OBJECTIVE: Though prior authorization (PA) programs are widely used in the managed care pharmacy environment, some stakeholders question whether these programs are effective. The objective of this article is to critically examine the effect of PA programs on health-related outcomes.

DATA SOURCES: A computer-aided search of the literature was conducted using several online databases to find studies that have evaluated PA programs. Other sources of information used were reference lists, authors of previous studies, and meeting abstracts.

STUDY SELECTION: In order for a study to be included in our analysis, it had to (1) appear in the peer-reviewed literature and (2) investigate the effects of a PA program on specified drugs. We excluded papers that studied the effectiveness of formulary systems, of which PA may be a component.

DATA EXTRACTION: From each study evaluated, we extracted data related to the study design and to the effect of the PA program on economic, clinical, and humanistic outcomes.

DATA SYNTHESIS: Six studies met our criteria. Overall, PA programs appear to be effective at reducing drug-related costs. There is some evidence that they reduce non-drug-related costs but little evidence that they have a positive impact on clinical or humanistic outcomes. None of the studies had a randomized, controlled design; most of the studies had severe methodological limitations.

CONCLUSION: Rigorously designed studies are urgently needed in order to evaluate the effects of PA on health-related outcomes.

KEYWORDS: Prior authorization, special authorization, drug cost containment, pharmacy benefit management, prescribing restrictions

Prior Authorization Programs: A Critical Review of the Literature

by Neil J. MacKinnon and Ritu Kumar

In modern health care it is unethical not to be concerned with evaluation, and no longer acceptable to be "evaluation illiterate."

Managed care organizations (MCOs) use many pharmacy benefit management tools and techniques to help guide appropriate medication usage. Popular methods are formularies, prescription drug caps, patient copayments, maximums, mandatory use of generics, drug-utilization review, and therapeutic interchange. The challenge faced by many MCOs is to deal with rising drug costs while not denying or limiting access to those drugs that improve therapeutic outcomes and health-related quality of life (HRQoL). The challenge is likely to become more difficult; prescription drug expenditures in the United States are projected to increase 11.0% in 2001 and 10.7% in 2002.

One pharmacy benefit management technique being used with increasing frequency is prior, or special, authorization (PA); a recent survey revealed that in 1996 43%, in 1997 54%, and in 1998 61% of employers reported using PA programs. PA is an administrative tool that requires the prescriber to get preapproval for prescribing a drug in order to qualify for reimbursement. The broad purpose of PA is to change prescribing behavior. The goal of the PA process is to encourage appropriate use of medications, both to reduce the incidence of preventable drug-related morbidity and to contain costs. The philosophy behind this mechanism, which intuitively seems to help promote the delivery of quality health care, is to target new, costly, or potentially toxic medications, and to encourage use of less-expensive, safer alternatives. Some view this technique as simply a means to contain costs rather than a quality-improvement or risk-management tool.

Not all agree with the use of PA to direct prescribing. Understandably, the pharmaceutical industry views PA programs as a barrier to market access. Similarly, patients often feel that PA programs impede their access to drugs that they perceive as necessary. Many physicians are exasperated by the time dedicated to PA paperwork. Some physicians in New Brunswick, Canada, reported filling out up to 10 PA forms a day; in September 2000, physicians in the province refused to fill out any PA forms because of the time burden.

Some physicians feel that PA programs actually prevent their patients from getting the medications they need in a timely manner. A survey in Ontario, Canada, revealed that only 34% (17 of 50) of the physicians who responded felt that a limited-use (PA) listing for medications helped them to more

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appropriately prescribe drugs. Sixty-six percent (29 of 44) said that in the past they have chosen not to prescribe a product primarily because of its limited-use status, even though the physician felt the patient might benefit from the drug.

Community pharmacists also complain about the administrative burden of PA programs; a recent study showed that, on average, a supermarket chain pharmacy spent 2.15 minutes and an independent pharmacy spent 2.97 minutes just on rejection resolution for each prescription that required PA. Last year, the North Carolina Board of Pharmacy passed special regulations to help reduce community pharmacists’ burdens of dealing with third-party payor administrative policies such as PA.

Perhaps the greatest controversy over the use of PA is the unintended effect of other prescribing restrictions such as restrictive formularies and benefit caps. One of the first studies to document unintended effects was a 1985 study of a closed formulary for drugs used in treating peptic ulcer disease for the West Virginia Medicaid program. After a formulary policy change, outpatient drug expenditures were reduced by 78.9%, but monthly physician payments increased 3.1% and monthly inpatient hospital costs increased 23.6%. A 1991 study found that drug use decreased but nursing home admissions increased after a three-prescription limit per patient per month was implemented in the New Hampshire Medicaid program.

A controversial 1996 study by Horn and colleagues further added to the literature on the unintended effects of prescribing restrictions by concluding that health maintenance organizations (HMOs) with more-restrictive drug formularies had higher overall utilization and costs of health care resources. There has been considerable debate over the methodology of the Horn study in particular and over prescribing restrictions in general, including several editorials in this journal.

Since PA programs are common in the managed care pharmacy environment, and because of the questions about these programs stimulated by previous studies, we considered it urgent to examine the effectiveness of PA programs. The objective of this article is to review the peer-reviewed literature on PA programs and to assess their effects on economic, clinical, and humanistic outcomes of health care.

Methods

Data Sources

A computer-aided search of the medical and pharmacy literature in English was conducted in spring 2001, using Medline, International Pharmaceutical Abstracts (IPA), Health Star, and Ecolit. Keywords such as prior authorization, prescribing restrictions, prior approval, special authorization, cost containment, exemption drug status, and restrictive formularies were used in the search. Other studies on PA were found in managed care textbooks, references, and reading materials previously collected by the lead author. We attempted to contact authors of published studies on PA and researchers on PA in search of studies that were not identified by our computer-aided search. We reviewed abstracts from recent educational conferences and annual meetings of the Academy of Managed Care Pharmacy (AMCP) and annual meetings of the Canadian Association of Population Therapeutics (CAPT), but a study had to be published in complete form in order to be included in our final analysis.

Study Selection

In order for a study to be included in our analysis, it had to (1) appear in the peer-reviewed literature, and (2) investigate the effects of a PA program on specified drugs. We excluded papers that studied the effectiveness of formulary systems, of which prior authorization may be a component, as it would be impossible to distinguish the effect of the PA program from the effect of the formulary itself.

Data Extraction

From each study evaluated, we extracted data related to the study design and the effect of the PA programs on health-related outcomes. In the critique of each study, each author of this article independently used a standardized data collection form based on the ECHO (economic, clinical, and humanistic outcomes) model proposed by Kozma, Reeder, and Schulz as our framework for evaluation. More specifically, for all studies we critically evaluated the methodology, study sample, outcomes measures, drugs studied, and economic (both drug costs and other health expenditures), clinical (both drug-related and non-drug-related), and humanistic outcomes (satisfaction and HRQoL).

Results

Six studies met our criteria for review. The study design, study sample, outcomes measures, and drugs in the PA programs are contained in Table 1, page 299.

Because no study had a randomized, controlled experimental design, all studies had significant threats to validity. The study by Smalley and colleagues had the most rigorous experimental design. Four of the six studies had no control group. One study did not use a baseline measurement period before the PA program was set up, and only one study had a follow-up period of more than one year to measure the long-term effects of the PA program.

Four of the six studies used a state Medicaid program for the study sample. The other studies used an urban teaching hospital and secondary data from a national survey. None of the studies was multi-center. The intended unit of analysis was often hard to determine; indeed, three of the studies did not specify the exact number of patients considered.

Outcome measures also varied considerably. One study measured simply the cost and utilization of the PA drugs. Only one study included clinical outcome measures. Four of the studies looked at a single drug class (nonsteroidal anti-inflamm-
## TABLE 1  Summary of Reviewed Studies on Prior Authorization Programs

<table>
<thead>
<tr>
<th>Article</th>
<th>Study Design</th>
<th>Study Sample</th>
<th>Outcome Measures</th>
<th>Drugs Studied</th>
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<tr>
<td>Kotzan, McMillan, Jankel, and Foster, 1993&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Time-series analysis that included data up to one year before policy change and up to seven months after</td>
<td>80,064 continuously eligible recipients in the State of Georgia Medicaid program</td>
<td>Cost and utilization of NSAIDs, other anti-arthritis agents, non-narcotic analgesics, physician claims, and other medical services (exact kinds not specified)</td>
<td>NSAIDs (except those available in generic form)</td>
</tr>
<tr>
<td>Smalley, Griffin, Fought et al., 1995&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Baseline year before policy change and the two-year period after policy change; interrupted time-series analysis with a control analysis</td>
<td>Two separate study groups: (1) enrollees at any time during the three-year period in the Tennessee Medicaid program (495,821 in baseline year to 547,403 in year 3), and (2) enrollees with uninterrupted enrollment for all three years who were regular users of NSAIDs (3,174 regular users of nongenerics and 1,849 regular users of generics)</td>
<td>Cost and utilization of NSAIDs, other analgesic or antiinflammatory drugs, psychotropic drugs, outpatient services, and inpatient admissions for management of pain or inflammation</td>
<td>NSAIDs (except those available in generic form)</td>
</tr>
<tr>
<td>Kotzan, Perri, and Martin, 1996&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Cross-sectional, equivalent control group; comparison of two groups for a three-month period</td>
<td>All prescription claims processed for the State of Georgia Medicaid program for Jan–Mar 1994 (2,957,850 prescriptions, including 71,187 for PA drugs), and cash prescriptions (6,347,617 total, including 357,546 for PA drugs) from approximately 1,100 Georgia pharmacies</td>
<td>Cost and utilization of 46 drugs; market-share analysis</td>
<td>46 drugs that were part of the Georgia Medicaid program and also represented in private-payment markets</td>
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<tr>
<td>Phillips and Larson, 1997&lt;sup&gt;4&lt;/sup&gt;</td>
<td>Baseline (12–24 months) before policy change and the 12-month period after the policy change: no control group. Operational performance based on two weeks of data</td>
<td>Iowa Medicaid enrollees for whom a prescription requiring PA was filled during the study period (approximately 250,000 enrollees; no number for patients for whom a PA prescription was filled)</td>
<td>Cost and utilization of 16 drugs; also administrative outcomes, such as approval rates and program response times</td>
<td>16 categories of individual medications</td>
</tr>
<tr>
<td>White, Atmar, Wilson et al., 1997&lt;sup&gt;5&lt;/sup&gt;</td>
<td>Baseline (July–Dec) six-month period before policy change and a six-month period (July–Dec) six months after the policy change; no control group</td>
<td>Patients in a 575-bed urban teaching hospital during the study period who received an antimicrobial agent (exact number of patients or prescriptions filled is not provided, though the total number of patient-days per month in the hospital decreased from 14,694 to 13,738)</td>
<td>Cost of parenteral antimicrobials, antimicrobial susceptibility patterns, gram-negative bacteremia survival rates, time from initial blood culture to receipt of an appropriate antibiotic, inpatient and ICU length-of-stay</td>
<td>Six intravenous antibiotics initially, plus two other antibiotics added over the next six months</td>
</tr>
<tr>
<td>Feldman, Fleischer, and Chen, 1999&lt;sup&gt;6&lt;/sup&gt;</td>
<td>Retrospective cross-sectional study of data from the National Ambulatory Medical Care Survey; sensitivity analyses were performed to determine whether a PA age of 25 is cost-effective</td>
<td>A cost and utilization model was created from previously published data (the National Ambulatory Medical Care Survey), normalized to 100,000 covered lives</td>
<td>Cost and utilization of topical tretinoin; costs of administering a PA program to an insurer were also considered</td>
<td>Topical tretinoin</td>
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Notes: NSAID is nonsteroidal anti-inflammatory drug. PA is prior authorization. ICU is intensive-care unit.
### TABLE 2: Outcomes Measured in Prior Authorization Studies

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<tr>
<td>Kotzan, McMillan, Jankel, and Foster, 1993</td>
<td>NSAIDs: monthly reduction in costs of about 54% from baseline to policy implementation period ($3,018,308 estimated savings over seven months); monthly non-narcotic analgesic use increased about 37% ($193,540 over first seven months); no other significant changes.</td>
<td>No significant changes in physician claims or other categories of medical services (exact categories not specified); administrative costs of the program were not measured.</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
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<tr>
<td>Smalley, Griffin, Fought et al., 1995</td>
<td>All enrollees: Annual expenditures of NSAIDs decreased by 53% during the two years after the start of the policy ($12,800,000 estimated savings over two years); no other significant changes; regular nongeneric NSAID users: a relative decrease in expenditures of 64% compared to generic NSAID users; no other significant changes.</td>
<td>All enrollees: no significant changes. Regular nongeneric NSAID users: no significant changes where sample size permitted analysis. Administrative costs to the Medicaid program: $75,000 for one year</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
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<tr>
<td>Kotzan, Perri, and Martin, 1996</td>
<td>Total estimated drug costs savings attributable to the Georgia Medicaid PA program for all 46 drugs: $8-$20 million annually.</td>
<td>Effects on non-drug costs were not measured. Administrative costs to the Medicaid program: About $1 million</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
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<tr>
<td>Phillips and Larson, 1997</td>
<td>Net savings (gross drug savings minus administrative costs) for four drug categories (anti-arthritis, benzodiazepines, antihistamines, and antibiotic drugs) estimated to be $2.51 million-$3.83 million.</td>
<td>Effects on non-drug costs were not measured. Administrative costs to the Medicaid program for four categories of drugs totaled $162,000.</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Satisfaction not directly measured, though response times and approval rates were</td>
<td>Not measured</td>
</tr>
<tr>
<td>White, Atmar, Wilson et al., 1997</td>
<td>Expenditures for all parenteral antimicrobials decreased by $431,548 (32%) for the six-month period in 1994 as compared to 1993 (this included an increase in expenditures for some antimicrobials not included in the PA program).</td>
<td>No significant change in inpatient or ICU length of stay Administrative costs to the hospital: less than $150,000 per year (estimated).</td>
<td>Increased susceptibility to isolates in ICUs and inpatient units but not outpatient sites; time to receipt of appropriate antibiotics unchanged</td>
<td>No significant change in survival rates in patients with gram-negative bacteremia</td>
<td>Satisfaction not directly measured, though response times and approval rates were</td>
<td>Not measured</td>
</tr>
<tr>
<td>Feldman, Fleischer, and Chen, 1999</td>
<td>Assuming a topical tretinoin unit cost per prescription of $28 and a unit expense of $10 for performing a single PA, the total cost per 100,000 covered lives is estimated to be $23,226 for a PA age of 25 and $22,685 for a PA age of 35. The tretinoin cost with no PA program is $23,800. Effects on non-drug costs were not measured.</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
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</tbody>
</table>

Notes: NSAID is nonsteroidal anti-inflammatory drug. PA is prior authorization. ICU is intensive-care unit. HRQoL is health-related quality of life.
matory drugs [NSAIDs] in two, intravenous antibiotics in one, topical tretinoin in one), while the two others evaluated several drug classes.

Table 2, page 300, contains the economic, clinical, and humanistic outcomes that were measured in these studies. We distinguished between drug and non-drug outcomes in both the economic and clinical outcome categories and between patient satisfaction and HRQoL humanistic outcomes.

All six studies documented drug cost savings from the PA programs. We had initially hoped to conduct a meta-analysis to better summarize the amount of drug cost savings from PA programs, but inconsistencies in the descriptions of the study samples and outcomes made it impossible to calculate an effect size. It is interesting, though, that the two studies that focused on a PA program for NSAIDs found similar drug cost savings (approximately 54% in Kotzan et al. and 53% in Smalley et al.). Some studies failed to distinguish between cost savings resulting from lower overall drug product cost (switch to generic or less expensive drug) or from lower drug utilization.

Of the three studies that measured the effect of the PA program on non-drug costs, none found a significant increase in costs elsewhere in the health care system. Five of the six studies calculated the administrative costs of operating the PA program, although they did not provide thorough descriptions of how these costs were measured, what they included, and costs to stakeholders outside of the direct organization of interest (e.g., community pharmacists, physicians, etc.). One study concluded that the administrative costs of the PA program outweighed the reduction in drug costs for a majority of age groups considered.

Only the study by White and colleagues measured how the PA program affected clinical outcomes. None of the studies measured how PA programs affected satisfaction (patient, pharmacist, physician, nurse, or other) or HRQoL, two primary humanistic outcomes.

Discussion

Our critical analysis of the literature indicates that although PA programs are common, their outcomes have not been adequately evaluated. PA is not alone, however; evaluation of administrative policies and programs in health care and in pharmacy benefit management today is rarely adequate. Still, the scarcity of quality evaluations of the outcomes of PA programs should be of concern to patients, health care professionals, administrators, and others who work in managed care pharmacy since these programs are widely used. Little has changed since 1993, when Kotzan, McMillan, Jankel, and Foster lamented: “The long-term impact of PA programs has not been documented. If the drug programs are devised solely on the basis of economic consideration without regard for medical consequences, then it is likely that more expensive services will replace those expensive drugs removed from the formulary.”

Why is there a lack of rigorous evaluations of PA programs? Ray has reflected on the general problem of inadequate health policy evaluations and concluded that a primary barrier is politics; conducting a randomized, controlled trial is an admission of uncertainty. The persons or organizations involved in PA programs may have a vested interest in the success of their programs. Moreover, expensive randomized controlled trials may not be practical for many organizations, although repeated time-series analyses, such as the one conducted by Smalley and colleagues, may be possible.

One can understand the reluctance to measure humanistic outcomes of PA programs, such as satisfaction, given that PA is an administrative policy. Still, measuring what happens to patients who are denied a PA request would be valuable. Fortunately, some MCOs are now trying to improve physician and patient satisfaction with PA programs, some by automating the PA process to eliminate paperwork or pharmacist intervention. Finally, another barrier to quality evaluations is that some organizations may have difficulty in separating the outcomes of a PA program from those of the total formulary-management system.

Why is there a need for more PA program evaluations that measure all three types of health-related outcomes? The principal reason is to determine how PA programs affect clinical and humanistic outcomes. Proof that PA programs improve patient outcomes would more strongly support their use. If they affect patient outcomes negatively, all stakeholders should reassess their use. Failure to measure the clinical outcomes of PA programs is of special concern: Our literature search found no published studies, and just one presentation abstract, that measured clinical outcomes outside the hospital.

Secondly, evaluation of programs and policies is a key part of a continuous quality improvement (CQI) philosophy, where benchmarks are determined and an attempt made to improve performance to exceed those benchmarks. As Phillips and Larson acknowledge, currently there are not even PA program benchmarks for such basic outcomes as processing times, approval rates, and administrative costs. Standard principles for PA programs could be helpful, perhaps like those recently developed for drug-formulary systems by AMCP and other organizations. Setting, and reporting on, standards should lead to increased accountability and transparency for PA programs. The accountability that must clearly become a priority for each stakeholder involved in putting such programs in place should include continual monitoring to determine if the program’s mandate is being achieved.

The burden of proof whether PA programs improve patient outcomes should be on those who have programs in place, even if this is a difficult process. As Hepler says, “It may be painful to be objective about our own sacred cows.” Program evaluation is especially urgent given that many policies that regulate access to and utilization of pharmaceuticals can have unintended neg-
Prior Authorization Programs: A Critical Review of the Literature

atte outcomes. PA programs that direct prescribers to follow evidence-based clinical practice should, in theory, lead to positive clinical and HRQoL outcomes. Yet, as at least two of the studies we reviewed acknowledged, because these outcomes were not measured, we cannot be certain whether PA programs have a positive or a negative effect on these outcomes. Given these important but still unanswered questions, now would appear to be an opportune time for evaluation of all policies that restrict prescribing, including PA.

++) Limitations

In any analysis of critical literature, some may differ with the inclusion/exclusion criteria or identify studies that have been omitted. We tried to minimize these problems by making our initial search as broad as possible through the use of multiple literature-retrieval methods and by making our criteria fairly conservative. As with any literature review, we are limited by inherent publication biases to publish only statistically significant results. Finally, we did intend to conduct a meta-analysis, but this proved impossible given the inconsistency in the description of the study samples and outcomes.

++) Conclusion

From a critical review of the literature, PA programs appear to reduce drug-related costs. There is some evidence that they may also reduce non-drug-related costs, but little evidence that they improve clinical or humanistic outcomes. Most existing studies have severe methodological limitations. There has been not one randomized controlled study to better establish the relationship of PA programs to these health-related outcomes. Resources for thorough program evaluations may be scarce, but an unformed acceptance of PA programs without consideration of their effects on health outcomes may be suboptimal at best, and dangerous at worst.

References