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THE FINAL REPORT OF THE SENATE PRESCRIPTION DRUG STUDY COMMITTEE

COMMITTEE MEMBERS

Senator Jack Murphy, Chairman
District 27

Senator Gloria Butler
District 55

Senator Lee Hawkins
District 49

Senator Ralph Hudgens
District 47

Senator John Wiles
District 37

Prepared by the Senate Research Office
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COMMITTEE FOCUS, CREATION, AND DUTIES

The Senate Prescription Drug Study Committee was created pursuant to Senate Resolution 619. Directing the Committee to examine the practice of prior authorization, Senate Resolution 619 asserts that the current statutes related to substituting generic prescription drugs in place of name brand drugs, as found in Article 5 of Chapter 4 of Title 26, do not adequately address how the prior authorization process should be carried out in such situations. The Resolution also questions whether prior authorization is a cost-effective, necessary, equitable practice, and if it is in the best interest of the health and welfare of Georgia citizens. Moreover, the Resolution contends that many treating physicians are opposed to the imposition of prior authorization requirements by insurers and pharmacy benefit management companies (PBMs) as these practices are costly and unnecessarily time consuming for doctors, medical staff, and patients.

Senator Jack Murphy of the 27th was appointed as the Committee's Chairman. The other members serving on the Committee were: Senator Gloria Butler of the 55th, Senator Lee Hawkins of the 49th, Senator Ralph Hudgens of the 47th, and Senator John Wiles of the 37th. The Committee met on August 21, 2007, September 25, 2007, and November 1, 2007 at the State Capitol.

The Committee heard testimony from the following individuals and organizations: Dr. Barry Jones; Ms. La Tosha Owen of Solvay Pharmaceuticals; Ms. Ellen Yeager of Mental Health America of Georgia; Mr. Robert Highsmith of Express Scripts; Dr. Ed Weisbart, the Chief Medical Officer for Medical Affairs for Express Scripts; Ms. Larisa Noble, Pharmacist; Ms. Judy Gardner, the President of the Georgia State Board of Pharmacy; Mr. Rick Allen, the Deputy Director of the Georgia Drugs and Narcotics Agency; Dr. Jane Keith, the Pharmacist Program Manager for Blue Cross/Blue Shield of Georgia (BCBS); Mr. John April of Wellpoint PBM; Mr. Brian Looby and Dr. Todd Williamson of the Medical Association of Georgia; and Ms. Caroline Holley and Dr. Ronald Koenig of BCBS.

COMMITTEE FINDINGS

Background

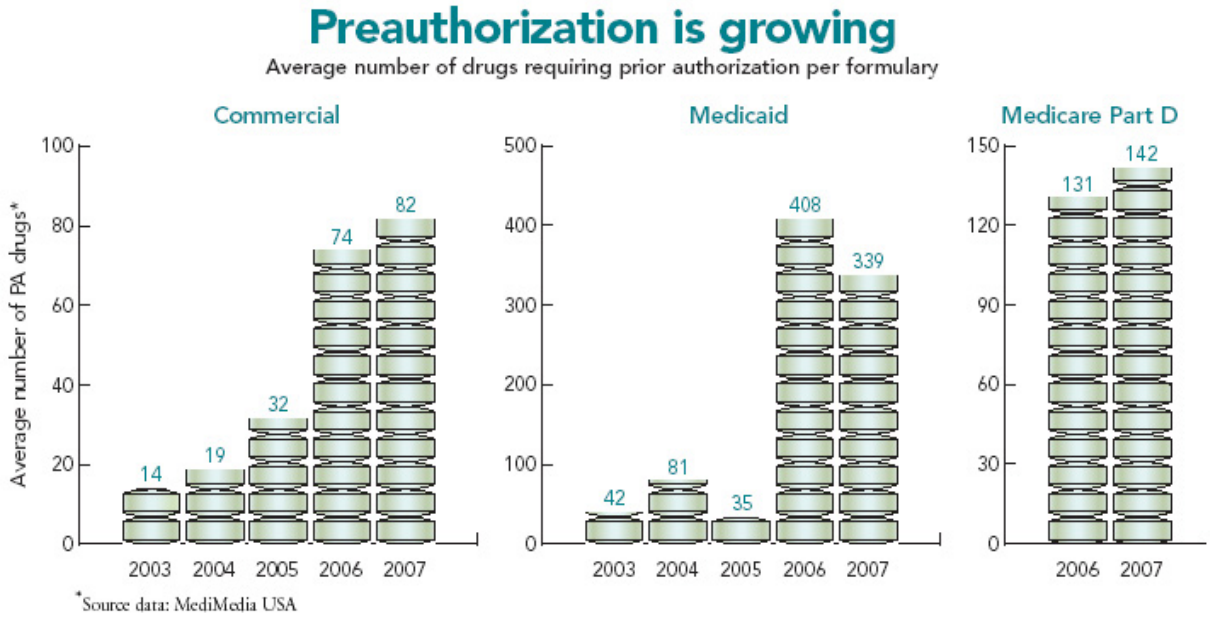
Traditionally, insurers use a number of utilization controls on the use of services to control costs and to ensure that only medically necessary services are reimbursed. Consequently, an insurer may apply a cost-saving process on prescription drugs, such as: a requirement for prior authorization, exclusion of specific drugs, limits on the number of brand name drugs that can be prescribed for a patient, or a requirement that drugs be on a "preferred" list in order to be covered. Prior authorization simply means that the insurer requires the prescribing provider to seek prior approval from the insurer or PBM for an otherwise covered outpatient drug.

For many years, traditional prior authorization systems have focused on potential abuse based upon the number of prescriptions. However, more recent prior authorization requirements are being implemented in a much more complex environment. Not only are insurers seeking to control the number of prescriptions, but they are also attempting to regulate the types drugs being prescribed.

While a number of processes are being used, the most common are described here. First, many insurers require the use of generic drugs whenever possible. Second, insurers establish lists of preferred drugs known as a formulary, in which case, prior authorization is required before a drug not on the list can be dispensed. Insurers may also impose limits on the number

of prescriptions that may be filled for an individual, or allowed a limited supply, i.e., 30 days, to be filled. The primary intent of these practices is to control costs. It is important to remember that prior authorization may only last for a short period of time, and rarely lasts more than six months. After it expires, the process between physician and insurer must be repeated.

Utilization controls over drug prescriptions can result in restricted patient access – individuals with the most severe needs and the least ability to pay out of pocket for medical services may be deprived of the medications they need. In addition to increasing the pain and anxiety of beneficiaries, the lack of necessary medications can result in more extensive and expensive medical procedures.



A Word on Generic Prescription Drugs

The Study Committee learned that doctors and patients regularly run afoul of the prior authorization process when a specific name brand drug is prescribed for which the insurer requires a generic drug instead. A brand name drug is the first version of a particular drug marketed by a specific drug company. Brand name drugs are exclusive and are protected by a patent. This exclusivity helps drug manufacturers recoup research, development, and marketing costs through higher prices.

When a drug patent expires, other companies may produce a generic version of the brand name drug. A generic medication is basically a copy of the brand name drug and is marketed under its chemical name. A generic drug may have a different color or shape than its brand name counterpart, but it must have the same active ingredients, strength, and dosage form (i.e., pill, liquid, or injection), and provide the same effectiveness and safety as its brand name counterpart. Specifically, generic drugs must meet the following criteria when compared to their brand name counterparts:

- Ability to deliver the same amount of active ingredient into the bloodstream in the same amount of time;
- Identical bioavailability; and
- Identical bioequivalency.

Bioavailability refers to the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action. Bioequivalence refers to equivalent release of the same drug substance from two or more drug products or formulations. This leads to an equivalent rate and extent of absorption from these formulations. Underlying the concept of bioequivalence is the notion that, if a drug product contains a drug substance that is chemically identical and is delivered to the site of action at the same rate and extent as another drug, then it is equivalent and can be substituted for that drug product.[1]

Methods used to define bioequivalence can be found in the Code of Federal Regulations, and include:

1. Pharmacokinetic (PK) studies,
2. Pharmacodynamic (PD) studies,
3. Comparative clinical trials, and
4. In-vitro studies.

The choice of study used is based on the site of action of the drug and the ability of the study design to compare drug delivery to that site by the two products.[2]

The statistical methodology for analyzing these bioequivalence studies is called the two one-sided test procedure. Two situations are tested with this statistical methodology. The first of the two one-sided tests determines whether a generic drug, when substituted for a brand name drug, is significantly less bioavailable. The second of the two one-sided tests determines whether a brand name drug, when substituted for a generic, is significantly less bioavailable. Based on the opinions of FDA medical experts, differences of up to 20 percent for each of the above tests is determined to be 'insignificant' or allowable, and therefore, desirable for all drug products.[3] In essence, generics are only required to have 81 percent of the bioavailability of that of the name brand drug. This disparity in bioavailability can lead to severe side effects in some patients.

Compounding the issue of bioavailability, is that manufacturers may use different tints, dyes, and fillers such as sugars, starches and waxes in a generic drug that are not present in its brand name equivalent.[4] Such inactive ingredients can trigger side-effects in certain people. This, as well as the bioavailability issues, are the major reasons why physicians will prescribe brand name drugs over their less-expensive generic equivalent.[5] This almost always triggers a preauthorization.

Formularies and Prior Authorization

The primary reason why a certain prescribed brand name drug will set off a preauthorization is because the physician has prescribed a drug that is not on the health plan's drug formulary or there is a less-expensive generic equivalent available. Certain medications, typically due to a potential safety risk, also require prior authorization.[6]

A formulary is a list of prescription drugs that have been approved for payment by a health plan. Typically, a formulary is developed by a committee whose voting members are physicians and clinical pharmacists. The committee uses medical literature to verify that the formulary drugs chosen are clinically effective and safe. The committee also reviews and updates the formulary

[1] U.S. Office of Generic Drugs, *Approved Drug Products with Therapeutic Equivalence Evaluations;* 27th edition. Page vii. As found at: http://www.fda.gov/cder/orange/obannual.pdf

[2] 21 CFR 320.24

[3] U.S. Office of Generic Drugs, Page viii.

[4] Testimony presented by Ms. La Tosha Owen; Solvay Pharmaceuticals; August 21, 2007.

[5] Testimony presented by Dr. Barry Jones; August 21, 2007.

[6] Testimony presented by Dr. Jane Keith, Pharmacist Program Manager for Blue Cross/Blue Shield of Georgia (BCBS); and Mr. John April of Wellpoint PBM; November 1, 2007.

quarterly to assist physicians in prescribing medically appropriate and cost-effective medications.[7]

Formularies are used to control the cost and utilization of prescription drugs without triggering a preauthorization. Moreover, and depending on their health care coverage, patients may have a lower copayment amount when a formulary medication is selected. Doctors and pharmacists use the formulary to aid them in selecting the medications best suited for a patient's needs. The medications are generally chosen based on the following criteria:

- Safety;
- Efficacy;
- Unique qualities of the medication compared to available alternatives; and
- Cost of the medication if the first three criteria are equal.

Formularies vary in their restrictiveness:

1. Closed Formularies: Provide coverage only for medications on the formulary;

2. Open Formularies: Provide coverage for both listed and non-listed drugs (Physicians are encouraged to prescribe listed drugs);

3. Tiered Formularies: Encourage the use of formulary drugs by charging higher copayments for non-listed drugs. The tiered system also favors generics by charging the lowest copayment for generics.[8] Generally, a three-tier benefit design looks like this:

Tier 1	Generic drugs	Lowest copayment
Tier 2	Formulary brand name drugs	Medium copayment
Tier 3	Non-formulary brand name drugs	Highest copayment

In essence, regardless of the type of formulary being utilized by the insurer, doctors are required to obtain prior authorization for certain drugs for one or more of the following reasons:

1. Has a potential for adverse reaction if not used correctly;
2. Has a high risk of misuse or of being prescribed inappropriately;
3. May only be a benefit when prescribed for certain uses, based on FDA guidelines;
4. May provide less clinical value than another drug in the same therapeutic class; or
5. Has a lower-cost brand or generic alternative that is equally effective for most individuals.

Dr. Ronald Koenig of BCBS pointed out that, all things being equal, the insurer or PBM will always select the least expensive drug; although quality will never be compromised by value.[9]

Drawbacks of Prior Authorization

Increasingly, physicians, pharmacists, and patients have been faced with dealing with the many obstacles imposed by the prior authorization process. Physicians especially resent the idea, whether perceived or actual, of insurers "practicing medicine." Moreover, there is a belief that the insurance industry's aim is to pressure doctors to prescribe generics as often as possible; the argument being that if a doctor is aware that she will have to spend a considerable amount of time dealing with prior authorization in order to prescribe a brand name product, she will stop prescribing that drug even if she believes it is the better choice.[10]

[7] Ibid.

[8] Testimony presented by Dr. Jane Keith, Pharmacist Program Manager for Blue Cross/Blue Shield of Georgia (BCBS); and Mr. John April of Wellpoint PBM; November 1, 2007.

[9] Testimony presented by Dr. Ronald Koenig of BCBS; November 1, 2007.

[10] Testimony presented by Dr. Barry Jones; August 21, 2007.

Cost to Physicians: Time and Money

As noted previously, insurers assert that prior authorization reduces the cost of health care and allows prescription drugs to be more affordable for plan members. But even when that is the case, prior authorization increases practice costs because of the extra time and additional staff needed to deal with the process. Prior authorization also consumes a lot of a physician's time. In addition to time spent with patients, listening, examining, speaking with them, explaining the diagnosis, prognosis, and possible solutions, and determining the referrals and tests; a physician is also required to carefully study the particular insurer's formulary in a world in which it is not unusual for a patient to be prescribed five or more drugs at the same time. Dr. Todd Williamson of the Medical Association of Georgia testified that it can add at least five minutes of additional work per drug per patient for a physician or his staff.[11] Even if the economic and time-consuming burden of prior authorization can be reduced, physicians resent the micromanagement it represents. Clearly, from the physician's perspective, the ultimate insult from prior authorization, aside from the aggravation and the expense, is the erosion of physician knowledge and prescriptive power.

Inconvenience to Patients

One of the most frustrating aspects of prior authorization is that it poses an increased burden and nuisance not only to the physician and pharmacist, but to the patient as well. If the patient takes his prescription to the pharmacy and it requires prior authorization, he might have to stand around or return later to pick up his medication while the pharmacist calls the physician's office or the insurer. In a world in which most people are already pressed for time, prior authorization only serves to add to our sense of daily haste.

COMMITTEE RECOMMENDATION

Based on testimony, the Committee has determined that prior authorization is ultimately approved between 87 and 99 percent of the time. This only serves to reinforce the notion that prior authorization is not only unnecessary, but it is also an inconvenience, burden, and cost to providers, pharmacists, insurers, and patients.

Moreover, generics are only required to have 81 percent of the bioavailability of that of the name brand. Many newer drugs are developed so as to provide fewer and less damaging side effects than the original. Most drugs effect specific pathways and may be substituted for by less expensive drugs which may not even affect those same targets. The Committee believes that the best drug is most often selected by the provider and not by the insurer or PBM.

After studying the issues involving prior authorization and hearing the testimony presented by several witnesses, the Senate Prescription Drug Study Committee recommends that the practice of prior authorization should be prohibited in Georgia.

[11] Testimony presented by Dr. Todd Williamson of the Medical Association of Georgia; November 1, 2007.

Respectfully Submitted,

THE SENATE PRESCRIPTON DRUG STUDY COMMITTEE

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