Plan-Sponsor Savings and Member Experience With Point-of-Service Prescription Step Therapy

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Objective: To examine the effect of prescription step-therapy programs in terms of plan-sponsor savings and member experience at the point of service.

Study Design: Plan-sponsor savings were measured using a quasi-experimental, case-control design. Member experience with step therapy was measured using a self-administered mailed survey.

Methods: A 20 000-member plan implemented 3 step therapy programs in September 2002: proton pump inhibitors, selective serotonin reuptake inhibitors, and nonsteroidal anti-inflammatory drugs. Pharmacy claims from September 1, 2001, through June 30, 2003, were examined to compare changes in per-member-per-month (PMPM) net cost between the intervention group and a random sample of members from commercial plans without the step therapy programs. A mailed, self-administered survey was sent to members with a step edit from September 1, 2002 to December 31, 2002.

Results: The employer experienced a decrease of $0.83 in net cost after implementing step therapy, while the comparison group had an upward trend of $0.10 PMPM for these therapy classes. Member-reported outcomes indicated that approximately 30% of patients received a generic, 23% were granted a medical exception for the brand, 17% received no medication, and 16% paid the full retail price for the brand. If the pharmacist vs the patient contacted the physician, members were 8 times more likely to receive a medication covered by the health plan (OR, 8.10; 95% CI, 2.94-22.33 vs OR, 8.23; 95% CI, 3.11-21.93). Compared with those who received first-line therapy, those who paid out of pocket for the brand medication vs those who did not receive any medication were less likely to be satisfied with their pharmacy benefit (OR, 0.25; 95% CI, 0.08-0.80 vs OR, 0.12; 95% CI, 0.04-0.41).

Conclusions: Step therapy produces significant drug savings. However, there appear to be opportunities to further members' and providers' understanding of these programs.

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Faced with continued double-digit growth in prescription drug costs,[1,2] plan sponsors are continually looking for ways to promote cost-effective use of medications. The growing availability of generic alternatives in many therapy classes has created an unprecedented opportunity for plan sponsors to better manage pharmacy benefits to the advantage of plan sponsors and their members.

One method of encouraging generic use is through step therapy. Step therapy is a pharmacy benefit program that promotes cost-effective use by requiring a trial of a first-line medication, often a generic alternative, before coverage is granted for a more expensive second-line agent, typically a brand. With the recent availability of generic alternatives in many therapy classes, the use of step therapy has grown dramatically.[3] Generic alternatives available for nonsteroidal anti-inflammatory drugs (NSAIDs), gastroprotective agents, and selective serotonin reuptake inhibitors (SSRIs) render these appropriate classes for step therapy. Step therapy programs have been offered for other classes, such as angiotensin-converting enzyme inhibitors and disease-modifying antirheumatic drugs.

Research supports the clinical appropriateness of step therapy programs. For example, the SSRI step-therapy program requires a trial of generic fluoxetine before coverage of brand SSRI step therapy. Supporting this strategy are conclusions from randomized controlled trials suggesting no difference in primary depression outcome measures across SSRIs.[4-7] In addition, retrospective analyses using medical chart review or administrative claims data have found no difference in switch rates among SSRIs[8] and no difference in depression-related outpatient and hospitalization costs based on initial choice of SSRI.[9,10] These findings, together with the fact that the mean cost for a brand SSRI was nearly double that of generic fluoxetine in 2002,[2] support an SSRI step-therapy policy with generic fluoxetine as first-line therapy.

Step therapy programs for NSAIDs require a trial of traditional or nonselective NSAIDs (eg, ibuprofen and naproxen) before granting coverage for the higher-cost, selective NSAIDs (ie, cyclooxygenase [COX] 2 agents). Research has shown that, in the management of acute pain and other conditions associated with pain, COX-2 inhibitors and nonselective or traditional NSAIDs are equally effective at equipotent doses.[11-22] Although COX-2 therapy has been shown to reduce the risk of

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gastrointestinal adverse events,[23,24] recent pharmacoeconomic analysis suggests that COX-2 agents are not cost effective for the average-risk patient, having a cost per quality-adjusted life-year gained of $275 809.[25]

The impetus for proton pump inhibitor (PPI) step therapy is research showing that 30% to 70% of patients with painful reflux symptoms do not have erosive gastrointestinal conditions for which PPIs are indicated.[26] Given that relief of heartburn symptoms occurs in up to 70% of patients taking lower-cost histamine$_2$ (H_2) receptor antagonists,[27] "stepping up" in those who have not achieved adequate symptom control has been shown to be a cost-effective alternative.[28]

Given the more recent popularity of step therapy, it is not surprising that no research, to our knowledge, has empirically examined the effect of step therapy programs. Therefore, the objective of this study was to examine the economic effect from the plan sponsor's perspective, as well as the member's experience with step therapy programs. Some key questions included the following: (1) What are the savings associated with a step therapy program from the plan sponsor's perspective, taking into consideration the administrative costs of the program? (2) How do members respond to a step therapy program, in terms of contacts with providers and benefits managers and overall satisfaction? (3) What is the final outcome, in terms of medication received, when members experience step therapy at the point of service?

This research is not subject to Department of Health and Human Services regulations and therefore is exempt from institutional review board approval (§46.101 of the Federal Policy for the Protection of Human Subjects, August 19, 1991). We follow the principles outlined in the Declaration of Helsinki and the recently approved Health Insurance Portability and Accountability Act regulations regarding use of personal health information for program evaluation.

METHODS

On September 1, 2002, an employer located in the Midwest with approximately 20 000 enrollees and dependents implemented 3 step therapy programs: PPIs, NSAIDs, and SSRIs. The employer had a 20% coinsurance benefit in place at the time of the study, and no other benefit design or clinical program changes were made during the study. The employer did not communicate with employees about the change before program implementation because of the inability to target the information to those likely to experience the edit.

The step criteria were automated and administered at the point of service by the employer's pharmacy benefit management (PBM) company. For all 3 step programs, prior users of the medications, as evidenced by their prescription claims history, were not subject to the step therapy program (ie, they were grandfathered). Therapy-specific criteria for PPIs required patients to try an H_2 receptor antagonist before receiving coverage for a PPI. The NSAID program required previous trial of 2 generic NSAIDs before receiving coverage for a brand NSAID, and the SSRI program required previous use of fluoxetine or fluvoxamine maleate before coverage for a brand SSRI would be granted. The program criteria were communicated to pharmacies at the time of adjudication, including instructions to call the physician and documentation of the covered first-line medications. Medical exceptions could be granted for those patients who had previously tried a generic or were already stabilized on the brand but for whom the claim had not been captured by the PBM (eg, because the patient used his or her spouse's insurance). Medical exceptions could also be granted for other clinical reasons (eg, failure with first-line agents not captured in the pharmacy claims data; history of a gastrointestinal bleed, perforation, or obstruction [NSAID step therapy]; and erosive gastrointestinal conditions [PPI step therapy]). To request a medical exception for brand coverage, the physician could call or fax the PBM. The employer paid $20 for each medical exception reviewed. No other program costs were incurred by the employer.

Two data sources were used in the study, member survey data and pharmacy claims data. Pharmacy claims from September 1, 2001, through June 30, 2003, for all members were examined to assess changes in per-member-per-month (PMPM) net cost (ie, ingredient cost plus dispensing fee, minus the member copay) for the 3 therapy classes of interest (intervention group). To allow for comparison with plans that did not implement step therapy, a random sample of members from commercial plans that did not have the 3 step therapy programs during the study was selected (comparison group). This comparison group included approximately 1.9 million members, representing 1021 different health plans.

A mailed survey was sent in February 2003 to adult members who had received a step therapy edit between September 1, 2002, and December 31, 2002. Members with more than 1 edit, including other edits such as refill too soon, were excluded from the sampling frame to avoid possible confounding. A presurvey postcard making members aware of the survey was sent approximately 3 days before the self-administered survey, and a $1 incentive was included with the survey.

The survey contained 22 questions based on sociodemographics (4 questions), satisfaction (3 questions),

member's experience with the step therapy program (12 questions), outcome of step edit (1 question), and 2 screener questions. Satisfaction with the pharmacy benefit was measured on a 5-point Likert scale (1, very satisfied; 5, very dissatisfied). "Satisfied" was defined as a response of "1" or "2." Satisfaction with the medication received was also measured. Questions were related to satisfaction with the member's pharmacy benefit, satisfaction with the medication received, and satisfaction with the pharmacy at which most prescriptions were filled. Data reported herein concern satisfaction with the pharmacy benefit and medication received. Questions related to the member's experience with step therapy ascertained what efforts were made to obtain coverage and the member's understanding of the process.

Basic univariate and bivariate statistics were used to describe the survey sample, to compare respondents and nonrespondents, and to examine relationships between variables. Logistic regression analysis was used to assess if any sociodemographic characteristics were predictors of whether the patient contacted the physician. Logistic regression analysis was also used to assess predictors of whether the patient received a medication subsidized by his or her employer (ie, generic or medical exception for the brand) vs no medication or a medication not subsidized by the employer (over-the-counter [OTC] products, samples, etc). Logistic regression analysis was also used to assess what factors predicted patient satisfaction with the pharmacy benefit. Finally, linear regression analysis assessed the immediate effect of the step therapy program on PMPM net cost, while adjusting for the time trend and periodicity of the data. The time series consisted of 22 values for monthly costs.

Figure 1. Intervention Group's Per-Member-Per-Month (PMPM) Net Cost for Proton Pump Inhibitors (PPIs), Selective Serotonin Reuptake Inhibitors (SSRIs), and Nonsteroidal Anti-inflammatory Drugs (NSAIDs) From September 2001 Through June 2003

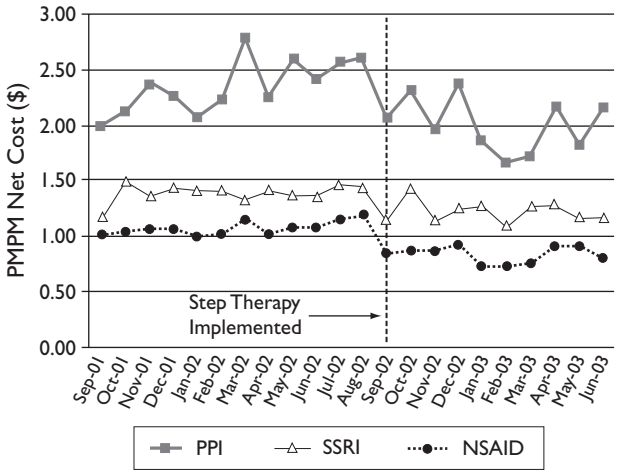
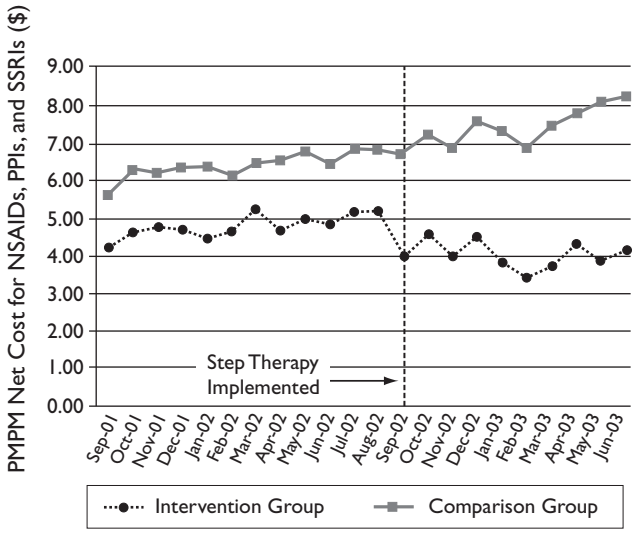


Figure 2. Total Per-Member-Per-Month (PMPM) Net Cost for Proton Pump Inhibitors (PPIs), Selective Serotonin Reuptake Inhibitors (SSRIs), and Nonsteroidal Anti-inflammatory Drugs (NSAIDs) From September 2001 Through June 2003 for the Step Therapy Intervention and Comparison Groups



RESULTS

Interrupted time series showed a $0.29 PMPM decrease in drug expenditures ($P < .001$, adjusted $r^2 = 0.83$) in the month following implementation of the step therapy program for NSAIDs (**Figure 1**). No statistically significant change in PMPM SSRI drug costs was observed, while PPIs showed a $0.48 decrease in net drug cost ($P < .05$, adjusted $r^2 = 0.42$). There were no significant time trends for any of the therapy classes.

Across all 3 therapy classes, there was an immediate decrease of $0.93 in PMPM costs ($P < .01$, adjusted $r^2 = 0.66$), representing a savings of 19% off net cost relative to the mean monthly preperiod expenditures for these 3 therapy classes (**Figure 2**). Plan costs for medical exception review totaled approximately $23 000 during the study, or $0.10 PMPM (number of medical exemption calls times $20 per call, divided by the total mem-

Table 1. Characteristics Among 176 Respondents

Characteristic	Respondents, %
Therapy class	
PPIs	36.4
SSRIs	22.2
NSAIDs	41.5
Age group, y	
18-34	17.9
35-44	32.9
45-54	24.9
≥55	24.3
Sex	
Male	40.9
Female	59.1
Annual household income, $	
<25 000	4.4
25 000-39 999	22.2
40 000-59 999	44.9
60 000-79 999	18.4
≥80 000	10.1
Health status	
Excellent	15.5
Good	59.2
Fair	22.4
Poor	2.9

NSAIDs indicates nonsteroidal anti-inflammatory drugs; PPIs, proton pump inhibitors; SSRIs, selective serotonin reuptake inhibitors.

bership, divided by 12). The comparison group had an increasing trend of $0.10 PMPM for the 3 therapy classes during the study, with no significant change in expenditures in the month following step therapy implementation for the intervention group ($P < .001$, adjusted $r^2 = 0.88$).

Between September 1, 2002, and December 31, 2002, there were 874 members with 1 or more step therapy edits. Of those, 217 had edits in more than 1 therapy class, leaving 657 members eligible for the survey. Seven surveys were returned undeliverable, and 212 completed surveys were returned, for a 33% response rate. Of the 212 returned surveys, 3 were excluded because of incomplete information, and 33 members (16% of respondents) indicated they did not recall the situation, leaving 176 useable responses for the analysis.

Approximately 60% of respondents were female, and 82% were 35 years of age or older (**Table 1**). The most commonly reported (45%) annual income level was $40 000 to $59 999. About 75% of respondents said they were in excellent or good health. There was no statistically significant difference ($\alpha = .05$) in the mean age, sex, month of edit, therapy class, or medication received (ie, generic vs brand) between respondents and nonrespondents (data not shown).

Only 43% of respondents reported that the pharmacist called the physician after the step therapy edit to facilitate a new prescription (**Table 2**), while 62% of members contacted their physician. Nearly 76% of respondents indicated that they or their pharmacist contacted the physician. Approximately 42% of respondents reported contacting the PBM call center, and 14% called their employer's human resource office after the step therapy edit. Logistic regression analysis showed that no sociodemographic characteristics were significantly related to whether the patient contacted the physician (data not shown). When asked whether their pharmacist or pharmacy staff told them why the drug was not covered by their employer, 58% reported that they had been told, and 6% were not sure or did not remember.

The most common outcome (29%) from a step therapy edit was having the prescription switched to a generic medication (**Table 3**). Approximately 23% of respondents reported getting a medical exception to receive coverage for the brand medication, and another 16% paid out of pocket for the brand medication. Nearly 17% reported getting no medication, and about 10% received a sample or an OTC alternative. Finally, 5% could not remember or had another outcome (eg, their spouse's insurance paid for the medication). No significant differences were seen across income categories in the percentage receiving no medication or the percentage paying out of pocket (data not shown).

The percentage paying out of pocket for the brand (Pearson $\chi^2_2 = 9.8$, $P < .01$) and the percentage purchasing an OTC product (Pearson $\chi^2_2 = 7.3$, $P < .05$) varied across therapy classes. The percentage paying out of pocket for PPIs was lower (5%), while the percentage getting an OTC product was higher for PPIs (11%), relative to the other 2 classes.

Logistic regression analysis showed that the probability of receiving a medication subsidized by the employer varied by therapy class (**Table 4**). First, patients with an SSRI step-therapy edit were more likely to receive a medication subsidized by their employer than those with an NSAID edit ($P < .05$). Second, the pharmacist calling the physician was associated with 710% greater odds of receiving a covered medication ($P < .01$), and the patient calling the physician increased the odds of receiving a medication covered by their employer to 720% ($P < .01$). The model classified 77% of the cases correctly.

Table 2. Types of Contacts Made to Resolve Coverage Denial*

Contact Made	Pharmacist Contacted Physician (n = 175)	Member Contacted Physician (n = 172)	Member Contacted Pharmacy Benefit Management (n = 175)	Member Contacted Human Resource Department (n = 174)
Yes	42.9	62.2	42.3	13.8
No	46.9	34.3	52.0	86.2
Do not know or do not remember	10.3	3.5	5.7	0.0

*Data are given as percentages.

Table 3. Patient-Reported Outcome After Step Therapy Edit*

Outcome	Overall (n = 174)	PPIs (n = 64)	SSRIs (n = 38)	NSAIDs (n = 72)
Different medication that was covered by plan	29	28	37	25
Medical exception for brand	23	23	24	22
No medication	17	22	11	15
Paid out of pocket for brand medication†	16	5	24	22
Over-the-counter product‡	5	11	0	3
Samples	5	5	0	7
Other outcome	3	2	5	4
Do not know or do not remember	2	5	0	1

NSAIDs indicates nonsteroidal anti-inflammatory drugs; PPIs, proton pump inhibitors; SSRIs, selective serotonin reuptake inhibitors.
*Data are given as percentages.
†$P < .01$.
‡$P < .05$.

Medication satisfaction was greater for brand users (including medical exception and out-of-pocket brand payers) vs generic users at 95% vs 53% (Pearson $\chi^2_1 = 28.0$, $P < .001$). Just over 50% of respondents reported they were satisfied with their overall pharmacy benefit. However, pharmacy benefit satisfaction varied based on the medication received ($P < .01$). Controlling for sociodemographics, logistic regression analysis found that paying out of pocket for the brand and receiving no medication were associated with significantly lower pharmacy benefit satisfaction compared with those who received a generic (odds ratio [OR], 0.25; 95% confidence interval [CI], 0.08-0.80 vs OR, 0.12; 95% CI, 0.04-0.41) (**Table 5**). The model classified 68% of the cases correctly. In addition, compared with members with household annual incomes less than $40 000, the odds of being satisfied with their pharmacy benefit was 22% lower among those in the highest annual income category (≥$60 000).

DISCUSSION

To our knowledge, this is the first study to examine plan-sponsor savings and member effect of a step therapy program. The findings suggest that step therapy produces significant savings for the employer, results in multiple drug product selections (many of which are not captured in administrative pharmacy claims data), and is associated with lower pharmacy benefit satisfaction for those who do not receive a medication subsidized by their health plan.

Limitations of the study should be considered. This study reflects the experience of 1 employer; while there is no reason to believe that other employers would have dramatically different outcomes, some variation is expected because of patient, provider, and other plan-specific factors. Similarly, the sample size at the therapy class level was small, making it impossible to report many results by therapy class and emphasizing the

Table 4. Odds Ratios for Receiving a Covered Medication Among 129 Respondents*

Variable	Odds Ratio (95% Confidence Interval)
Sex	
Female	1.00
Male	1.61 (0.62-4.22)
Age, y	
18-34	1.00
35-44	0.72 (0.20-2.57)
45-54	1.04 (0.24-4.49)
≥55	2.36 (0.52-10.80)
Health status	
Fair or poor	1.00
Good	1.37 (0.44-4.22)
Excellent	0.72 (0.16-3.21)
Annual household income, $	
<40 000	1.00
40 000-59 999	1.08 (0.35-3.33)
≥60 000	1.08 (0.29-4.03)
Therapy class	
NSAIDs	1.00
SSRIs	4.10 (1.12-14.95)†
PPIs	2.62 (0.90-7.64)
Pharmacist contacted physician	8.10 (2.94-22.33)‡
Patient contacted physician	8.23 (3.11-21.93)‡

NSAIDs indicates nonsteroidal anti-inflammatory drugs; PPIs, proton pump inhibitors; SSRIs, selective serotonin reuptake inhibitors.
*Covered medication defined as a generic or a brand covered with medical exception. Noncovered medication includes brand without medical exception, over-the-counter product, sample, or other outcome (eg, covered under spouse's insurance).
†$P < .05$.
‡$P < .01$.

need to view therapy class–level results with caution.

This analysis did not include evaluation of plan-sponsor medical claims costs. Research measuring these costs, in addition to patient health–related outcomes, is critical to understanding the full economic and clinical consequences of these and other PBM programs. A portion of program savings was achieved in part due to members paying out of pocket or obtaining medication from sources not subsidized by the health plan (ie, OTC products and samples). For those paying out of pocket, it is not known whether these were members who were unaware of the lower cost alternatives or whose time was valued at a rate greater than the cost of the medication. Similarly unknown is whether those who did not obtain a medication had any negative health consequences.

Some respondents indicated that they did not remember the step therapy edit. This could be due to the time lapse between when the edit took place and the survey administration (although we saw no relationship between date of edit and remembering the event). More likely, it is a reflection of random patient variability in remembering the event and, to some extent, the fact that patients do not always pick up the prescription from the pharmacy.[29]

The step therapy program was associated with a mean decrease of $0.83 PMPM in drug costs for this employer after factoring in the administrative program costs. This figure underestimates savings because, as seen in the comparison group, costs for these therapy classes were increasing at a rate of $0.10 PMPM during the same period among plans without step therapy. Therefore, savings at 10 months following implementation approximated $1.83 PMPM ($0.83 + [$0.10 × 10] months) or 38% of the total net cost for these 3 classes. Comparisons with savings from other step therapy programs are not available. Savings were not limited to the employer.

Plan-sponsor savings resulted from different medication alternatives after the step therapy edit, some of which were appropriate and others that were not the intended outcome. It is assumed that physicians were prescribing the generic alternative when they considered it clinically appropriate, and were requesting a medical exception when they believed the brand medication was medically necessary. For patients who paid full price for the brand medication, it is unknown whether the patient simply chose to do so rather than to contact the physician, or whether the patient did not understand that alternative medications were covered. Similarly, those who received no medication or an OTC alternative could have done so because of the "hassle factor," because they had a less severe condition for which an OTC alternative or no medication seemed appropriate, or for other reasons. Income did not appear to affect whether the patient received no medication, as there were no differences in the percentage receiving no medication across income categories, and the percentage paying out of pocket was higher among lower-income groups.

The significant variation in medication received across therapy classes (ie, SSRIs were associated with increased likelihood of receiving a covered medication)

could be due to greater clinical need for SSRI users or fewer OTC alternatives relative to NSAIDs and PPIs. This could also explain the nonsignificant trend in PMPM costs for SSRI medication. It is not surprising that pharmacy benefit satisfaction was lower for patients paying full price and for those who did not receive a medication. To that end, efforts to increase member understanding and satisfaction with these programs are needed. Further research is needed to assess the reasons why patients do not receive a medication covered by their health plan, the extent to which they are informed about their alternatives, the extent to which patients consult with their physician and pharmacist about this decision, and the clinical outcomes across the various drug agents received.

In addition, we believe this to be the first study to look at pharmacist and member contacts after receiving a utilization management edit. There are multiple explanations for why fewer than half of the respondents said their pharmacists contacted the physician. First, patients may not have necessarily known or remembered that the pharmacist contacted the physician (reported by 10%). Second, there may be pharmacies in which the computer system does not show the message from the PBM (eg, the message appears temporarily) and the pharmacist does not understand the reason for coverage denial. It may be that pharmacists consult with patients and then call the physician if the patient says he or she is willing to take the generic, or that pharmacists call only during nonpeak hours when they have more time for such activities. Pharmacists may also request that the member shoulder the administrative burden and follow up with his or her physician or health plan with additional questions. As found in this study, pharmacist or member contact with the physician significantly increases the likelihood of receiving a medication subsidized by the employer. The hassle factor and administrative burden placed on pharmacists support the use of electronic prescribing, in which physicians are made aware of plan design features and can make the appropriate changes at the point of care.

This study demonstrated that step therapy programs can produce savings for plan sponsors but identified opportunities to further members' understanding of these programs and pharmacist intervention, potentially improving drug selection and member satisfaction. More generally, this study highlights the importance of ongoing evaluation of the economic, clinical, and humanistic effect of pharmacy benefit design tools, such as step therapy, to ensure that intended objectives are being achieved without untoward consequences.

Table 5. Odds Ratios for Satisfaction With Pharmacy Benefit Among 126 Respondents

Variable	Odds Ratio (95% Confidence Interval)
Sex	
Female	1.00
Male	1.01 (0.43-2.37)
Age, y	
18-34	1.00
35-44	1.19 (0.35-4.01)
45-54	0.92 (0.27-3.13)
≥55	1.34 (0.36-5.15)
Health status	
Fair or poor	1.00
Good	1.28 (0.46-3.54)
Excellent	1.12 (0.28-4.47)
Annual household income, $	
<40 000	1.00
40 000-59 999	0.51 (0.18-1.45)
≥60 000	0.22 (0.07-0.69)*
Therapy class	
NSAIDs	1.00
SSRIs	0.43 (0.15-1.26)
PPIs	0.62 (0.23-1.67)
Pharmacy benefit	
Generic user	1.00
Brand, medical exception	1.04 (0.37-2.96)
Brand, paid out of pocket	0.25 (0.08-0.80)†
No medication	0.12 (0.04-0.41)*

NSAIDs indicates nonsteroidal anti-inflammatory drugs; PPIs, proton pump inhibitors; SSRIs, selective serotonin reuptake inhibitors.
*$P < .01$.
†$P < .05$.

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