Clinical and Financial Outcomes Associated With a Proton Pump Inhibitor Prior-Authorization Program in a Medicaid Population

Thomas Delate, PhD; Douglas E. Mager, BS; Jagat Sheth, PhD; and Brenda R. Motheral, PhD

Objective: To examine the clinical and financial outcomes associated with a proton pump inhibitor (PPI) prior-authorization policy.

Study Design: Interrupted time-series analyses of antisecretory prescription drug claims. Separate 6-month retrospective cohort analyses were conducted to estimate the clinical and financial effects of the policy.

Patients and Methods: More than 1.2 million Medicaid enrollees, with subgroup analyses of 5965 continuously eligible, potential antisecretory medication users. Measures included antisecretory drug expenditures, proportions of patients with at least 1 gastrointestinal diagnosis and gastrointestinal-related ambulatory and inpatient medical service visit, and subsequent gastrointestinal-related and total medical service expenditures.

Results: There was a 90.9% decrease in PPI per-member-per-month expenditures and a 223.2% increase in histamine$_2$-receptor antagonist (H_2A) per-member-per-month expenditures in the month immediately following the implementation of the policy ($P < .001$ for both). A greater proportion (80.7%) of prior-authorization eligible enrollees who received a PPI had at least 1 diagnosis for a gastrointestinal condition than enrollees who received an H_2A (64.1%) or no antisecretory drugs (48.4%) ($P < .001$ for both). Two-part, finite mixture regression analyses indicated that the enrollees who received an H_2A or no antisecretory drugs were no more likely to have incurred greater total medical care expenditures than enrollees who received a PPI.

Conclusion: Prior authorization for PPIs had the effect of reducing use of high-cost PPIs, while encouraging use of lower costing H_2As without evidence of adverse medical consequences.

(Am J Manag Care. 2005;11:29-36)

Increasing enrollment in Medicaid, combined with rising drug and health service costs, has led to large increases in Medicaid expenditures.[1,2] Approximately 20% of states' budgets are devoted to financing for Medicaid, and expenditures for Medicaid are among the fastest growing items in the federal and state budgets.[3] On average, fee-for-service Medicaid programs have seen rises of 19.6% per year in ambulatory prescription drug expenditures between fiscal years 1998 and 2001.[4] Therefore, Medicaid programs are taking assertive measures to manage drug expenditures.[5-8]

The Omnibus Reconciliation Act of 1990, as amended in 1993, allows prior authorization (PA) as a means of drug cost containment.[9] Prior authorization restricts the use of specific medications by requiring an advance approval by the Medicaid program or its agent for the drug before dispensing to qualify for reimbursement.[10] High-cost drugs that have a history of inappropriate use and effective drugs for which there are lower costing therapeutic equivalents typically are placed in PA programs.[11] Prior authorization is designed to allow patient access to essential pharmacotherapies while promoting cost-effective prescription drug use.

States may require PA for any drug 6 months after Food and Drug Administration marketing approval.[11] It is estimated that more than 40 states and the District of Columbia have some type of drug PA policy.[4] Notwithstanding the widespread use of these programs, limited empirical evidence exists on their effects. The available evidence suggests that such programs reduce drug expenditures without incurring increased medical services use[10]; however, only 3 retrospective evaluations of Medicaid PA programs were found in the peer-reviewed literature.[11-13] As PA programs expand to include other classes of drugs, research is needed to evaluate the clinical and economic effects of the programs.

Proton pump inhibitors (PPIs) are an example of a therapy class that is a candidate for PA. Proton pump inhibitors are indicated for short-term therapy of acute upper gastrointestinal (GI) disorders (eg, peptic ulcers and esophagitis), pathologic gastric hypersecretory conditions (eg, Zollinger-Ellison syndrome), and maintenance therapy with healed ulcers and erosive esophagitis.[14] However, an estimated 30% to 70% of patients with painful reflux symptoms do not have GI conditions with sustained tissue damage.[15] An alternate treatment for nonacute hypersecretory conditions exists in lower-cost histamine$_2$-receptor antagonists

From Outcomes Research, Express Scripts, Inc, Maryland Heights, Mo.
This study was funded by Express Scripts, Inc.
Address correspondence to: Thomas Delate, PhD, Clinical Rx Research, Kaiser Permanente Centretech Parkway, Aurora, CO 80011. E-mail: tdelate@express-scripts.com.

(H_2As).[16,17] To channel potential PPI users to less expensive H_2A alternatives when clinically appropriate (eg, dyspepsia and reflux without complications), the fee-for-service Medicaid program implemented a PA program that used diagnosis- and risk-based criteria[18-23] to establish medical necessity (eg, erosive or ulcerative GI conditions) for approval of PPIs. During the 12 months before the implementation of the PPI PA policy, PPIs accounted for 5.6% ($45.5 million) of the net pharmacy expenditures and ranked first in expenditures among all drug therapy classes for the Medicaid program (data not shown).

This study used population-based, retrospective, longitudinal analyses of pharmacy and medical claims to evaluate the effects of the Medicaid program's PA policy for PPIs. The objective of the study was to examine the effectiveness of the PPI PA program from the perspective of the Medicaid program payer[11,24-26] in regards to (1) its effect on antisecretory drug (ie, PPIs and H_2As) expenditures and use, (2) the channeling of PPIs to those patients demonstrating a medical need for a PPI, and (3) the incurrence of unintended medical consequences.

METHODS

Prior-Authorization Policy

Beginning on February 1, 2002, the Medicaid program required that PA be obtained for all PPI prescriptions (esomeprazole magnesium, lansoprazole, omeprazole, pantoprazole sodium and rabeprazole sodium) to qualify for reimbursement. Diagnosis- and risk-based clinical criteria were established for the PA program.[18-23] Prescribers and pharmacies participating in the Medicaid program were sent notification of the PA requirement before the implementation of the policy. In addition, notifications of the impending requirement were appended as a banner message to Medicaid program remittance advices sent to prescribers and pharmacies. When a patient presented at the pharmacy with a PPI prescription without first receiving PA approval, pharmacists were alerted during the prescription adjudication process that authorization was required. Prescribers or pharmacists submitted PA requests by mail, fax, or toll-free telephone call to the Medicaid program's pharmacy benefit manager agent, and these requests were initially reviewed by a PA representative. Requests that were not approved during the initial phase were then reviewed by a pharmacist. The response was handled at the point of service for telephone calls, within 24 hours for a faxed request, or within 48 hours for a mailed request. For those patient requests that were denied, the prescriber was made aware of the 2 levels for appeals. The PA program was modified on April 1, 2002, because of concerns expressed by prescribers and patient advocates regarding the GI-related and other medical conditions for which initial therapy with PPIs was approvable.

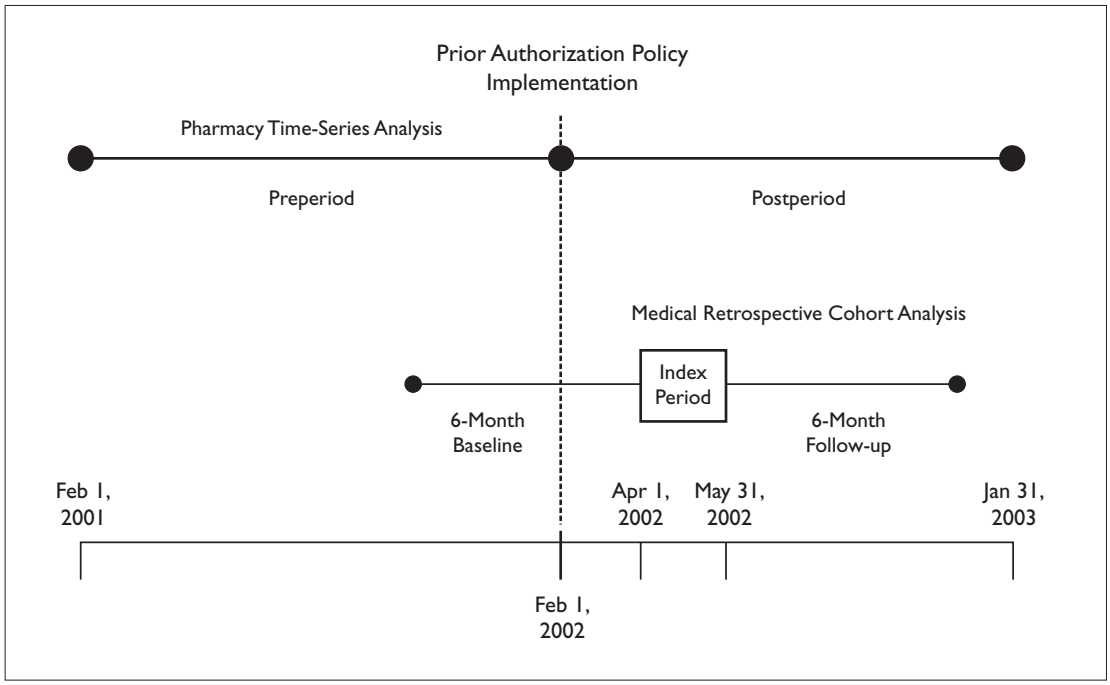
Authorizations were valid for 6 months. Patients requesting a prescription for esomeprazole or rabeprazole were required to document therapeutic nonresponse with at least a 2-week course of 1 of the 3 preferred PPIs (lansoprazole, omeprazole, or pantoprazole). In addition, the PA program incorporated step therapy, whereby patients with nonerosive hypersecretory conditions were required to document therapeutic nonresponse with at least a 2-week course of an H_2A (cimetidine, ranitidine, famotidine, or nizatidine) before approval for a PPI would be granted. Patients with a *Helicobacter pylori* infection were granted a 1-month PPI supply for use with antibiotic eradication therapy. The Medicaid program paid an administrative fee of $20 per PA request.

Study Design and Data Sources

To compare the change in net expenditures (including the administrative costs of the PA program) for antisecretory drugs, this study used the pharmacy benefit manager's ambulatory pharmacy reimbursement claim records for the Medicaid program for the 12 months before (hereafter referred to as the preperiod) and 12 months after (hereafter referred to as the postperiod) the implementation of the PA policy (February 1, 2002) (**Figure 1**). Antisecretory prescriptions were converted to 30-day supplies (hereafter referred to as claims). The pharmacy benefit manager's pharmacy edit, PA request record, and eligibility information electronic files were used to identify continuously eligible patients (hereafter referred to as subjects) who attempted to have a PPI prescription filled from April 1, 2002, through May 31, 2002 (hereafter referred to as the index period) and their subsequent PA approval or denial status. These dates were chosen because the modified criteria that were put in place on April 1, 2002, were, at the time of the manuscript preparation, the current criteria used by the Medicaid program and because they allowed for an adequate follow-up with the data available.[14,27] Patients without continuous eligibility were not included because these patients would not have complete data to allow for an adequate assessment of their health conditions and medical service use.

To assess the channeling of PPIs and possible unintended medical consequences, subjects' ambulatory and inpatient medical service claim records were obtained from MEDSTAT, the Medicaid program's medical claims database manager. These medical claims

Figure 1. Pharmacy Time-Series and Medical Retrospective Cohort Designs



were examined to assess GI-related diagnoses and expenditures in the 6 months before (hereafter referred to as baseline) and after (hereafter referred to as follow-up) subjects' first attempt to have a PPI prescription filled (hereafter referred to as the index date) (Figure 1).

Subject Groups

All Medicaid Enrollees. Because the PA was applied to all enrollees in the Medicaid program, the base-case analysis consisted of all persons enrolled in the Medicaid program at any time during the preperiod and the postperiod. The base case provided a broad assessment of the effects of the PA policy change by allowing for the adjustment of per month expenditures based on increases or decreases in the enrollee population (ie, the prevalence of use of antisecretory drugs was not assumed to be static).

Antisecretory Medication Users. To assess drug channeling and possible unintended medical consequences, subjects were categorized by cohorts who, subsequent to their index date, (1) had a pharmacy claim for a PPI (hereafter referred to as PPI users), (2) had a pharmacy claim for an H_2A (hereafter referred to as H_2A users), or (3) had no antisecretory drug pharmacy claim (hereafter referred to as nonusers). The latter 2 subject groups served as natural comparators to examine the effects of the policy change on medical care use. The research was performed in accord with the principles outlined in the Declaration of Helsinki and recently approved Health Insurance Portability and Accountability Act regulations regarding use of personal health information for program evaluation.

Study Outcomes

This study evaluated prescription expenditures and use and ambulatory services (including physician, other healthcare professional, emergency department visits, and GI-related screenings) and inpatient care (including long-term care) events and expenditures for the management of GI-related and all health conditions. The analysis was restricted to drugs, services, and facility charges for which the Medicaid program made at least a partial payment. Expenditures reported were net payments for the Medicaid program. These are credible outcomes assessable with data available in a retrospective analysis of a PA program.[10]

Pharmacotherapy. Antisecretory drugs were identified in the pharmacy claim records using generic product indicator codes beginning with "4927" for PPIs and "4920" for H_2As.[28] Expenditures (ie, [prescription drug cost plus tax plus administration fee plus applicable PA administration fee] minus copay) and claims for these drugs were tabulated separately on a per-member-per-month (PMPM) basis.

Ambulatory Care. The ambulatory services and events were identified by the place of service identifier

codes not assigned to inpatient admissions. Gastrointestinal-related diagnoses and procedures were identified with *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* and diagnosis related grouping codes (appendix available from the author). Gastrointestinal-related emergency department visits were identified with *ICD-9-CM* and Current Procedural Terminology codes. Ambulatory GI-related screening visits were identified with Current Procedural Terminology codes. A comprehensive definition of GI-related procedures was used because physicians and other healthcare professionals might have treated hypersecretory-related GI conditions during the course of visits for other GI problems[11] and because Medicaid diagnostic data for ambulatory visits may be incomplete for enrollees with dual eligibility in Medicaid and Medicare.[29] Gastrointestinal-related expenditures for ambulatory service visits (including screenings) included only payments for study procedures; GI-related expenditures for emergency department visits included payments for all services rendered on the day of the visit.

Inpatient Care. The inpatient care services and events and long-term care services were identified by the place of service identifier codes assigned to inpatient admissions and long-term care, respectively. Gastrointestinal-related inpatient and long-term care diagnoses and services were identified with *ICD-9-CM*, diagnosis related grouping, and Uniform Bill (UB-92) revenue codes (appendix available from the author). Gastrointestinal-related expenditures for inpatient and long-term care included payments for all services rendered during the facility stay associated with the claim.

Analysis

Interrupted time-series analysis with adjustment for the time trend and effect of the policy implementation was used to assess the immediate effect of the PA program on antisecretory drug expenditures and use.[30] The 4 time-series analyses consisted of the 24 PMPM values for the PPI and H_2A expenditure and claim outcome variables for the entire Medicaid program's population.

To assess the channeling of PPIs, logistic regression analysis controlling for sex, age in years, race (white vs nonwhite), and Chronic Disease Score, an adjuster for health status across time that affects healthcare expenditures and use,[31] was used to compare the proportions of subjects between the subgroups who had at least 1 GI-related diagnosis, condition, or screening during baseline. Gastrointestinal-related diagnoses were categorized based on erosive or ulcerative and symptomatic conditions (appendix available from the author).

To assess the incurrence of possible unintended medical consequences, logistic regression analysis controlling for sex, age in years, race, and Chronic Disease Score was used to compare the proportions of subjects between the subgroups who had received at least 1 GI-related ambulatory or inpatient visit or screening during follow-up. Two-part, finite mixture modeling for zero-inflated cost data,[32,33] controlling for possible explanatory variables, was used to assess across subgroups during follow-up (1) the probabilities of GI-related or any medical service events and (2) GI-related and total net medical costs. Typical of medical costs, the distributions of the costs were strongly right-skewed, with sizeable proportions of zero-cost observations. Zero costs were replaced by $0.50, and logarithmic transformations of the cost values were performed. Explanatory variables included a dummy variable indicating the presence or absence of baseline net medical costs, the logarithm of the baseline net medical costs, sex, age in years, race, and Chronic Disease Score (appendix available from the author).

Incomplete diagnostic and medical procedure data for Medicare beneficiaries receiving Medicaid benefits (ie, dual enrollees) possibly may bias the results of Medicaid claims data analyses.[29] To eliminate this source of possible bias, sensitivity analysis was performed using only the data

Table 1. Sample and Subject Group Characteristics*

Characteristic	All Medicaid Enrollees (n = 1 244 497)	Subject Group		
		PPI Users (n = 2664)	H_2A Users (n = 1860)	Nonusers (n = 1441)
Age, y				
0-17	63.8	9.6	6.5	10.2
18-34	14.4	8.1	13.0	15.8
35-44	4.9	13.4	15.0	16.0
45-54	3.9	17.9	15.8	15.8
55-64	3.6	19.2	17.5	15.0
≥ 65	9.4	31.8	32.2	27.2
Male sex	41.4	25.4	22.7	27.2
White race	40.6	53.2	43.4	42.7
Disabled	16.4	64.4	62.0	64.0

*Data are given as percentages as of February 1, 2002. Subject groups are based on pharmacotherapy received following implementation of prior-authorization program: proton pump inhibitor (PPI Users), histamine$_2$-receptor antagonist (H_2A Users), or no antisecretory drug pharmacy claim (Nonusers).

from subjects who were not eligible for Medicare benefits.

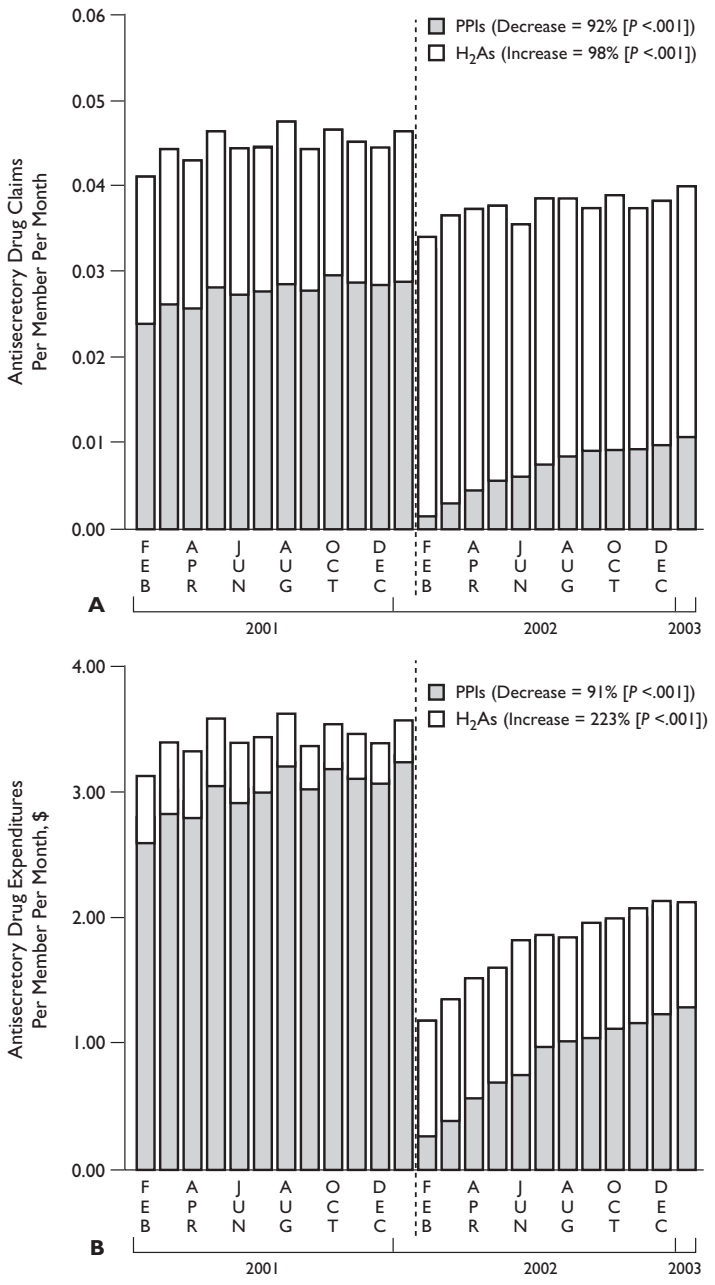
RESULTS

Enrollment in the Medicaid program population increased from 1 142 866 to 1 324 643 enrollees during the 24-month study period. Midpoint characteristics indicated a primarily young, female, nonwhite, and nondisabled population (**Table 1**). Subject groups generally were comparable and were predominantly older, female, and disabled. However, most PPI users were white, while most H_2A users and nonusers were nonwhite.

There were 377 574 PPI and 238 157 H_2A claims during the preperiod and 105 745 PPI and 467 047 H_2A claims during the postperiod. Proton pump inhibitor drug expenditures decreased (from $44.1 million to $13.2 million, including the cost of the administration of the PA program) and H_2A drug expenditures increased (from $6.0 million to $13.5 million) from the preperiod to the postperiod. Time-series analyses showed a decrease in the rate of PPI PMPM claims (92.2%) and expenditures (90.9%) and an increase in the rate of H_2A PMPM claims (98%) and expenditures (223.2%) in the month immediately following the implementation of the PA policy ($P < .001$ for all) (**Figure 2**). The mean PMPM expenditures for antisecretory drugs decreased 49.9%, from $3.44 in the preperiod to $1.74 in the postperiod, realizing the Medicaid program a net expenditures decrease of $23.4 million.

Pharmacy records indicated that 7966 of the Medicaid program's enrollees attempted to have a PPI prescription filled during April and May of 2002. Of these enrollees, 74.9% were continuously eligible during baseline and follow-up. Approximately 50% of these continuously eligible enrollees did not attempt to go through the PA process. Of those who did not go through the PA process, 56.5% were later identified as having a claim for an H_2A, while 43.5% did not have a prescription claim for any antisecretory drug although they could have received an H_2A without going through the PA process. Among enrollees who went through the PA process, 95.1% were approved. Of those who went through the PA process and were denied, 63.7% had a claim for an H_2A.

Figure 2. Rates of Pharmacy Antisecretory Drug Claims (A) and Expenditures (Including Program Costs) (B) per Month Among All Medicaid Enrollees in the 12 Months Before and After Implementation of the Prior-Authorization Program



The dashed line indicates the date of the implementation. The percentage decrease refers to the decrease for proton pump inhibitor (PPI) values, and the percentage increase refers to histamine$_2$-receptor antagonist (H_2A) values that were estimated in the interrupted time-series analysis to be the immediate effect of the program.

Proton pump inhibitor users were more likely to have had at least 1 diagnosis for a GI condition and GI-related screening during baseline than H_2A users and nonusers

Table 2. Proportions of Subjects With At Least 1 Gastrointestinal (GI)–Related Diagnosis or Condition by Severity Category and Subject Group*

Variable	Subject Group		
	PPI Users (n = 2664)	H_2A Users (n = 1860)	Nonusers (n = 1441)
GI diagnosis or condition			
Erosive or ulcerative	14.6	8.2†	8.4†
Symptomatic	79.1	63.2†	47.1†
Any GI-related diagnosis or condition	80.7	64.1†	48.4†
GI screening during baseline	14.0	8.3†	8.5†

*Data are given as percentages. Diagnosis or condition and screening occurred in the 6 months before the subjects' first attempt to obtain a PPI following the implementation of the prior-authorization program. Gastrointestinal severity was categorized based on having had a diagnosis for an ulcerative (eg, peptic ulcer) or symptomatic (eg, dyspepsia) GI condition. For explanation of subject group abbreviations, see Table 1.
†$P < .001$ compared with PPI users, adjusted for sex, age, race, and Chronic Disease Score.

($P < .001$ for both) (**Table 2**). Proton pump inhibitor users were more likely to have had at least 1 GI-related inpatient and ambulatory (including emergency department visits) medical service event during follow-up compared with nonusers ($P < .05$), and there was no statistical difference compared with H_2A users (**Table 3**). No evidence of an increase in the use of GI-related screenings from baseline to follow-up was found among H_2A users (8.3% vs 7.3%) and nonusers (8.5% vs 5.6%). Removing Medicaid and Medicare dual enrollees' data from the analyses provided similar results.

Table 3. Proportions of Subjects Using At Least 1 Gastrointestinal (GI)–related Medical Service and Screening by Subject Group*

Variable	Subject Group		
	PPI Users (n = 2664)	H_2A Users (n = 1860)	Nonusers (n = 1441)
GI medical service			
Inpatient	2.5	2.0	1.3†
Ambulatory	27.1	27.1	23.7‡
GI screening during follow-up	10.9	7.3‡	5.6‡

*Data are given as percentages. Medical service use and follow-up screening occurred in the 6 months after and baseline screening occurred in the 6 months before the subjects' first attempt to obtain a PPI following the implementation of the prior-authorization program. For explanation of subject group abbreviations, see Table 1.
†$P < .05$ compared with PPI users, adjusted for sex, age, race, and Chronic Disease Score.
‡$P < .001$ compared with PPI users, adjusted for sex, age, race, and Chronic Disease Score.

The Medicaid program's net payments for GI-related and total medical service visits were $13 558 872 and $37 899 979, respectively, during baseline vs $12 428 928 and $37 424 469, respectively, during follow-up for the subjects. Comparing baseline with follow-up, increases in the mean net payments for GI-related and total medical service visits were not found for H_2A users or nonusers (**Table 4**). Finite mixture regression analysis of the follow-up indicated that, compared with PPI users, H_2A users ($P < .01$ and $P > .05$) and nonusers ($P < .001$ and $P < .05$) were no more likely to have had at least 1 GI-related and any medical service visit, respectively (appendix available from the author). Similarly, H_2A users ($P < .01$ and $P > .05$) and nonusers ($P < .001$ and $P < .001$) were no more likely to have had greater GI-related and total medical service visit expenditures, respectively, during follow-up compared with PPI users. Removing Medicaid and Medicare dual enrollees' data from the analyses provided similar results.

COMMENT

Prior authorization for PPIs in this Medicaid population had the effect of reducing the use of high-cost PPIs, while encouraging increased use of lower costing H_2As, leading to a decrease of $23.4 million in annual net expenditures for antisecretory drugs. Requiring administrative approval for PPI reimbursement did not increase ambulatory or inpatient medical services use for the management of GI-related conditions and total medical care expenditures among those enrollees who did not receive a prescribed PPI. If enrollees who did not receive a PPI had more severe GI-related disease, they might have been more vulnerable to adverse effects of the policy change. Our data indicate that this PA program achieved its desired effects of decreasing the Medicaid program's pharmacy expenditures for antise-

cretory drugs by channeling PPIs to those patients with demonstrated medical need. Sensitivity analysis excluding Medicaid and Medicare dual enrollees provided additional evidence to support these findings.

The retrospective database analysis design of this study precluded the assessment of GI disease–specific clinical (eg, esophageal healing and symptom relief) and humanistic (eg, quality of life and satisfaction) outcomes.[34] In theory, PA programs that direct prescribers to adhere to evidence-based clinical practice should result in positive clinical and humanistic outcomes.[10] Our data suggest that, if any negative outcomes occurred and affected overall health, they were not sufficient enough to increase the use of medical services by the patients affected by this policy change. In addition, acceptability for this PA program among stakeholders may have been enhanced by the state's extending the PA requirement to its beneficiaries outside of the Medicaid program.[6]

Table 4. Table 4. Mean Baseline and Follow-up Net Payments for Gastrointestinal (GI)–Related and Total Medical Services by Subject Group*

Period	Subject Group		
	PPI Users (n = 2664)	H_2A Users (n = 1860)	Nonusers (n = 1441)
Baseline			
GI related	1971 (0)	2404 (0)	2663 (0)
Total medical	6369 (1405)	6200 (1033)	6522 (851)
Follow-up			
GI related	2470 (0)	1921 (0)	1578 (0)
Total medical	7320 (1390)	5634 (1087)	5167 (723)

*Data are given as mean (median) dollars. Baseline services occurred in the 6 months before and follow-up services occurred in the 6 months after the subjects' first attempt to obtain a PPI following the implementation of the prior-authorization program. For explanation of subject group abbreviations, see Table 1.

We were unable to measure the effect of the policy on prescribers' time spent when managing the PA administrative process instead of on other clinical or administrative tasks. However, participating prescribers in the Medicaid program were made aware of the PA policy through 2 channels, and they are compensated for in toto episodic care of the Medicaid program's patients. Although we could not compare the underlying trend in unmanaged Medicaid expenditures for PPIs with the examined Medicaid program's, it is reasonable to expect that PPI expenditures would have continued to increase or, at a minimum, remain constant during the study period in the absence of the PA program. Although no antisecretory prescription claims were identified for the nonusers subgroup, these enrollees could have obtained antisecretory drug samples from their physician or purchased out-of-pocket prescription PPIs or H_2As or over-the-counter H_2As or other antacids.[35] We were unable to examine the possible effect of the use of these drugs. However, the availability of these therapies provides patients with therapeutic options with which they can manage their health conditions outside of Medicaid. In addition, such use would not have affected the Medicaid program's pharmacy expenditures. Restricting the study to Medicaid enrollees may have limited its generalizability to other patient populations. However, given that an estimated 30% to 70% of patients with painful reflux symptoms do not have GI conditions with sustained tissue damage,[15] positive outcomes should be realized across patient populations when limiting PPI prescriptions to those with a demonstrable medical need.

To our knowledge, this is the first study of the effects of PA to include in the analysis the administrative costs of the PA program.[36] Despite the inclusion of these costs, our findings are still in agreement with other studies[3,11-13] of pharmacy reimbursement restrictions, which found substantial reductions in drug expenditures without concomitant increases in other medical expenditures.

As Medicaid expenditures continue to rise, states are faced with the options of restricting Medicaid eligibility or benefits or eliminating other public programs to attain budget neutrality. The challenge for Medicaid programs has been to craft healthcare policies that provide access to essential therapies while concomitantly applying monetarily responsible control over their healthcare budgets. Since completion of data collection for this study, the introduction of over-the-counter Prilosec[37] and the stabilization of supply and price for generic prescription of other omeprazole products[38] have presented new opportunities for managing the PPI benefit. Limiting PPI formularies to generic-only products or offering coverage for over-the-counter Prilosec are 2 benefit management strategies now available. In addition, the inclusion of over-the-counter and generic PPI products and H_2As in PPI PA programs can further direct patients and prescribers to cost-effective, appropriate therapy options.

Managed care organizations and other healthcare plan sponsors have been challenged to control rising drug costs while not denying or limiting access to those medications that improve clinical and humanistic outcomes. From a policy perspective, PA offers a strategy to reduce expenditures for PPIs without incurring adverse medical consequences. Plan sponsors that have implemented PPI PA programs with appropriate diagnosis- and risk-based clinical criteria should be encouraged that they have moved in the right direction to cost-effectively manage rising drug costs.

Acknowledgments

We thank Kathleen Fairman, MA for her analytic assistance and Edmond Weisbart, MD, for his clinical expertise.

REFERENCES

1. Kaiser Commission on Medicaid and the Uninsured. Medicaid and prescription drugs. October 2002. Available at: http://www.kff.org/medicaid/1609-index.cfm. Accessed June 23, 2003.

2. Kaiser Commission on Medicaid and the Uninsured. Medicaid: fiscal challenges to coverage. May 2003. Available at: http://www.kff.org/medicaid/upload/14341_1.pdf. Accessed June 23, 2003.

3. Cromwell DM, Bass EB, Steinberg EP, et al. Can restrictions on reimbursement for anti-ulcer drugs decrease Medicaid pharmacy costs without increasing hospitalizations? *Health Serv Res.* 1999;33:1593-1608.

4. Kaiser Commission on Medicaid and the Uninsured. States strive to limit Medicaid expenditures for prescribed drugs. February 2002. Available at: http://www.kff.org/medicaid/4030-index.cfm. Accessed June 23, 2003.

5. Gencarelli DM. Medicaid prescription drug coverage: state efforts to control costs. *NHPF Issue Brief.* 2003;790:1-17.

6. Kaiser Commission on Medicaid and the Uninsured. Prior authorization for Medicaid prescription drugs in five states: lessons for policy makers. April 2003. Available at: http://www.kff.org/medicaid/4094-index.cfm. Accessed June 23, 2003.

7. Gondek K. Prescription drug payment policy: past, present, and future. *Health Care Financ Rev.* 1994;15:1-7.

8. Soumerai SB, Ross-Degnan D. Experience of state drug benefit programs. *Health Aff (Millwood).* 1990;9(3):36-54.

9. Social Security Act, §1927(d)(5).

10. MacKinnon NJ, Kumar R. Prior authorization programs: a critical review of the literature. *J Manag Care Pharm.* 2001;7:297-302.

11. Smalley WE, Griffin MR, Fought RL, Sullivan L, Ray WA. Effect of a prior-authorization requirement on the use of nonsteroidal anti-inflammatory drugs by Medicaid patients. *N Engl J Med.* 1995;332:1612-1617.

12. Kotzan JA, McMillan JA, Jankel CA, Foster AL. Initial impact of a Medicaid prior authorization program for NSAID prescriptions. *J Res Pharm Econ.* 1993;5:25-41.

13. Kotzan JA, Jankel CA, McMillan JA, Foster AL, Myers S. Initial impact of a Medicaid maintenance dose program for H_2 antagonist prescriptions. *J Res Pharm Econ.* 1993;5:43-58.

14. Sachs G, Shin JM, Vagin O, et al. Current trends in the treatment of upper gastrointestinal disease. *Best Pract Res Clin Gastroenterol.* 2002;16:835-849.

15. Shaheen N, Ransohoff DF. Gastroesophageal reflux, Barrett esophagus, and esophageal cancer: scientific review. *JAMA.* 2002;287:1972-1981.

16. Harris RA, Kupperman M, Richter JE. Prevention of recurrences of erosive esophagitis: a cost-effectiveness analysis of maintenance proton pump inhibition. *Am J Med.* 1997;102:78-88.

17. Vigneri S, Termini R, Leandro G, et al. A comparison of five maintenance therapies for reflux esophagitis. *N Engl J Med.* 1995;333:1106-1110.

18. Soll AH, Practice Parameters Committee of the American College of Gastroenterology. Consensus conference: medical treatment of peptic ulcer disease: practice guidelines [published correction appears in *JAMA.* 1996;275:1314]. *JAMA.* 1996;275:622-629.

19. DeVault KR, Castell DO, Practice Parameters Committee of the American College of Gastroenterology. Updated guidelines for the diagnosis and treatment of gastroesophageal reflux disease. *Am J Gastroenterol.* 1999;94:1434-1442.

20. Marks RD, Richter JE, Rizzo J, et al. Omeprazole versus H_2-receptor antagonists in treating patients with peptic stricture and esophagitis. *Gastroenterology.* 1994;106:907-915.

21. Dent J. Long-term aims of treatment of reflux disease, and the role of non-drug measures. *Digestion.* 1992;51(suppl 1):30-34.

22. Sampliner RE, Practice Parameters Committee of the American College of Gastroenterology. Practice guidelines on the diagnosis, surveillance, and therapy of Barrett's esophagus. *Am J Gastroenterol.* 1998;93:1028-1032.

23. Yousfi MM, el-Zimaity HMT, al-Assi MT, Cole RA, Genta RM, Graham DY. Metronidazole, omeprazole and clarithromycin: an effective combination therapy for *Helicobacter pylori* infection. *Aliment Pharmacol Ther.* 1995;9:209-212.

24. Soumerai SB, Ross-Degnan D, Avorn J, McLaughlin TJ, Choodnovoskiy I. Effects of Medicaid drug-payment limits on admissions to hospitals and nursing homes. *N Engl J Med.* 1991;325:1072-1077.

25. Soumerai SB, Avorn J, Ross-Degnan D, Gortmaker S. Payment restrictions for prescription drugs under Medicaid: effects on therapy, cost, and equity. *N Engl J Med.* 1987;317:550-556.

26. Soumerai SB, McLaughlin TJ, Ross-Degnan D, Casteris CS, Bollini P. Effects of a limit on Medicaid drug-reimbursement benefits on the use of psychotropic agents and acute mental health services by patients with schizophrenia. *N Engl J Med.* 1994;331:650-655.

27. Tamblyn R, Laprise R, Hanley JA, et al. Adverse events associated with prescription drug cost-sharing among poor and elderly persons. *JAMA.* 2001;285:421-429.

28. First DataBank (Medispan). *Generic Product Identifier Number.* Indianapolis, Ind: First DataBank (Medispan); 2002.

29. Ray WA, Griffin MR. Use of Medicaid data for pharmacoepidemiology. *Am J Epidemiol.* 1989;129:837-849.

30. Ward MM, Leigh JP. Pooled time series regression analysis in longitudinal studies. *J Clin Epidemiol.* 1993;46:645-659.

31. McLachlan GJ, Peel D. *Finite Mixture Models.* New York, NY: John Wiley & Sons Inc; 2000.

32. Clark DO, Von Korff M, Saunders K, Baluch WM, Simon GE. A chronic disease score with empirically derived weights. *Med Care.* 1995;33:783-795.

33. Duan N, Manning WG, Morris CN, Newhouse JP. A comparison of alternative models for the demand for medical care. *JBES.* 1983;1:115-126.

34. Soumerai SB, Ross-Degnan D, Fortess EE, Abelson J. A critical analysis of studies of state drug reimbursement policies: research in need of discipline. *Milbank Q.* 1993;71:217-252.

35. Martin BC, McMillan JA. The impact of implementing a more restrictive prescription limit on Medicaid recipients. *Med Care.* 1996;34:686-701.

36. Lexchin J. Effects of restrictive formularies in ambulatory care settings. *Am J Manag Care.* 2001;7:69-76.

37. Food and Drug Administration Web site. FDA approves Prilosec OTC to treat frequent heartburn. June 20, 2003. Available at: http://www.fda.gov/bbs/topics/news/2003/NEW00916.html. Accessed October 20, 2003.

38. Food and Drug Administration Web site. FDA approves generic omeprazole: first marketing of cost-saving drug product to begin November 1, 2002. Available at: http://www.fda.gov/bbs/topics/NEWS/2002/NEW00848.html. Accessed October 20, 2003.