions of drugs on the PDL, including strength and form, will be reviewed by DMAS and approved by DMAS’ Director or his/her designee who will determine if a drug review by P&T Committee is necessary.
- 5) The P&T Committee will evaluate the drug for clinical effectiveness and safety at the next scheduled annual review of the drug class. If the P&T Committee determines that the new drug represents a substantial breakthrough in therapy, the Committee can review the drug at their next scheduled meeting even if the annual review of its drug class is not being conducted.
- 6) The Committee will review appropriate studies and publications as part of the decision process. In addition, the Committee will be provided with information such as disease categories and demographics on the affected Medicaid population in order to assess the potential impact on the population. If the drug meets clinical efficacy and safety

standards, the Committee will request applicable pricing information. Based on clinical information and pricing standards, the P&T Committee will determine if the drug will be included in the PDL or require prior authorization.

- 7) If the new drug product does not fall within a drug class previously reviewed by the P&T Committee, the DMAS' Director or his/her designee will make the determination as to whether the drug requires P&T Committee review.