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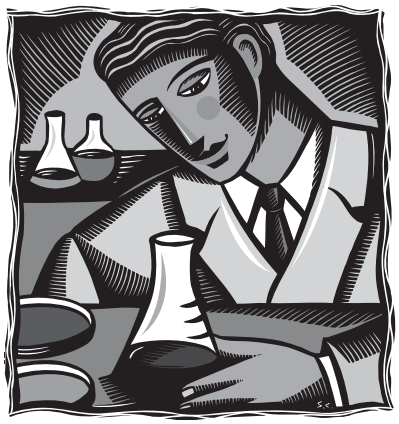
"For Professional Recognition of the Health Actuary"

Pharmacoeconomics: Why Should Actuaries Care?

by Jill Van Den Bos

There is clearly a communication gap between pharmaceutical manufacturers and managed care organizations (MCOs). While pharmaceutical companies have important medical and cost information to share with MCOs, some parts of their message may get lost in the translation for several reasons. One reason is that MCOs seem to view economic research funded by pharmaceutical companies with some skepticism. To them, it resembles advertising rather than information. Second, while medical research conducted to satisfy FDA requirements seems to address treatment issues in a manner that all parties can understand, it is less clear how published economic studies of drug utilization can be used. This article presents an argument for why actuaries should become interested and involved in the field of pharmacoeconomics in order to facilitate its translation between pharmaceutical company economic research and useful information for widespread use within MCOs.



According to the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) lexicon, pharmacoeconomics (PE) is defined as "the field of study that evaluates the behavior of individuals, firms and markets relevant to the use of pharmaceutical products, services and programs, and which frequently focuses on the costs (inputs) and consequences (outcomes) of that use."[1] The consequences of most interest to MCO actuaries would also be costs.

Currently, most PE research is published within a more academic rather than a business framework. Researchers conducting this research are often economists or pharmacoeconomists, many of whom are also academicians. Pharmaceutical companies typically sponsor this research in support of their rollout of a new drug. In the past this research was really a part of their marketing efforts, potentially done with far less planning and funding than was involved in clinical trial research for FDA approval. Such studies usually compare a new drug against one competitor drug or placebo. This research often targets MCO P&T committees with the goal of getting a new drug added to an MCO formulary as a preferred choice.

As a somewhat new discipline, pharmacoeconomics seems to be trying

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to establish itself. The PE literature, for example, has several unique problems. Many of the studies published use sample sizes that are too small for drawing the conclusions desired. While relatively small groups of people randomly assigned to treatment groups may be adequate for studying the efficacy of drug treatment options, studying cost implications of these treatments such as side effects requires much larger sample sizes. Drug side effects might be infrequent but costly events such as hospitalizations, in which case the difference of one occurrence between groups may change the conclusions one might draw about the comparative total costs of two drug treatments in a study with small sample size. In one such published study, the two treatment groups were comprised of 6 and 10 people. The group with 10 people experienced one side effect requiring hospitalization, the cost of which overwhelmed all other costs associated with this treatment. The author concluded that the other treatment was therefore more cost effective.[2]

Sponsorship bias is a problem of particular interest when it comes to research funded by pharmaceutical companies. This occurs in two ways. One is due to the sponsor's interest in publishing only studies that result in favorable conclusions regarding its own drugs. Studies that do not support the preferred conclusion are not published at all, and only studies expected to produce a conclusion favorable to the sponsor are ever funded. Another results when the conclusions of a published study are presented so as to seem favorable to the sponsor's drug when the data in the study may not support this conclusion. In a review of 56 pharmaceutical company funded studies, 40 of the studies concluded that the sponsor's drug was as effective as the comparator and the remaining studies concluded that the sponsor's drug was superior. Out of 22 studies where drug toxicity was compared, the study author concluded that the sponsor's drug was less toxic in 19 cases while the author of the review article thought that conclusion was warranted in only 12 of them.[3]

A final problem with the PE literature is the inability of the reader to ascertain important details about how the study was conducted. In other words, many published studies are not transparent. When trying to evaluate the quality of a study, the reader must be able to determine what measures were taken, how they were taken, what other assumptions the authors made, and so forth.

Prior to now it seems that actuaries have not shown interest in PE data. This may partially be due to the problems with many of the published studies. It may also be due to the study methods employed and the type of results presented. Economists usually publish PE studies with results that are not oriented toward actuarial and other business needs. For example, many comparisons of drug costs in the literature use relative ratios rather than comparing per member per month claim costs (PMPMs). While such results do impart information, the information is not readily usable for MCO purposes. Cost rates per member would be more consistent with the "language" used within an MCO and make PE analysis more useful.

The Academy of Managed Care Pharmacy (AMCP) recently disseminated a Format for Formulary Submissions. This is a guideline to aid pharmaceutical companies in their preparation of formulary submissions for new drugs. The Format is a template, rather than a mandate, to be used to ensure that formulary submissions with MCOs include adequate quality information, enabling MCOs to better decide what drugs should be included on their formularies. The Format suggests information that demonstrates the following five points:

1. Disease description and the agent's role in treatment
2. Clinical efficacy, safety and effectiveness
3. Economic evaluations
4. Modeling
5. Clinical value

Since economic information is now being requested by MCOs through the Format as one of five main areas of interest, PE research is moving from the realm of marketing to the realm of data. Consequently, improved quality and increased quantity of available PE research seems likely in the near future.

With more plentiful and better PE research on the horizon, PE information should find a broader audience within an MCO. Actuarial input into PE research would make such information more useful to MCOs primarily by changing the type of results presented to something more readily usable within an MCO environment. PE research results focusing on the direct costs of using a drug treatment such as drug cost and the cost of treating side effects could be combined with claims data and clinical research to yield total costs affiliated with drug treatment, presented as expected PMPM claim costs. Treatment costs and medical cost offsets in other areas of the claims budget could be estimated and monitored. PE data would therefore become

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useful to not only to the pharmacy department but also potentially to the MCO actuaries, utilization management, and executive management, people who are responsible for the total MCO bottom line.

In order to demonstrate one possible way in which PE research might be modified by an actuarial approach, we used published research to compare treatments for osteoarthritis. We focused on non-steroidal anti-inflammatory drugs (NSAIDs), which are the primary drug treatment used for this condition. Our research suggested that, while NSAIDs have roughly the same efficacy in the population in general, the extent to which one NSAID is more effective than the other seems to be an individual matter. The side effects associated with NSAIDs, however, vary substantially. We found that it is primarily the cost of treating gastrointestinal side effects resulting from NSAID use that made one treatment more or less expensive than another. Incidentally, since greater cost was associated with greater probability of side effects, we also assumed that greater quality of life would be associated with the least expensive treatment option as well. Our goal, therefore, was to make a suggested order in which individual NSAIDs are tried as treatment until an individual finds one that is suitable such that the least expensive drug treatment options are tried first.

We created a decision tree for NSAIDs available in the United States at the time of our study using data from PE studies, clinical trial drug studies, AWP and proprietary drug frequency data. We added acetaminophen as a low-cost and low-side-effect treatment option to be tried first. The reader should note that our research was done prior to the introduction of the COX-2 inhibitors, including Celebrex and Vioxx, which are currently experiencing large utilization. For each person treated, we considered the probabilities of the most likely outcomes, including adverse reactions to the drug treatment. The probably of ending up at any "branch" multiplied by the cost of treating any side effects along that path all summed and added to the cost of the drug itself comprised the total direct cost associated with that choice of drug. This is how we modeled costs associated with each potential drug's use, for a total of three months in this case.

The total decision tree has 17 nodes in it for 17 different drug treatments. Figures 1 and 2 present the nodes for two of those drugs, one for nabumetone, which has relatively low toxicity, and one for ketoprofen, which has relatively high toxicity. In each figure, the dollar values to the right represent the cost of that path. The percentages to the left of these values represent the percentage of time this path is expected to occur. The dollar value above the name of the drug is the cost of the three-month supply of the drug. The dollar value to the right represents the total direct cost of the three-month treatment that includes the cost of the drug and the costs of the five paths multiplied by the probability of each path. Note that while the drug costs for both drugs are not vastly different, the total costs of the treatments with the two drugs are due primarily to the high cost of treating ulcers developed while taking ketoprofen.

Figure 1: Total Treatment Costs for a 3-Month Period Using Mean Ulcer Rates Nabumeteone

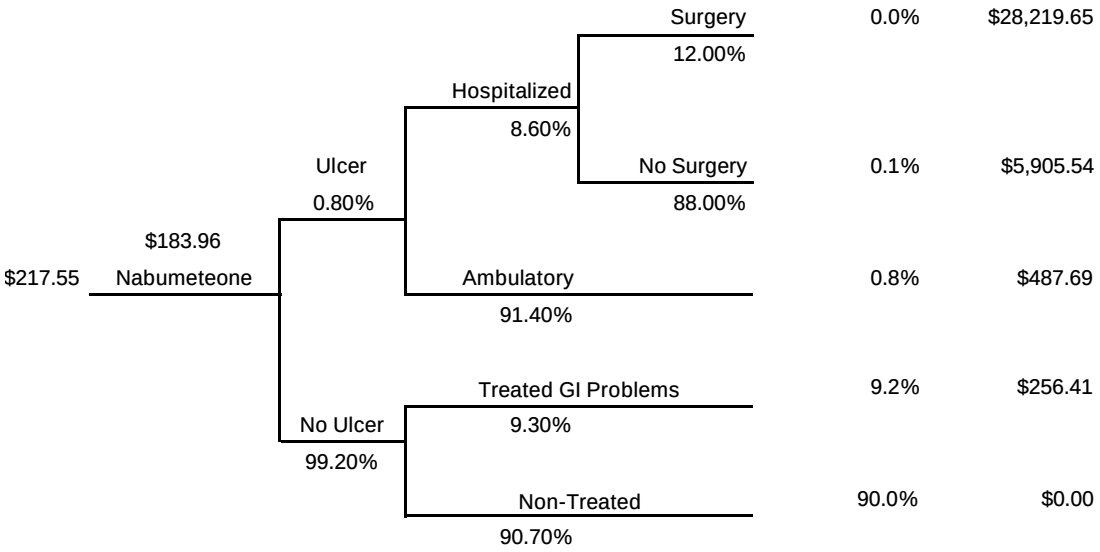
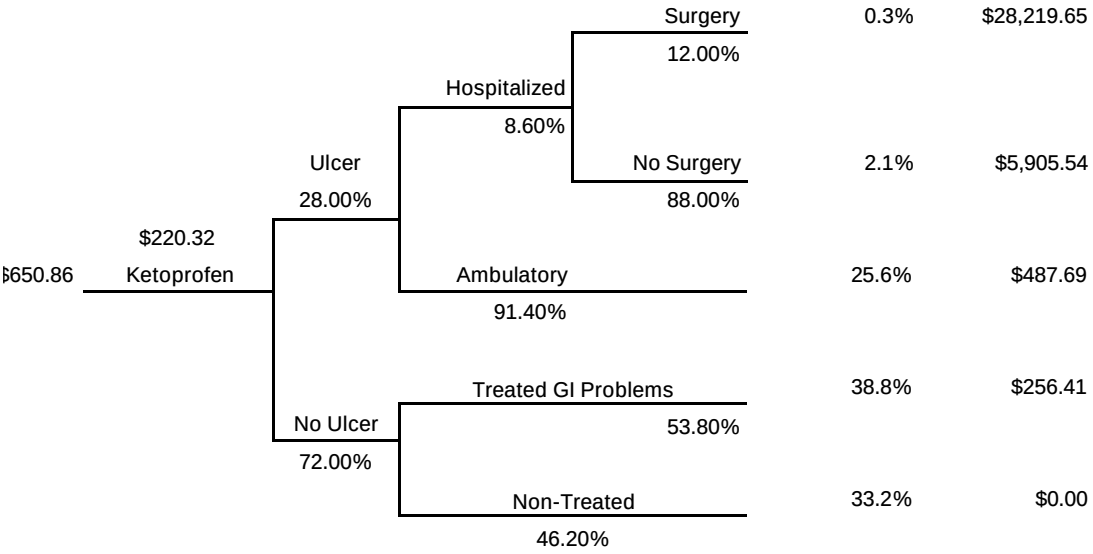


Figure 2: Total Treatment Costs for a 3-Month Period Using Mean Ulcer Rates Ketoprofen



Using costs estimated from this decision tree and current utilization of the drugs therein, we developed an estimated PMPM claim cost for each of the drugs for a standard Medicare population mix. These costs are presented in Table 1.

Table 1 Estimated Current Cost of OA Drugs for Medicare Enrollees

Treatment	Rate of Use	Cost per month	Cost PMPM
Acetaminophen	0.000%	$0.00	$0.00
Ibuprofen	0.515%	66.65	0.34
Nabumetone	0.000%	72.52	0.00
Piroxicam Gel	0.155%	74.58	0.12
Indomethacin	1.573%	98.57	1.55
Naproxen	5.949%	109.14	6.49
Piroxicam	0.470%	114.52	0.54
Ibuprofen+Misoprostol	0.031%	126.35	0.04
Diclofenac	3.264%	129.39	4.22
Fenoprofen	0.155%	134.99	0.21
Naproxen+Helidac	0.005%	136.02	0.01
Sulindac	0.957%	144.83	1.39
Aspirin	1.546%	152.34	2.35
Etodolac	0.069%	161.30	0.11
Diclofenac+Misoprostol	0.094%	194.33	0.18
Flurbiprofen	0.587%	216.66	1.27
Ketoprofen	0.98%	216.95	0.21
TOTAL	15.465%	-	$19.03

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Table 2 Estimated Cost of OA Drugs for Medicare Enrollees, Following Intervention

Treatment	Rate of Use	Cost per month	Cost PMPM
Acetaminophen	1.551%	--	--
Ibuprofen	1.551%	$66.65	$1.03
Nabumetone	1.551%	72.52	1.12
Piroxicam Gel	0.776%	74.58	0.58
Indomethacin	2.017%	98.57	1.99
Naproxen	3.723%	109.14	4.06
Piroxicam	0.310%	114.52	0.36
Ibuprofen+Misoprostol	0.620%	126.35	0.78
Diclofenac	1.551%	129.39	2.01
Fenoprofen	0.155%	134.99	0.21
Naproxen+Helidac	0.310%	136.02	0.42
Sulindac	0.465%	144.83	0.67
Aspirin	0.465%	152.34	0.71
Etodolac	0.031%	161.30	0.05
Diclofenac+Misoprostol	0.155%	194.33	0.30
Flurbiprofen	0.155%	216.66	0.34
Ketoprofen	0.078%	216.95	0.17
TOTAL	15.465%	_	$14.80

We then assumed a new target distribution after intervention in which patients starting a new NSAID regimen would be directed toward treatments starting with the top of the table and moving down. We assumed a certain percentage of utilization in each category from the current distribution would move to a treatment that is above it on the list. The estimates of claim costs after this intervention are presented in Table 2.

While this is only one possible method for using PE data to create a model of drug costs that is useful to an MCO, it demonstrates how a combination of data sources and focus on a more actuarial approach can help transcend usual problem of "silo economics." Other studies might focus on medical cost offsets from the use of various drug treatment regimens in other claim cost areas; hospital utilization or office visits, for example. An important element from an MCO standpoint, however, is to state results in terms of PMPM claim costs so that the information is readily comparable to other aspects of data and actuarial analysis being used by the MCO.

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Footnotes

1) Pashos CL, Klein EG, Wanke LA, eds. *ISPOR Lexicon*, 1st Edition, 1998.

2) Jansen RB, Burrell A, Nuijten MJC, Hardens M. An economic evaluation of meloxicam 7.5 mg versus diclofenac 100 mg retard in the treatment of osteoarthritis in the UK: a decision analysis model based on gastrointestinal complications. *Br J Med Econ*. 1996;10:247-262.

3) Rochon PA, Gurwitz JH, Simms RW, et.al. A study of manufacturer-supported trials of non-steroidal anti-inflammatory drugs in the treatment of arthritis. *Arch Intern Med*. 1994;154:157-163.