

SPECIAL ARTICLE

Medicaid Prior-Authorization Programs and the Use of Cyclooxygenase-2 Inhibitors

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ABSTRACT

BACKGROUND

Over the past five years, selective cyclooxygenase-2 inhibitors (coxibs) have accounted for a growing proportion of prescriptions for nonsteroidal antiinflammatory drugs (NSAIDs). To control these expenses, many state Medicaid programs have implemented prior-authorization requirements before coxibs can be prescribed. We evaluated the effect of such programs on the use of coxibs by Medicaid beneficiaries.

METHODS

We surveyed state Medicaid agencies to determine whether prescription of coxibs required prior authorization and, if so, the criteria for authorization. For each program, we compared these criteria with evidence-based recommendations for prescribing of coxibs. Using data for all filled prescriptions in 50 state Medicaid programs from 1999 through the end of 2003, we calculated the proportion of defined daily doses of NSAIDs accounted for by coxibs. Time-series analyses were used to measure the changes in prescription patterns after the implementation of each prior-authorization program.

RESULTS

By 2001, coxibs accounted for half of all NSAID doses covered by Medicaid. This proportion varied widely according to the state in 2003, from a low of 11 percent to a high of 70 percent of all NSAID doses. Twenty-two states implemented prior-authorization programs for coxibs during the study period. Overall, the implementation of such programs reduced the proportion of NSAID doses made up by coxibs by 15.0 percent (95 percent confidence interval, 10.9 to 19.2 percent), corresponding to a decrease of \$10.28 (95 percent confidence interval, \$7.56 to \$13.00) in spending per NSAID prescription. The effect of such programs was not influenced by the degree to which a prior-authorization program incorporated evidence-based prescribing recommendations.

CONCLUSIONS

The use of coxibs and spending on NSAIDs varies widely by state and declined substantially after the implementation of prior-authorization programs. Determining whether these reductions are clinically appropriate will have important implications for the development of rational drug-reimbursement policies.

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SELECTIVE CYCLOOXYGENASE-2 INHIBITORS (coxibs), a type of nonsteroidal antiinflammatory drug (NSAID), were introduced in December 1998. The antiinflammatory activity of these agents is similar to that of nonselective NSAIDs,^{1,2} and they have lower rates of gastrointestinal complications.³ The use of coxibs has been widely adopted, with sales of almost \$6 billion in 2004.⁴ Their popularity and cost have imposed financial stress on many prescription-drug insurance programs, including state Medicaid programs,^{5,6} whose mandate is to cover the medical expenses of the poor.

Although Medicaid programs are prohibited from creating restrictive drug formularies, they have discretion in determining many aspects of coverage.⁷ Facing constrained Medicaid budgets and sharply rising drug expenditures, states have sought to control drug costs⁸ through measures such as prior authorization, a policy requiring physicians to submit patient information for review before reimbursement is approved for a given medication.⁷

The choice between nonselective NSAIDs and coxibs provides a useful case study of the effect of such prior-authorization programs. Both drug classes are broadly prescribed for indications including osteoarthritis, rheumatoid arthritis, and acute pain and have virtually identical clinical efficacy,^{1,2,9} with most nonselective NSAIDs available at much lower cost.¹⁰ The main advantage of the coxibs is a lower risk of gastrointestinal hemorrhage. Five risk factors for this complication have been recommended as criteria for identifying patients who are more likely to benefit from coxibs than from nonselective NSAIDs.¹¹⁻¹⁴

Faced with constrained pharmacy budgets, policymakers have developed prior-authorization programs to allow the use of coxibs by patients who meet high-risk criteria while reducing use by others, thus targeting the use of these expensive agents to appropriate patients. Numerous state Medicaid programs have implemented various prior-authorization policies for coxibs, with markedly different approval criteria, whereas some states have no such policies. This variability creates a large-scale natural experiment, making possible the evaluation of the effect of prior-authorization programs on the prescribing of coxibs. We used data from state Medicaid programs to calculate the proportion of NSAID use accounted for by coxibs and evaluated the effect of prior-authorization programs on the

use of coxibs. This study focused on the effect of prior-authorization policies for coxibs before rofecoxib (Vioxx, Merck) was withdrawn from the market. Although the removal of this drug will certainly influence future patterns of use of coxibs, the present study addresses the general effects of prior-authorization programs, with coxibs serving only as an example.

METHODS

SOURCES OF DATA

The Center for Medicare and Medicaid Services provides quarterly data on drug use by Medicaid programs.¹⁵ These state-level data include the total number of prescriptions filled, the total number of pills or capsules dispensed, and the total Medicaid reimbursement for each medication. We also obtained data on the number and age distribution of Medicaid recipients.^{16,17} No data at the level of individual patients were used in this analysis.

We contacted all state Medicaid agencies between September 2003 and March 2004 to determine whether the state Medicaid program had any prior-authorization policy regarding coxibs. (Arizona has a decentralized Medicaid program and was not included; analyses are for the other 49 states and the District of Columbia.) The agencies were asked to provide all manuals, instructions, and submission forms for the prior-authorization process. We also checked whether state programs covered over-the-counter analgesics.⁷

On the basis of information provided by the state Medicaid agencies, we determined the extent to which each prior-authorization program restricted access to coxibs. Two components were considered: the extent to which evidence-based guidelines regarding high-risk users of NSAIDs were incorporated into the policies, and whether previous treatment with nonselective NSAIDs was required.

Investigators who were blinded to the use data reviewed prior-authorization criteria for each state to determine how many of the five major clinical risk factors for gastrointestinal adverse effects were included (old age, prior upper gastrointestinal bleeding, prior peptic ulcer disease, use of anticoagulant drugs, and use of systemic glucocorticoids).¹¹⁻¹⁴ We classified criteria as strict if they incorporated at least four of the five risk factors. Investigators also reviewed criteria to assess requirements with

respect to prior use of nonselective NSAIDs. We considered criteria strict if they required patients to have a history of gastrointestinal complications due to the use of a nonselective NSAID. We defined a state's prior-authorization policy as more restrictive if the criteria were strict in both areas — that is, the programs incorporated four or more of the clinical risk factors in their criteria and the programs required patients to have a history of gastrointestinal complications from nonselective NSAIDs. We defined all other programs as less restrictive.

STATISTICAL ANALYSIS

We calculated the number of defined daily doses for nonselective NSAIDs and coxibs, using World Health Organization standards.¹⁸ The defined daily doses for some of the commonly used products included 200 mg of celecoxib (Celebrex, Pfizer), 25 mg of rofecoxib, 1200 mg of ibuprofen, and 500 mg of naproxen. We determined the total number of defined daily doses of prescription NSAIDs used in each state Medicaid program and the proportion accounted for by the coxibs: celecoxib, rofecoxib, and valdecoxib (Bextra, Pfizer).

We identified the date of implementation of prior-authorization programs and performed interrupted time-series analyses to estimate their effect on drug use. The weighted average of the trend for the use of coxibs in states without prior-authorization programs was used for comparison. The

time frame for each state's data was standardized relative to the quarter in which the prior-authorization policy was initiated. All analyses were conducted with the use of Stata software.¹⁹

We developed general linear models, adjusting for repeated observations by using generalized estimating equations in which the correlation structure was assumed to be autoregressive with a lag time of one quarter. The models included terms indicating the temporal relationship of each quarter with implementation of a prior-authorization policy.²⁰ Terms for interaction between the level and slope indicators and the prior-authorization indicator were included to estimate the time-trend-adjusted effects of the prior-authorization policies. We used z-test results based on the estimated β coefficients and standard errors from the generalized estimating equations to determine statistical significance, with a P value of less than 0.05 used to indicate statistical significance. (Additional details about the interrupted time-series model can be found in the Supplementary Appendix, available with the full text of this article at www.nejm.org.)

We stratified secondary analyses according to whether the prior-authorization criteria were more restrictive or less restrictive.¹¹⁻¹⁴ We considered several possible covariates that could modify the effect of prior-authorization programs, including the age distribution of Medicaid beneficiaries, whether the state's Medicaid program covered over-the-coun-

Table 1. Trends in the Use of NSAIDs and Spending for Coxibs by Medicaid from 1999 through 2003.*

Year	Total No. of NSAID Prescriptions	Defined Daily Doses of NSAIDs		Total No. Enrolled†	No. of Elderly Enrollees†	Total Spending on NSAIDs	Spending on Coxibs	
		Total No.	% Accounted for by Coxibs				Total	Amount per Enrollee
1999	11,152,602	379,270,292	20	32,800,000	3,800,000	\$409,791,354	\$186,771,176	\$5.69
2000	14,813,749	510,739,835	46	34,000,000	3,900,000	\$759,914,571	\$560,455,327	\$16.48
2001	16,386,549	568,472,226	52	37,700,000	4,000,000	\$894,709,959	\$720,403,988	\$19.11
2002	17,027,307	594,609,564	52	39,900,000	4,200,000	\$962,695,209	\$786,166,696	\$19.70
2003	17,969,876	639,558,144	50	41,400,000	4,300,000	\$1,007,854,366	\$813,692,815	\$19.65

* Annual prescriptions and spending are based on quarterly data. Information for some quarters was missing for some states; in these cases, data were annualized for the given state. No data were provided for Mississippi and Texas in 1999 or for Rhode Island in 2000. Data were included for the District of Columbia; Arizona did not provide data for any year. Detailed data according to calendar quarter are provided in the Supplementary Appendix.

† Enrollment data refer to person-years of enrollment and are projections for the fiscal years listed, prepared by the Office of the Actuary for the President's fiscal year 2004 budget.¹⁷

ter analgesics, and the baseline level of prescribing of coxibs before the implementation of a prior-authorization program.

RESULTS

Table 1 summarizes national trends for the prescription of NSAIDs in Medicaid programs and Medicaid enrollment. (Additional details are provided in the Supplementary Appendix.) From 1999 through 2003, the total use of NSAIDs increased, driven by the increased use of coxibs; in fact, the volume of defined daily doses of nonselective NSAIDs per Medicaid recipient declined slightly. The use of coxibs grew rapidly after their introduction,

stabilizing at about 50 percent of all defined daily doses of NSAIDs covered by Medicaid programs. Annual spending on all NSAIDs increased by nearly \$600 million over the study period, almost all of that due to increased spending on coxibs. There was wide variation among states in the proportion of defined daily doses of NSAIDs that were accounted for by coxibs (Fig. 1), ranging from 11 percent to 70 percent.

Eight states implemented prior-authorization programs for coxibs immediately after the introduction of these drugs to the market in late 1998; these states were excluded from the time-series analysis since there were no data available from the period before the implementation of the policy. The main analyses included the 22 states that initiated prior-authorization programs between 2000 and the beginning of 2003 and had at least three quarters of use data before and after implementation. The remaining 20 states provided control data on coxib-use trends in the absence of prior-authorization programs. Five of the control states implemented prior-authorization programs in late 2003, and one additional state had a program scheduled to begin in 2004.

Figure 2 presents the trends in the proportion of coxib use, with time standardized relative to the initiation of the prior-authorization program. In the 22 states that implemented a prior-authorization program, the proportion of coxib use decreased by an average of 11.1 percent (95 percent confidence interval, 5.7 to 16.5 percent) from the six months before implementation to the six months after. Six of the states had no change or a small increase in coxib use, whereas seven had decreases in coxib use of more than 20 percent. Regression analysis with control for secular trends in coxib use showed that the implementation of a prior-authorization program was associated with a reduction in the percentage of defined daily doses of NSAIDs accounted for by coxibs by 15.0 percent (95 percent confidence interval, 10.9 to 19.2 percent; $P < 0.001$). There was a slight upward trend of 1.6 percent (95 percent confidence interval, 0.0 to 3.1 percent; $P = 0.03$) in the slope of the curve for coxib use in the six quarters after the implementation of a prior-authorization program. Thus, implementation of a prior-authorization program was associated with an initial downward shift in the level of coxib use, with a much smaller rise in use subsequently.

The prior-authorization programs of 9 states included more restrictive criteria, whereas the oth-

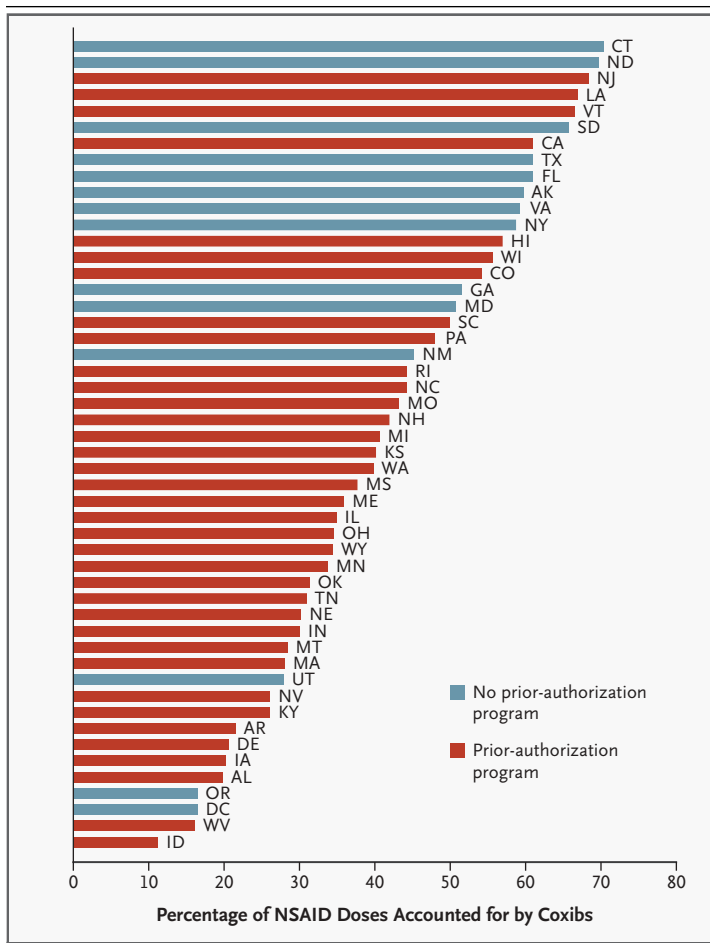


Figure 1. Percentage of Defined Daily Doses of NSAIDs Accounted for by Coxibs in the Fourth Quarter of 2003, According to Whether a Prior-Authorization Program Had Been Implemented.

Data are presented in descending order according to state. Data are presented for 49 states and the District of Columbia. (Data were not available for Arizona.)

er 13 state programs had less restrictive criteria. Figure 3 shows the trends in coxib use in these states. The reductions in coxib prescribing after the implementation of a prior-authorization program were similar in states with less restrictive and states with more restrictive criteria (15.6 percent and 14.6 percent, respectively). The slopes of the trend lines increased slightly at 2.0 percent (95 percent confidence interval, 0.0 to 3.7 percent; $P=0.013$) in states with less restrictive criteria and at 1.2 percent (95 percent confidence interval, 0.0 to 2.9 percent; $P=0.15$) in states with more restrictive criteria.

States with more restrictive criteria had lower levels of use of coxibs before the implementation of the prior-authorization program than states with less restrictive programs (Fig. 3). Adding terms for the interaction between levels of use of coxibs before the implementation of prior-authorization programs and the stringency of criteria in such programs (more restrictive vs. less restrictive) had no significant effect (P for interaction=0.29). Additional models showed no modification of the effect of prior-authorization programs by coverage of over-the-counter medications (P for interaction=0.27) or by the proportion of Medicaid beneficiaries who were over 65 years of age (P for interaction=0.52).

Before the implementation of prior-authorization programs, the level of spending per NSAID prescription was similar in states that subsequently initiated a prior-authorization program and states that did not initiate such a program (Fig. 4). After the initiation of such programs, there was an immediate shift corresponding to a \$10.28 reduction in spending per prescription (95 percent confidence interval, \$7.56 to \$13.00; $P<0.001$). This change represents an 18 percent decrease in the cost per NSAID prescription.

DISCUSSION

The use and costs of NSAIDs in state Medicaid programs have increased dramatically in recent years, driven partly by the introduction of coxibs.^{8,21} Our analysis of state-by-state data found a large variation among states in the use of coxibs. During the study period, a majority of states implemented prior-authorization programs for coxibs, which were associated with a sustained reduction in their use. The cost of an average NSAID prescription decreased by about \$10 after the initiation of prior-authorization programs. With nearly 18 million NSAID prescriptions covered by Medicaid in 2003,

this decrease can be projected to an annual reduction in spending of \$185 million.^{22,23}

Although only 8 states had prior-authorization programs for coxibs when the drugs first became available, 22 states instituted such programs during the ensuing four years. By the end of 2003, only 14 states did not have a prior-authorization program for coxibs either in place or scheduled to begin.

Other studies have addressed the effect of Medicaid prior-authorization programs on the use of brand-name nonselective NSAIDs.^{24,25} Evaluations of these state programs found considerable savings, without increases in other medical expenses or effects on patients' quality of life.^{25,26} The introduction of coxibs in 1998 created new pressures and new issues. Whereas there are no important differences in efficacy among nonselective NSAIDs, the potential for reduced gastrointestinal complications with coxibs presents a more important clinical issue. This difference, combined with the large difference in cost between coxibs and nonselective NSAIDs, has led to a focus on limiting coxib use to patients in whom this difference would matter most — a more complex policy goal than reducing the use of brand-name medications. The natural ex-

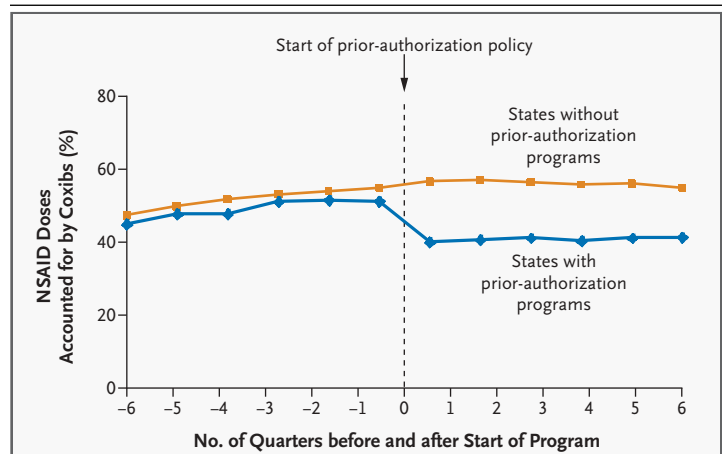


Figure 2. Proportion of Defined Daily Doses of NSAIDs Accounted for by Coxibs before and after the Implementation of a Prior-Authorization Program.

Time is measured in calendar quarters relative to the quarter in which a prior-authorization program for coxibs was implemented. Only states with data available for at least three quarters before and after the implementation of the program were included in the time-series analysis. The weighted average of coxib use in states without prior-authorization programs was used to generate quarterly control data for each state that did have a program. The time frame for the control data was standardized relative to the quarter in which the prior-authorization policy was initiated in the intervention state.

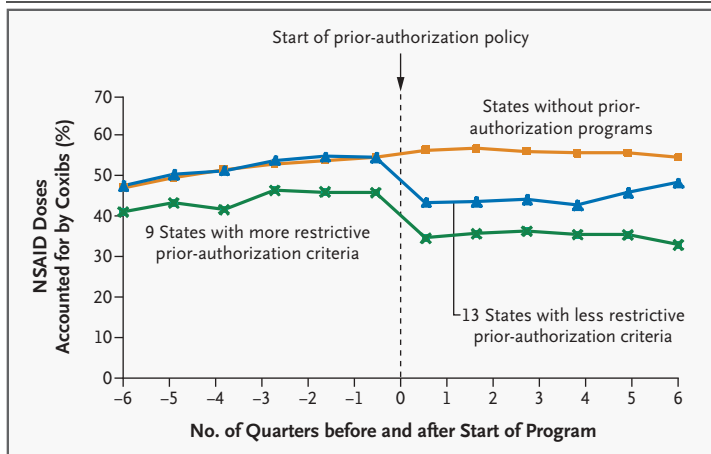


Figure 3. Proportion of Defined Daily Doses of NSAIDs Accounted for by Coxibs before and after the Implementation of a Prior-Authorization Program, According to Whether a Program Had Been Implemented and the Restrictiveness of Prior-Authorization Criteria.

Time is measured in calendar quarters relative to the quarter in which a prior-authorization program for coxibs was implemented. The weighted average of coxib use in states without prior-authorization programs was used to generate quarterly control data for each state that did have a program. The time frame for the control data was standardized relative to the quarter in which the prior-authorization policy was initiated in the intervention state.

periment created by variability in state Medicaid programs' prior-authorization criteria for coxibs presents a unique opportunity to study this policy instrument at a national level.

Whereas some states required detailed clinical information on patients' characteristics, drawn from evidence-based guidelines for the prescribing of NSAIDs and coxibs, other states required only limited information to be obtained to meet prior-authorization criteria, such as whether a patient had previously tried a nonselective NSAID. States also varied in the explicitness of the descriptions of the criteria for coxib approval that were made available to the public. However, we found similar reductions in the prescription of coxibs regardless of how restrictive the prior-authorization criteria were. Although we were not able to study this issue directly, we suspect that the administrative burden of the prior-authorization process and the responsiveness of officials making authorization decisions had a large effect on the rate of authorization of coxib prescriptions. States with more restrictive prior-authorization criteria had lower baseline use of coxibs, and such states may take a generally more stringent approach to prescription-drug reimbursement. The use of coxibs slowly in-

creased after the initial reduction. The durability of the reductions in coxib use over time should be examined in future studies.

Our findings must be viewed in the light of several important considerations. Foremost among these is the aggregate nature of our data. We have no information on the clinical characteristics of individual patients and cannot comment on whether the reduced use of coxibs that was associated with the implementation of prior-authorization programs was clinically appropriate. Previous research has shown that many patients receiving coxibs have no major contraindications against the use of nonselective NSAIDs.^{26,27} However, many patients for whom nonselective NSAIDs are prescribed have potentially important gastrointestinal risk factors.^{26,27} The clinical appropriateness of changes in use associated with prior-authorization policies is an important area for future research.

States with prior-authorization programs may have differed systematically from states without such programs in ways not captured by our data, since states with these programs had slightly lower rates of coxib use before the programs were implemented. Such states may have been more aggressive in their use of Medicaid managed-care programs or in implementing other strategies to manage pharmaceutical budgets, such as changes in patients' copayments or pharmacies' dispensing fees. A strength of interrupted time-series analyses is the possibility of adjusting for baseline trends and thus obtaining accurate estimates of the effect of the policy,²⁸ although interventions implemented at exactly the same time as prior-authorization policies could either obscure or magnify the effect. We found considerable variation among states in the proportion of NSAID prescriptions accounted for by coxibs. Regional variation in the patterns of medical care has been documented in several areas.²⁹⁻³¹ Patterns of NSAID prescribing for Medicaid beneficiaries appear to have similar variability, even independent of the effects of prior-authorization programs, and should be a target of subsequent studies.

Economic analyses of individual managed-care programs, both private and public, have demonstrated savings when prior-authorization programs for coxibs were implemented.^{32,33} Our analyses permit an approximation of the financial effect of prior-authorization programs in a very large public insurance program. We found a difference of about

\$10 per NSAID prescription associated with the implementation of these programs, corresponding to an annual reduction of \$185 million nationally. We believe this finding has special importance in the light of the recently enacted Medicare prescription-drug benefit.

Medications have been the fastest-rising component of health care costs for several years, and cost-effective prescribing will assume even greater importance once the Medicare drug benefit begins in 2006.³⁴ Almost immediately after this legislation was approved, public estimates of its cost began to rise.³⁵ Like all health insurance programs, Medicare will be challenged both by already high expenditures for medications and by rising pharmacy expenditures attributable to the availability of new and more expensive medications. Many of these medications will be appropriate choices for some patients but less so for others. Yet vigorous promotion of costly products, directed at both physicians and patients, can be expected to continue. The state Medicaid programs' use of prior-authorization policies represents one attempt to direct the use of costly medications to the patients who will benefit most from them. Our data suggest that such programs can substantially reduce the use of coxibs. However, it will also be important to measure how well such policies direct the more expensive medications to the right patients.

Our earlier work indicates that there is substantial overuse of these medications among patients at low risk for complications of traditional NSAIDs, whereas some high-risk patients appear to receive traditional NSAIDs inappropriately, when a coxib or concomitant therapy with a gastroprotective agent may be indicated.^{26,27} With the proliferation of costly and increasingly complex drugs, health care policymakers will be forced to devise strategies that help ensure that resources are available to pay for these drugs for patients who require them. This will often require restricting their use by patients with less clear indications for receiving them.

Other strategies to improve the efficiency of drug use include reference pricing,³⁶ tiered copayment systems,^{37,38} and physician-education programs.³⁹ Each has potential strengths and weaknesses that will have to be defined empirically. Rigorous analyses of new policies will allow better

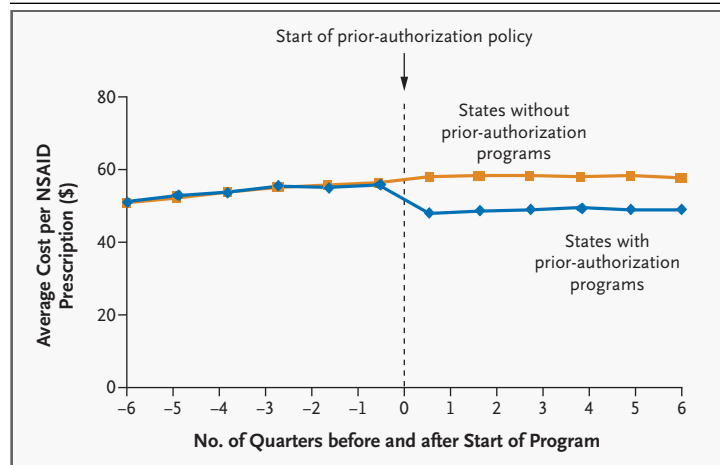


Figure 4. Average Spending per NSAID Prescription before and after the Implementation of a Prior-Authorization Program.

Time is measured in calendar quarters relative to the quarter in which a prior-authorization program for coxibs was implemented. The weighted average of coxib use in states without prior-authorization programs was used to generate quarterly control data for each state that did have a program. The time frame for the control data was standardized relative to the quarter in which the prior-authorization policy was initiated in the intervention state.

drug-use programs to be designed for government and private-sector drug-entitlement programs.

In conclusion, we found that the implementation of Medicaid prior-authorization programs was associated with a substantial decrease in the use of coxibs and consequent large reductions in spending by state Medicaid programs. As private and public insurers continue to struggle with rising expenditures for prescription drugs and policymakers wrestle with the structure of medication coverage for Medicare beneficiaries, better understanding of policies such as these will help to shape sustainable drug-insurance systems that can contain escalating pharmaceutical costs while preserving appropriate clinical decision making.

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