Clinical Pharmacist Intervention in a Primary Care Medical Group Reduces Financial Losses

Global capitation contracts based on a percent of premium and including pharmacy benefit costs have pushed physician-hospital organizations (PHOs) into bankruptcy, including large PHOs with as many as 150,000 members enrolled under such risk contracts.1 A recent report from an academic PHO with more than 1,000 physicians operating under a global capitation contract showed that providing primary care physicians (PCPs) with information resulted in a 22% reduction in the use of high-cost drugs.2 Specifically, the PHO employed a clinical pharmacist to help create claims-based prescribing reports for PCPs generated from a relational (MS Access) database. Prescriber-specific reports were distributed to 57 PCPs operating under a global capitation contract with 9,046 enrolled members. A total of 795 high-cost prescriptions were identified, and 477 (60%) letters were generated to patients for new (substituted) prescriptions. The most common drug class that underwent substitution was oral contraceptives (278 patients), followed by antihistamines (150) and antihyperlipidemics (20). The one-time start-up developments costs were reported as $35,000, with annualized savings of $103,635—a 3-to-1 return on investment in the first year.

The report of the intervention in that academic PHO did not identify the time period and did not provide enough information to determine relative (percentage) savings. However, the reported savings per member can be derived as $11.46 per-member-per-year (PMPY) or $0.95 per-member-per-month. This study did employ comparison data from the remainder of the integrated delivery network that did not use the information intervention with PCPs and found the 22% reduction in use of high-cost drugs to be greater than the comparison group (P<0.001). Yet, it is noteworthy that the information intervention with PCPs coincided with a change in drug benefit design for the health plan members in which a copayment for third-tier (presumably nonformulary) drugs was added at $25 per prescription. This 3-tier copayment design ($5 for generic drugs, $10 for tier-2 brand drugs, and $25 for tier-3 brand drugs) replaced a 2-tier ($5 generic and $10 brand drug) copayment design. Implementation of a 3-tier drug benefit copay design has been shown to slow the rate of increase in total drug utilization by at least 40% versus a comparison group and reduce the utilization of tier-3 copay drugs by 18% compared with baseline (preintervention for the same group) and by 23% versus the comparison group.1

In an article in this issue of the Journal, a clinical pharmacist intervention in a nonacademic primary care medical group operating under a global capitation agreement was successful in reducing the adverse drug cost trend that threatened the financial integrity of the medical group.4 The study by Walker and Willey did not have a control group but did use national data by drug class. The clinical pharmacist was hired by the medical group for a specific purpose: to reduce the increase in drug costs incurred by members enrolled in the health plan with the global capitation agreement. Cost outcomes were the principal focus of this intervention, but the authors found that the participating physicians reported no incidences of patient complaints or dissatisfaction associated with the medication therapy management intervention.

The study by Walker and Willey perhaps confirms what one would expect—that a clinical pharmacist employed by a medical group and armed with information about relative drug costs can guide physicians to selection of lower-cost therapeutic alternatives. The combination of a physician financial incentive (global capitation) and information (physician-specific prescribing information derived from pharmacy claims data) was aided further by employment of the clinical pharmacist by the medical group. Others have observed that staff pharmacists employed in staff-model health plans are more likely to be viewed as clinical partners and educators compared with independent physician associations (IPAs) in which pharmacists employed by the health plan or pharmacy benefit managers are more likely to be viewed as “regulators and cost cutters.”5

Walker and Willey differentiate the favorable effect on drug cost trend (from an increase in per-member costs of 31% in the prior year to a decrease of 2% in the intervention year) between utilization and price and do so by drug class. The results are noteworthy. Antibiotic costs were reduced by 22% through a combination of the use of lower-cost therapeutic alternatives (15% reduction in the average cost per antibiotic prescription claim) and 8% reduction in antibiotic utilization.

For the clinical conditions associated with cardiovascular disease, the clinical pharmacist intervention derived cost savings from drug cost rather than from reduction in utilization. A 24% increase in utilization of angiotensin-converting enzyme inhibitors (ACEI) was offset by a 26% reduction in the average cost per ACEI claim, resulting in lower ACEI costs PMPY. The use of calcium channel blockers (CCB) increased by 20%, but PMPY costs for CCBs were reduced by a reduction in the average cost per CCB claim. The utilization of statins increased 16% in the medical group, but a reduction in the average cost per statin claim held the increase in statin costs to 10% PMPY compared with the prior year.

At a time when proton pump inhibitors (PPI) were driving up the pharmacy costs for heartburn and gastro-esophageal reflux disease nationwide, this PCP medical group with clinical pharmacist intervention experienced a 9% increase in the combined utilization of PPIs and histamine2-blockers, similar to the national data, but the increased use of generic ranitidine helped to reduce the average cost per pharmacy claim, resulting in no increase in PMPY costs in the intervention year. One other study has been published from clinical pharmacist intervention in an academic IPA,6 but that report was primarily descriptive and did not identify the specific PMPY cost savings nor the effects of the clinical pharmacist intervention on either drug cost per unit (i.e., per prescription or per day of therapy) or utilization, by therapeutic class.
Step-Therapy Edits for PPIs and COX-2 Drugs—What We Do and Do Not Know

Cox, Henderson, and Motheral in this issue of the Journal add to our knowledge of the effects of drug therapy step edits administered by pharmacy benefit managers on behalf of drug plan sponsors. While these results add information to help us better determine the potential value of step-therapy edits, there are several limitations to their study results. Particularly important is the fact that the researchers did not assess actual prescription utilization of the survey respondents. It is therefore not possible to determine if these were relatively low utilizers of the prescription drug benefit, high utilizers, or a representative mix of beneficiaries of prescription drug plans. One might expect high utilizers of prescription drugs to have opinions of their experience with step-therapy claim rejections that are different from the opinions of beneficiaries who seldom use their prescription drug benefits.

A MEDLINE search of the published medical literature produced only one citation on the step-therapy method applied to pharmacy benefit management. The citation was not a methods or outcomes article but, rather, presented a philosophical discussion of the ethical considerations, concluding that drug formularies and step therapy are ethically justifiable if they are “efficiently instituted.” Last year in this Journal, Stacy, Shaw, Arledge, and Howell-Smith described the results of pharmaco-economic modeling of a prior-authorization (PA) intervention for cyclooxygenase 2 (COX-2) drugs and concluded that the drug cost savings overwhelmed the administrative costs. In that PA study, 1,644 (73%) of the PA requests that were approved met the criterion of failure of 2 different nonspecific nonsteroidal anti-inflammatory drugs (NSAIDs). A step-therapy edit implemented as part of the process of electronic adjudication of pharmacy claims in real time has the potential to improve quality by reducing (a) member disruption (humanistic outcome), (b) administrative costs incurred by pharmacy and physician providers in obtaining pharmacy/physician overrides to the PA rejection, and (c) PBM administrative costs in processing the pharmacy override requests.

About 3 out of 4 rejections for COX-2 drugs in the PA program reported by Stacy et al. could be avoided with a step-therapy edit that uses their principal criterion (prior use of 2 nonspecific NSAIDs) for approval of a COX-2 drug. Pharmacy benefit management can therefore be made more efficient in the implementation of drug treatment guidelines by moving part of the PA to prospective administration in which the PBM searches its drug claims history for evidence of prior use of the required first-step therapy (e.g., use within the previous 6 months of one or more generic NSAIDs). This search for evidence to fulfill the principal criterion for acceptance of a pharmacy claim for a COX-2 drug is performed electronically in a step-therapy edit, and the process is transparent to both the drug plan member and to the pharmacist.

There is a dearth of published information regarding the clinical, service, and cost outcomes of the use of the step-therapy tool in pharmacy benefits management. Cox et al. have argued previously that step therapy for the use of nonselective NSAIDs before the use of higher-cost COX-2 inhibitors is warranted since 65% of patients new to COX-2 therapy did not have an indication of being at risk for gastrointestinal events and 68% had no evidence of prior use of a nonselective NSAID.

As is so often the case with research, many questions are raised by the findings or are otherwise not answered by the research. For the potentially valuable tool using electronic claim edits to increase first-line drug therapy, plan sponsors and managed care pharmacists want to be able to measure the clinical, service, and cost outcomes of step-therapy interventions. In the study by Cox, Henderson, and Motheral, only 15% of the beneficiaries who experienced a step-therapy edit received an override authorization from their physician in order to receive the target drug (19% for proton pump inhibitor rejections and 12% for COX-2 claims rejected by the step-therapy edit). By a more than 5-to-1 ratio, beneficiaries subjected to a step-therapy edit either changed to first-line therapy, obtained an over-the-counter drug, or paid 100% out of pocket for the drug. It is also significant that only 11% paid full price for the drug excluded by the step-therapy edit, and an equal proportion (11%) reported receiving no medication as a result of the intervention. The answer to the larger question is still elusive—i.e., what is the cost-benefit of the intervention? It is not known whether members understood or accepted the fact that these drugs were excluded due to the existence of lower-cost therapeutic alternatives, i.e., that the cost savings were not offset by a large additional cost in member dissatisfaction (service outcome).

Disease Management Opportunities for IBS—Placebo Versus Active Therapy

Hulisz in this issue of the Journal draws our attention to the illness burden that irritable bowel syndrome (IBS) imposes on society. Survey data suggest that IBS may affect as much as 20% of the U.S. population. But since as few as 10% of persons with IBS report their symptoms to physicians, the U.S. prevalence rate derived from administrative claims data ranges from 1% to 6% of the population. Data from the National Ambulatory Medical Care Survey from 1997 to 1999 and the National Center for Health Statistics for 1996 show that about 1% of the U.S. population is affected by IBS, as determined from the primary diagnosis field in medical claims, and these IBS patients accounted for more than 4.4 million physician visits between 1997 and 1999 (Table 1). There are about 7 times as many physician office visits for a diagnosis of asthma as for IBS and about 5.5 times as many office visits each year for migraine compared with IBS. Interestingly, IBS patients have about the same number of office visits per year as asthma patients.

While IBS symptoms can be debilitating, results of the survey conducted by the International Foundation for Functional Gastrointestinal Disorders of 350 adults with IBS showed that only about 1 of 4 reported that they had missed...
A noteworthy aspect of the IBS clinical research is the large number of placebo responders in most clinical trials, in the range of 30% to 40%. This range of placebo response is similar to the placebo response rates observed in most clinical trials of SSRI antidepressants,\textsuperscript{25} with the highest placebo response rate of 53% in a study of fluoxetine.\textsuperscript{26} In the U.S. Food and Drug Administration records of the advisory committee meeting held on June 26, 2000, to consider NDA 21-200 (tegaserod, at that time referred to as Zelmac), the 3 Phase III studies submitted with the application (B301, B307, B351) showed placebo response rates that ranged from 30.2% to 37.0% on the new Subject Global Assessment (SGA) of Relief scale.\textsuperscript{27} SGA scores for the active compound appeared to be dose-related, with the 38.4% to 45.7% response at the 12 mg per day (highest) dose of tegaserod. In other words, the absolute benefit increase (ABI) was in the range of 6% to 12% in the 3 studies. Assuming a mid-range ABI of 9%, it would require treatment of 11 patients with 12 mg tegaserod per day for 12 weeks to obtain 1 improvement in SGA relief. Based upon the price of Zelnorm at drugstore.com, a reasonable approximation of actual drug cost for managed care organizations, the cost of tegaserod to obtain 1 improvement in SGA relief is about $4,900.\textsuperscript{28}

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\begin{table}[h]
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\caption{Office Visits With Primary Diagnosis: 1997-1999}
\begin{tabular}{|l|l|l|l|}
\hline
 & Asthma & Migraine & IBS \\
\hline
Persons affected & 14.6 million & 11.5 million & 2.1 million \\
Office visits & 32.0 million & 9.4 million & 4.4 million \\
Office visits per person & 2.19 & 0.82 & 2.10 \\
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school or work because of their symptoms.\textsuperscript{16} Other survey data show that 70% of persons in the United States with IBS symptoms do not consult a health care professional regarding their symptoms.\textsuperscript{17} These facts, coupled with the episodic nature of the disease, suggest that there might be a significant disease management opportunity, attained by stratiﬁying IBS patients by symptom severity and symptom frequency for disease management purposes.

Contravening the apparent disease management opportunity is the elusive diagnosis of the disease. At this time, there are no specific physiological, biochemical, or structural markers for deﬁnitive diagnosis of IBS. Typing “irritable bowel syndrome” into the PubMed literature search engine of the National Library of Medicine produced more than 150 references, including estimates of 20% to 60% comorbidity of psychiatric conditions in IBS patients.\textsuperscript{18} At least 40% and as much as 60% of patients who seek medical advice for IBS have depression or anxiety or both.\textsuperscript{19} A letter in Neuroendocrinology earlier this year correlated migraine, fibromyalgia, IBS, and other “treatment-resistant conditions” that respond to the dopamine-blocking and anti-inﬂammatory effects of cannabinoids.\textsuperscript{20} While the relationship between psychiatric conditions such as anxiety and depression and IBS remains unclear, some physicians may have negative stereotypes of IBS and chronic fatigue syndrome that interfere with effective treatment, including mental health interventions.\textsuperscript{21}

Amitriptyline has been shown to improve at least 4 measures of IBS disease severity in adult patients: abdominal pain, global improvement scores, a feeling of well-being, and satisfaction with bowel movement.\textsuperscript{22} The results of a randomized controlled clinical trial of a high-ﬁber diet alone and with either paroxetine or placebo in IBS patients showed that food avoidance and work functioning, of the 6 outcome measures, were improved with paroxetine, P = 0.03 and P = 0.08, respectively.\textsuperscript{23} Before unblinding of patients to the identity of the active drug versus placebo, more paroxetine patients wanted to continue their study medicine (84% versus 37%; P<0.001). The researchers concluded that the difference in overall well-being in this clinical trial was greater than that found in previously published placebo-controlled trials for IBS. An editorial by Nicholas Talley that accompanied this study published in May 2004, in the same issue of the American Journal of Gastroenterology, described the use of selective serotonin reuptake inhibitors (SSRIs) as, at best, only a “band-aid” approach to the management of IBS since the SSRIs may improve patient satisfaction or quality of life without relieving most of the primary gastrointestinal symptoms.\textsuperscript{24}

REFERENCES

Letters to the Editor

*JMCP* welcomes letters that serve to clarify subjects published in previous issues of the *Journal* or regarding subject matter of interest to managed care pharmacists. Letters in *JMCP* are not peer reviewed but are subjected to editorial review. When a submitted letter refers to an article published in a previous issue of the *Journal*, the letter is sent to the authors of the subject article to allow their response to be published with the letter.

Each letter should be signed by no more than 3 authors. Submissions must include your title, affiliation, complete mailing address, telephone number, and e-mail address. Potential bias or conflicts of interest must be disclosed.

Letters should be submitted in electronic format, preferably using Microsoft Word, and may be sent by e-mail to Fred Curtiss, editor-in-chief, at fcurtiss@amcp.org or to Tamara Faggen, managing editor, at tfaggen@amcp.org.