

A Review of Prior Authorization Programs: Antihemophilic, Antineoplastic, and Antiretroviral Agents

POLICY REPORT

Submitted to the Texas Health and Human Services Commission

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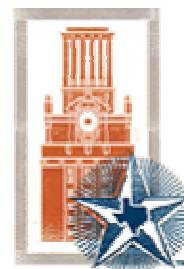
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OVERVIEW

The purpose of this report is to present a review of the literature in order to investigate the realized or potential effects of prior authorization programs for medications used in the treatment of hemophilia, cancer, and HIV/AIDS on the health outcomes of Texas Medicaid clients. This report reviews the purpose of prior authorization as a cost-containment measure, examines the evidence of performance of these programs in practice, and discusses potential implications related to medication access. We found that information regarding implementation of prior authorization programs for antihemophilic, antineoplastic, and antiretroviral agents is quite limited. Therefore, these drug classes are examined in light of the published prior authorization research, to date. Finally, we offer a recommendation to the Texas Health and Human Services Commission based upon the findings of our review.

INTRODUCTION

Medicaid expenditures have exhibited steady growth over the past few years, with prescription drugs accounting for an ever-increasing portion of states' budgets. Spending for drugs is expected to rise 70 percent faster than all other Medicaid health care service components between 2001 and 2006.¹ Given this trend, states are closely tracking prescription utilization and spending trends within their Medicaid pharmacy programs and are implementing aggressive cost-containment mechanisms to slow the growth of drug expenditures. A strategy that is gaining momentum is the introduction of prior authorization (PA) programs – a mechanism whereby certain drugs require approval from Medicaid administrators before payment to the pharmacy is allowed.

The goal of PA is to limit the rate of prescribing of non-preferred drug products within a given therapeutic class. The intended result is to increase the prescribing rate of clinically equivalent and less costly drug agents, serving to control expenditure growth. When a request for a medication is denied, payment is not authorized, leaving the patient with the obligation to cover the cost of the medication, if it is dispensed. As an alternative, a prescriber can select an appropriate product from a list of “preferred agents” that are not subject to PA requirements.

¹ Ku L, Guyer J. Medicaid spending: Rising again, but not to crisis level. Center on Budget and Policy Priorities. April 20, 2001.

In order to determine the appropriateness of assigning specific drug classes to a PA program, a review of the issues should be carefully considered. These issues include:

- The intended goal of a prior authorization program;
- The historical performance of PA programs; and
- The PA program's potential effect on health outcomes.

We present the findings of our literature review by addressing each of these issues as a means to judge the appropriateness of a PA program for antihemophilic, antineoplastic, and antiretroviral medications within the Texas Medicaid Vendor Drug Program.

PRIOR AUTHORIZATION – INTENT

The adoption of the 1990 Federal Omnibus Budget Reconciliation Act (OBRA '90) allowed states to utilize prior authorization as a measure to control the growth of drug expenditures. The legislation imposed Federal guidelines for implementing PA programs that mandate appropriate authorization request review and response procedures. In order to require approval before payment of a drug is authorized, the state must (1) provide a response within 24 hours of a request for prior authorization; and (2) allow for at least a 72-hour supply of a covered outpatient prescription drug to be dispensed in an emergency situation, if the 24-hour response time cannot be met.²

Traditionally, publicly- and privately-funded health plans have implemented PA to curb inappropriate prescribing of non-preferred, usually more expensive, medications.³ However, in the current environment of soaring public health care expenditures and increasing state budget deficits, some states have considered implementation of PA for many expensive drugs, regardless of their rates of appropriate prescribing. To further incentivize drug manufacturers to provide a supplemental rebate within preferred drug list programs, states often mandate prior authorization status for products of non-participating manufacturers.

Although the intent of the Federal law is not explicit in its scope of products that may or may not be subject to PA, some argue that PA was not necessarily intended for every drug or drug class. Based upon reports of the committee that drafted the Federal legislation, it appears that it intended for states to use the option of PA to control

² 42 U.S.C. 1396r-8(d)(5).

³ Olson BM. Approaches to pharmacy benefit management and the impact of consumer cost sharing. *Clinical Therapeutics* 2003;25:250-72.

unnecessary prescribing.^{4,5} The committee was careful to ensure that a PA mechanism was used appropriately. Ultimately, PA would strike a balance between Medicaid beneficiaries receiving their needed drug therapies, and allowing prescribers' judgments regarding appropriate therapy to remain unhindered.⁶

Antihemophilic, antineoplastic, and antiretroviral drugs are among the most expensive treatment regimens available today, however, there are no known peer-reviewed, published reports that describe consistent trends in inappropriate use or over-prescribing. Therefore, given the intent of the Federal legislation, these medication classes do not appear to be ideal candidates for implementing a prior authorization requirement.

PRIOR AUTHORIZATION – HISTORICAL PERFORMANCE

As previously mentioned, in theory, PA mechanisms increase the prescribing rates of less-costly equivalent therapies, resulting in a decreased rate of drug expenditure growth over time, without any undesired effects on patient health outcomes. As recently as 2001, a critical review of the literature revealed that, in fact, PA programs did realize overall net savings for some public and private payers.⁷ It should be noted, however, that a review of the literature did not produce any studies that evaluated the impact of PA on patient clinical outcomes or quality of life. Furthermore, none of the reviewed studies included antihemophilic, antineoplastic, or antiretroviral agents as part of a PA program.

One of the earliest studies, conducted by Smalley et al., investigated the effects of a PA program on anti-inflammatory medications within the Tennessee Medicaid Program between 1988 and 1991. The results showed that the program created significant savings within the class of medications, with no significant differences in other areas of health care

⁴ Ranjan JN. Medicaid and the unconstitutional dimensions of prior authorization. *Michigan Law Review* 2002;101:602-47.

⁵ H.R. Rep. No. 101-881. "As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure the payments are consistent with efficiency, economy, and quality of care. However, the Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment."

⁶ Somers S, Perkins J. Model Prescription Drug Prior Authorization Process for State Medicaid Programs. Kaiser Commission on Medicaid and the Uninsured. April 2003.

⁷ MacKinnon NJ, Kumar R. Prior authorization programs: A critical review of the literature. *Journal of Managed Care Pharmacy* 2001; 7:297-302.

spending by enrolled patients.⁸ However, the authors cautioned that their study of anti-inflammatory agents could not be necessarily applicable to all drug classes, attributing this to the fact that “more diverse pharmacologic properties of individual drugs lead to differences in both efficacy and safety.”⁹ A similar study evaluating a Georgia Medicaid PA program for anti-inflammatory drugs showed similar results in cost-savings, with no apparent increases in the utilization of medical and physician services.¹⁰

A more recent study within the Iowa Medicaid Program included a review of the following drug classes: anti-inflammatory agents, sedative/hypnotic agents, antihistamines, anti-ulcer agents, antimicrobial drugs, and clozapine (at the time, a new antipsychotic agent). Results showed similar cost-saving trends as shown in previous research. Prior authorization approval rates varied widely, ranging from 52 percent for acne products, to 93 percent for clozapine.¹¹

In a 2000 study of Medicaid and private health plan members, a limited PA program resulted in cost savings for the commercial health plan members, but not for the Medicaid population.¹² In a review of 53 managed care organizations’ PA programs for Viagra[®], Enbrel[®], Zyban[®], and Celebrex[®], many plans reported that they had discontinued these requirements due to administrative costs that exceeded any cost savings.¹³

When initial PA approval rates are high, the mechanism will have little effect on utilization rates of the non-preferred agents and program administration costs are likely to approach or exceed any anticipated savings, limiting its cost-effectiveness. Therefore, a modestly low approval rate is important to the economic success of a PA program. As seen in previous research, PA approval rates are lower for some classes of medications compared to others. Those with lower approval rates typically fall into the category of “elective”

⁸ Smalley WE, Griffin MR, Fought RL, et al. Effect of a prior authorization requirement on the use of nonsteroidal anti-inflammatory drugs by Medicaid patients. *New England Journal of Medicine* 1995; 332: 1612-17.

⁹ Ibid.

¹⁰ Kotzan JA, McMillan JA, Jankel CA, et al. Initial impact of a Medicaid prior authorization program for NSAID prescriptions. *Journal of Research in Pharmaceutical Economics* 1993;5(1):25-41.

¹¹ Phillips CR, Larson LN. Evaluating the operational performance and financial effects of a drug prior authorization program. *Journal of Managed Care Pharmacy* 1997;3:699-706.

¹² Mascari TA, Johnson KA. Cost of administering a prior-authorization program at a health plan, and associated cost savings. Poster presentation: AMCP 2000 Educational Conference. *Journal of Managed Care Pharmacy* 2000;6:376.

¹³ Titlow K, Randel L, Clancy CM, Emanuel EJ. Drug coverage decisions: The role of dollars and values. *Health Affairs* 2000;19:240-47.

medications, or those with several less expensive, therapeutically equivalent alternatives.¹⁴ Some PA programs do not appear to have rigorous authorization requirements. A study of Medicaid HMO members showed that the PA approval rate was as high as 95.6 percent overall, and did not include antihemophilic, antineoplastic, or antiretroviral classes of drugs.¹⁵

PA approval rates have not been reported in the literature for antihemophilic, antineoplastic, and antiretroviral drugs. It is anticipated, however, that approval rates for these drugs would be very high given that they are not considered “elective” medications, but rather are used to treat life-threatening illnesses.

PA programs have their highest positive economic impact within a pharmacy program through a “channeling” of prescribers’ product selection behavior. In order to avoid going through the process of requesting authorization for a “non-preferred” agent, the prescriber may decide that the “preferred” agent(s) designated by the PA program is/are clinically appropriate for the patient. This scenario is most likely common in therapeutic classes where individual patient response is similar across the population, regardless of the product selected. However, given the lack of PA programs instituted for hemophilia, cancer, and HIV/AIDS medication classes, heterogeneity in patient responses to these agents is likely to exist.

PRIOR AUTHORIZATION – ACCESS TO CARE

The use of PA appears to be most effective in cases where patients exhibit a homogeneous clinical response to a number of drug products within a given therapeutic class.¹⁶ When it is determined that the restriction of prescribing choices may not have negative effects on patient outcomes (either clinically or financially), the benefits of a PA program outweigh any potential risks to adequate patient care. However, careful consideration should be given in order to avoid cases where establishing additional

¹⁴ Feldman SR, Fleischer AB, Chen GJ. Is prior authorization of topical tretinoin for acne cost effective? *American Journal of Managed Care* 1999;5:457-63.

¹⁵ LaPensee KT. Analysis of a prescription drug prior authorization program in a Medicaid health maintenance organization. *Journal of Managed Care Pharmacy* 2003;9:36-44.

¹⁶ Soumerai SB. Benefits and risks of increasing restrictions on access to costly drugs in Medicaid; some policies can decrease drug spending, but their effects on patients’ health and costs remain largely unknown. *Health Affairs* 2004; 23(1):135-46.

procedural requirements for prescribing medications to treat chronic, life-threatening conditions may result in unintended morbidity or mortality.

Hemophilia, cancer, and HIV/AIDS are life-threatening illnesses requiring urgent and/or un-interrupted treatment to achieve positive patient outcomes and avoid further exacerbation of serious illness or death. PA procedural requirements that delay or interrupt the medication treatment regimen put patients at risk of using alternative medical resources. The result of this scenario is typically an increase in utilization and costs of overall health services.¹⁷ In developing a model PA program, researchers at the Kaiser Family Foundation stated that “chronic medical conditions (e.g., HIV/AIDS, schizophrenia) can particularly be exacerbated by improper limitations and delays in connection with necessary medication.”¹⁸ The report goes on to specifically state that anti-viral medications should be exempt from prior authorization. If delayed access results in a possible worsening of disease, the medications may not be good candidates for PA requirements.

By requiring approval before a drug can be dispensed, a PA program may impede a patient’s access to care from providers due to the increased time and resources necessary to acquire authorizations.¹⁹ Provider groups traditionally contend that PA programs require physicians and pharmacists to spend additional time on the telephone and filling out paperwork, further limiting their time spent treating and counseling patients. Researchers suggest that prescribers might even avoid PA hassles altogether and prescribe less appropriate medications.²⁰

Patient advocates voice concerns regarding sick clients having to go to the pharmacy multiple times to obtain medications.²¹ They contend that patients may give up on obtaining the medication once they are aware that it requires approval.²² The Centers for Medicare and Medicaid Services has also expressed concerns about states limiting coverage of medications for Medicaid clients, specifically for HIV/AIDS medications.^{23,24} Medicaid

¹⁷ Ibid.

¹⁸ Somers S, Perkins J, 2003.

¹⁹ Burton SL, Randel L, Titlow K, Emanuel EJ. The ethics of pharmaceutical benefit management. *Health Affairs* 2001; 20:150-63.

²⁰ Soumerai SB, 2004.

²¹ Tilly J, Elam L. Prior Authorization for Medicaid Prescription Drugs in Five States: Lessons for Policy Makers. Kaiser Commission on Medicaid and the Uninsured. April 2003.

²² Soumerai SB, 2004.

²³ CMS. Dear State Medicaid Director letter. December 5, 1994. Available at: www.cms.hhs.gov/hiv/hiv12594.asp.

²⁴ CMS. Dear State Medicaid Director letter. June 19, 1996. Available at: www.cms.gov/hiv/hiv61996.asp.

clients with HIV and AIDS already are reported to have limited access to care in some states with low rates of reimbursements for medications.²⁵ PA requirements may have the potential to exacerbate this problem.

PRIOR AUTHORIZATION – OTHER STATE MEDICAID PROGRAMS

A 2002 National Pharmaceutical Council survey of state Medicaid drug program administrators reported that PA programs had been instituted for the following drug classes (Table 1)²⁶:

Table 1. Most Common Therapeutic Classes Subjected to PA Requirements within State Medicaid Programs (2002)

Drug Class	Number of States
Growth Hormones	32
Analgesics, Antipyretics, NSAIDs	23
Antihistamines	19
Miscellaneous GI Products	18
Anoretics	14
Prescribed Smoking Deterrents	11
Anabolic Steroids	9
Anxiolytics, Sedatives, Hypnotics	9
Prescribed Cold Medications	5

No state reported PA requirements for antihemophilic, antineoplastic, or antiretroviral agents. In addition, the states that are currently using preferred drug lists (Michigan, Louisiana, Florida, West Virginia, and Vermont) have not required prior authorization for these therapeutic classes of agents. Many state Medicaid programs report that all HIV/AIDS drugs are automatically covered, with little exception.²⁷

DRUGS USED FOR SUPPORTIVE CARE FOR HEMOPHILIA, CANCER AND HIV/AIDS

This report addresses narrow classes of drugs that are indicated specifically for the treatment of hemophilia, cancer, and HIV/AIDS. It is important to also note that drugs within other therapeutic categories (e.g., appetite stimulants for HIV/AIDS wasting, narcotics for cancer pain, and many others) may be prescribed to Medicaid clients as

²⁵ Conviser R, Murray M, Lau D. Medicaid managed care reimbursement for HIV and its implications for access to care. *American Journal of Managed Care* 2000; 6:990-99.

²⁶ National Pharmaceutical Council. *Pharmaceutical Benefits under State Medicaid Programs, 2002*. pp. 4-38 – 4-40.

²⁷ Infectious Diseases Society of America. Center for HIV Quality Care. *States Implementing Policies to Control Prescription Drug Costs in Medicaid, 2002*.

supportive therapy within the course of treatment for the conditions that we have studied in this report. Through our review of the literature, we were unable to identify any studies that investigated the impact of prior authorization programs on treatment outcomes or use of additional medical services for these supportive agents used in the treatment of hemophilia, cancer and HIV/AIDS.

In many instances, drugs prescribed for supportive care have indicated uses for other conditions that are not exclusive to hemophilia, cancer and HIV/AIDS. Because of this, decisions regarding the use of prior authorization for therapeutic categories that include these supportive agents may also have implications on the treatment of hemophilia, cancer and HIV/AIDS. Therefore, state Medicaid programs should carefully consider the risks and benefits of the prior authorization mechanism with respect to particular patient populations and attempt to limit any potential negative impact on Medicaid clients being treated for hemophilia, cancer or HIV/AIDS, to the extent that is possible.

CONCLUSION

We conclude that there is a general consensus among researchers that studies on the effects of PA on patient health outcomes are urgently needed.^{28,29} There is little information, other than anecdotal reports, regarding PA's role in influencing patient quality of life and overall health care costs.³⁰ We anticipate that prior authorization, as a measure to promote cost-effective prescribing in cases where appropriate, will continue to be used by states to control prescription drug expenditure growth.

However, the lack of rigorous studies investigating the clinical and economic impact of PA programs within patient populations affected by chronic or life-threatening disease states should warrant caution for state Medicaid programs when considering the implementation of this cost-containment mechanism for these drug categories. Therefore, due to the lack of evidence currently found in the literature, and until prospective research is conducted to establish its effects on patient outcomes, we conclude that the use of a PA program should be avoided within therapeutic drug classes such as antineoplastic, antihemophilia, and HIV/AIDS medications.

²⁸ MacKinnon NJ, Kumar R, 2001.

²⁹ Tilly J, Elam L, 2003.

³⁰ Soumerai SB, 2004.

ADDENDUM

REVIEW OF END STAGE RENAL DISEASE (ESRD) AND MULTIPLE SCLEROSIS (MS) MEDICATIONS

A thorough literature review was conducted to identify studies that have evaluated prior authorization programs related to medications to treat ESRD and MS. Within both therapeutic categories, no published reports or studies were found in the literature that report the ongoing impact of prior authorization programs currently implemented for patients prescribed these medications. Therefore, state Medicaid programs should consider the risks and benefits of the prior authorization mechanism prior to implementing the programs within these therapeutic categories.

MULTIPLE SCLEROSIS (MS)

Six state Medicaid programs (West Virginia, Florida, Louisiana, Maryland, Illinois, and Hawaii) have included MS medications within a Preferred Drug List (PDL). Prior authorization is required for “non-preferred” agents within each class. The Pharmacy and Therapeutics (P&T) Committee established by the West Virginia Medicaid Program originally reviewed the MS class of drugs for its PDL in January 2003 and required prior authorization for two agents. During a follow-up review in January 2004, no adjustments were made to the prior authorization policy within the West Virginia Medicaid Program.³¹

END STAGE RENAL DISEASE (ESRD)

Five state Medicaid programs (West Virginia, Florida, Louisiana, Maryland, and Georgia) have reviewed medications used to correct for electrolyte imbalances common with ESRD patients as part of their PDL process. Prior authorization has been implemented for certain agents deemed “non-preferred” by the P&T committees in each state. After its PDL review, the P&T committee within Louisiana designated all agents within the therapeutic category classified as “Phosphate Binders” available for use without prior authorization.³²

³¹ West Virginia Department of Health and Human Resources, Bureau for Medical Services, Pharmacy and Therapeutics Committee, January 21, 2004.

³² Louisiana Department of Health and Hospitals, Medicaid Pharmaceutical and Therapeutics Committee, May 5, 2004.

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Since its establishment in 1994, The Center for Pharmacoeconomic Studies at The University of Texas at Austin has conducted economic and policy research on the impact of pharmaceutical services and products on patients' quality of life and health care outcomes in Texas and across the U.S. The Center serves as a bridge in bringing researchers together from different sectors of the health care delivery system, in addition to fostering collaborations with other academic institutions to disseminate scholarly findings. Researchers at the Center provide expertise in the areas of study design, methodology, data collection and analysis, and interpretation of economic and policy research. The Center also develops and presents educational programming to further the understanding of pharmacoeconomics and its role in the decision-making process within the health care delivery system.

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