

Health Plan Member Experience With Point-of-Service Prescription Step Therapy

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ABSTRACT

OBJECTIVE: To better understand health plan member experience with point-of-service prescription step-therapy edits and outcomes in terms of drug received.

METHODS: Self-administered mailed surveys were sent to 1,000 members who experienced a step-therapy edit from September 1, 2002, through January 31, 2003, for proton pump inhibitors or nonsteroidal anti-inflammatory drugs. Based upon these findings, a second survey was conducted by telephone among 617 members who experienced a step-therapy edit from January through April 25, 2003, and who had no subsequent prescription claim for the drug therapy class associated with the edit.

RESULTS: The mailed survey generated a 23% response rate, and the telephone survey generated a 33% response rate. Just over 66% of the mail survey respondents indicated that they contacted their physician directly to try to remedy the situation, while 40% indicated that their pharmacist contacted their physician. Forty-four (44%) percent of members indicated that they received a different medication than was originally prescribed, 15% obtained prior authorization for the brand medication, 11% received no medication, 11% paid full price for the branded medication, 8% got an over-the-counter medication, and 4% received samples from their physician. Approximately 7% sought other means of obtaining coverage (i.e., they used spouse's insurance) or did not remember the outcome. Member and pharmacy contact with the physician significantly influenced whether the member obtained a medication covered by their health plan (odds ratio [OR] = 6.5; 95% confidence interval [95% CI], 2.76-15.12 and OR = 4.6; 95% CI, 1.96-10.60, respectively).

In a separate survey conducted by telephone among a different group of members, insight into reasons why members did not obtain any medication was obtained. Using a closed-ended question, 12% (n = 25) of members indicated receiving no medication. Upon further questioning, however, 32% of those who indicated that they had not received a medication said that they had in fact received a medication to treat their condition some time after the step edit. The second most common reason for not receiving a medication included issues related to cost (i.e., willingness to pay) or affordability (16% and 28%, respectively).

CONCLUSIONS: The results of this study suggest that a majority of members receive a medication covered by their health plan subsequent to rejection of a claim for a prescribed drug that is the target of a step-therapy edit. However, there are opportunities for better member and provider communication designed to increase the use of first-line drugs and reduce the number of members paying out-of-pocket or receiving no medication.

KEYWORDS: Step therapy, Pharmaceutical cost containment, Drug costs, Cost-effectiveness

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With prescription expenses continuing their double digit growth,¹ plan sponsors are adopting cost-management strategies aimed at controlling the trend by encouraging cost-effective prescribing. One such strategy is step therapy. Step therapy is designed to encourage the use of therapeutically equivalent, lower-cost alternatives (i.e., first-line therapy) before “stepping up” to more expensive therapy (i.e., second-line therapy). In 2000, it was estimated that 21% of employers surveyed had implemented step therapy for one or more therapy classes.² From 2002 to 2003, the number of members enrolled in a plan with at least one step-therapy program administered by the pharmacy benefit manager (PBM), Express Scripts, Inc., grew from 4.5 to 9.8 million—approximately 20% of total PBM enrollment.

One reason for the growth in pharmaceutical step-therapy programs is the growing number of therapeutically equivalent treatment alternatives available for many health conditions. For example, in the management of acute pain and other conditions associated with pain, COX-2 inhibitors and nonselective or traditional nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) have been shown to have similar clinical efficacy at equipotent doses.³⁻⁷ COX-2 therapy averages \$50 to \$70 more per prescription than traditional NSAIDs,¹ but it has been shown to reduce the risk of serious gastrointestinal adverse events.^{8,9} While some COX-2 cost-effectiveness studies have concluded that the added benefit is worth the added cost¹⁰⁻¹², more recent findings call into question the widespread use of these drugs by concluding that they are only cost-effective in patients at risk for NSAID-related gastrointestinal problems.¹³

Similarly, both histamine₂ (H₂) receptor antagonists and proton pump inhibitors (PPIs) are recommended therapy for nonerosive hypersecretory conditions, such as heartburn and dyspepsia.¹⁴ While PPIs are recognized as more effective in treating these conditions, H₂ receptor antagonists improve or relieve symptoms in 50% to 70% of patients with gastroesophageal reflux disease (GERD). With the average ingredient cost for brand PPIs nearly 3 times that of generic H₂ antagonists,¹ initiating patients on lower-cost H₂ receptor antagonists and “stepping-up” those patients who have not achieved adequate symptom control has been shown to be a cost-effective alternative.¹⁵

With today's pharmacy claims adjudication software and rapid claims processing, many step-therapy programs can be administered at the point of service. Online messaging is sent directly to the pharmacist from the PBM adjudication computer system. The reason for coverage denial and the suggested first-line covered drug therapy can be included in the electronic

message. While adoption of these programs continues to grow, nothing is known about the members' experience with this process, if and who they contact to obtain a covered medication, and what medication is ultimately received. While claims analysis can provide insight into the medication members receive, they can seek alternatives not captured in the claims data (e.g., over-the-counter medications). Therefore, the purpose of this study is to more broadly understand the members' experiences with pharmaceutical step therapy, the process they go through to obtain coverage, and the outcomes, in terms of medications received.

Methods

A managed care plan located in the northeastern United States with 2 step-therapy programs in place in 2002 was identified, and approval was obtained to contact members who encountered a step-therapy edit. In 2002, this managed care plan had approximately 33 groups representing 130,000 lives enrolled in step therapy. The plan design for the 33 groups varied, with approximately 40% of members enrolled in groups with a 3-tier benefit designs, 40% in 1- or 2-tier plans, and 20% of members enrolled in groups with coinsurance. A mailed, self-administered survey was sent to members 18 years or older who encountered a step-therapy edit between September 1, 2002, through January 31, 2003. A premailer postcard, alerting members to the upcoming survey, was sent approximately 7 business days prior to the mailing of the survey on March 6, 2003.

The survey contained 23 questions, including 9 related to the members' experience with step therapy; 6 questions regarding satisfaction with the components of the step-therapy program, their pharmacy benefit in general, and the medication received; 4 sociodemographic questions; and 4 miscellaneous questions (e.g., screener). Satisfaction with the pharmacy benefit was measured on a 5-point Likert scale (1 = very satisfied to 5 = very dissatisfied). For analysis purposes, "Satisfied" was defined as a response of "1" or "2" on the Likert scale; all other responses were defined as "Dissatisfied."

In 2002, the plan sponsor had 2 step-therapy programs in place; 1 for PPIs and 1 for NSAIDs. In both programs, the-step therapy criteria only applied to those members with no use of the brand (target) drugs in the previous 180 days for NSAIDs or the previous 130 days for PPIs. In other words, claims were paid for those with prior use of the target drug within this time frame, a process known as "grandfathering." The PPI step-therapy program required that members new to therapy try a generic H₂ receptor antagonist prior to beginning a PPI. The NSAID step-therapy module required that members new to therapy first try 2 generic NSAIDs prior to use of COX-2 therapy. In both step-therapy programs, medical exceptions were granted through the standard prior-authorization (PA) process. Medical exceptions could be granted for those patients who had previously tried a generic drug or were already stabilized on the

brand drug but the claim had not been captured by the PBM (e.g., because the patient used the spouse's insurance or was a new member with no drug claims history). Medical exceptions could also be granted for clinical reasons (e.g., failure with first-line drugs not captured in the pharmacy claims data; history of a gastrointestinal bleed, perforation, or obstruction [NSAID step therapy]; erosive gastrointestinal conditions [PPI step therapy]). To request a medical exception for brand (target drug) coverage, the physician could call or fax the PBM. The step-therapy edits for these 2 programs impacted less than 1% of total prescription claims.

The step-therapy programs apply coverage rules at the point of service when the claim is adjudicated. If the step-therapy rule was not met for a second-line (target) drug (i.e., prior use of first-line drug or use of second-line drug), an electronic message was transmitted to the pharmacy. The message sent for patients new to brand NSAID therapy was, "Call doctor, use 2 generic NSAIDs first." The pharmacy message for patients new to brand PPI therapy was, "Call doctor, use generic H₂ antagonist first."

Concerned about the percentage of respondents in the initial mail survey who reported having received no medication, a separate telephone survey was conducted among members with a step-therapy edit over the time period from January 1, 2003, through April 25, 2003, who had no subsequent prescription claim for the therapy class associated with the step edit from the date of the edit through April 30, 2003. Similar to the mailed survey, the telephone survey contained a series of closed-ended questions about medications received. In addition, for those indicating that no medication had been received, survey administrators probed further using an open-ended question format.

Analysis

Descriptive statistics and chi-square tests were used to describe the survey respondents and evaluate differences in outcomes between those with PPI versus NSAID step edits. Logistic regression was used to evaluate both the likelihood of receiving a first-line drug and any covered medication (i.e., first-line or PA for second-line), controlling for patient-related (i.e., age, gender, household income) and process-related factors (i.e., contacts made to physician). Logistic regression was also used to evaluate the impact of outcome, in terms of final drug received, on overall satisfaction with the pharmacy benefit, controlling for patient-related factors.

Results

A total of 3,929 adult members had at least 1 step-therapy edit over the 5-month period from September 1, 2002, through January 31, 2003. To determine that the survey response reflected their step-therapy experience only, members with other utilization management or safety edits over this time period (i.e., refill too soon, quantity limits exceeded, concurrent drug-use review [DUR] edits) were excluded (n = 2,128). Among the 2,128 excluded for this reason, 60% had a concurrent DUR

edit. An additional 197 members were excluded due to missing or bad addresses. Of the 1,604 remaining members, 1,000 were randomly selected to receive a survey. Of the 1,000 mailed surveys, 9 were undeliverable and returned to sender and 230 were returned completed, for a 23% response rate.

When respondents were asked whether they remembered trying to fill a prescription that was not covered by their health plan, 13% percent (29) indicated that the event had not happened. These members were excluded from further analysis, leaving 201 respondents for analysis. Analysis of response bias indicated that those who responded were older ($t = 5.26$, $P < 0.001$), were more likely to respond if claims data indicated that they received a prescription for a first- or second-line drug ($\chi^2 = 10.44$, $P = 0.005$), and differed based upon the month the edit was hit ($\chi^2 = 10.30$, $P = 0.036$). No differences between responders and nonresponders were found for gender or type of step-therapy edit (i.e., PPI versus NSAID).

Among the 201 respondents who remembered the step edit, 52% had a step-therapy edit for PPIs and 48% had a step-therapy edit for NSAIDs. The demographic profile of respondents indicates that overall, 57% were female, 74% were aged 45 years or older, 1 in 4 had incomes of \$60,000 or higher, and 86% reported being in good or excellent health (Table 1).

Member's Experience With the Process of Step Therapy

Point-of-service step-therapy edits require that ultimately the physician's office be contacted to either change the prescription to the first-line drug or to pursue PA for coverage of the second-line (target) drug. When asked about attempts to contact their physician, 67% of respondents reported that they contacted their physician directly and 40% reported that their pharmacist contacted their physician on their behalf to try to remedy the situation (Table 2). Approximately 80% of respondents indicated that either they and/or their pharmacist contacted their physician.

Other contacts were also made, including 10% who contacted the human resource (HR) department at their employer and 25% who contacted the PBM call center. Taken together, 16% made no contact or no contact was made on their behalf, 43% indicated that 1 contact was made, 31% 2, 8% 3, and 2% indicated that all 4 means of contact were made (i.e., member contacts physician, pharmacist contacts physician, member contacts PBM, and member contacts HR department). Among those who made one or more contacts, 68% received a covered medication (i.e., PA for the brand-target drug or change to first-line drug). Among those who reported paying out of pocket, receiving no medication, or receiving an over-the-counter (OTC) drug, 55%, 55%, and 75%, respectively, had a contact of some type.

Of the 131 members who contacted their physician, 124 (95%) contacted them by telephone. Among those who contacted their physician by telephone, 48% made 1, 20%

TABLE 1 Respondent Demographics by Type of Step Program, Percentages

| | PPI N = 105 | NSAID N = 96 | Total N = 201 |
|-----------------------------|----------------|-----------------|------------------|
| Female | 57.1 | 57.0 | 57.1 |
| Age group | | | |
| 18 to 34 years | 11.5 | 4.2 | 8.0 |
| 35 to 44 years | 21.2 | 16.7 | 19.0 |
| 45 to 54 years | 37.5 | 33.3 | 35.0 |
| 55 years and older | 29.8 | 45.8 | 38.0 |
| Annual household income | | | |
| Less than \$25,000 | 17.4 | 12.7 | 15.2 |
| \$25,000 to \$39,999 | 23.9 | 27.8 | 25.7 |
| \$40,000 to \$59,999 | 31.5 | 31.6 | 31.6 |
| \$60,000 to \$79,999 | 15.2 | 13.9 | 14.6 |
| \$80,000 and above | 12.0 | 13.9 | 12.9 |
| Self-reported health status | | | |
| Excellent | 19.4 | 21.3 | 20.3 |
| Good | 66.0 | 64.9 | 65.5 |
| Fair | 13.6 | 12.8 | 13.2 |
| Poor | 1.0 | 1.1 | 1.0 |

PPI = proton pump inhibitor; NSAID = nonsteroidal anti-inflammatory drug.

TABLE 2 Types of Contacts Made to Obtain Assistance and/or Coverage*

| | Pharmacist Contacts MD N (%) | Member Contacts MD N (%) | Member Contacts PBM N (%) | Member Contacts HR N (%) |
|-----------------------------|------------------------------------|--------------------------------|---------------------------------|--------------------------------|
| Yes | 79 (40.1) | 131 (66.5) | 49 (24.9) | 17 (8.8) |
| No | 98 (49.7) | 63 (32.0) | 143 (72.6) | 177 (91.2) |
| Not sure/ don't remember | 16 (10.2) | 3 (1.5) | 5 (2.5) | NA |

* Responses were not mutually exclusive.

MD = physician; PBM = pharmacy benefit manager; HR = human resource department of employer.

made 2, and 31% made 3 or more contacts. One member could not remember the number of telephone contacts made to the physician.

In order to understand whether the online messaging was being communicated to members, respondents were asked whether their pharmacist or pharmacy staff told them why the drug was not covered. Sixty-four percent reported that they had been told why the medication was not covered, 28% said that their pharmacist/pharmacy staff did not tell them why the medication was not covered, and 8% were not sure or did not remember. Even though 64% reported that their pharmacist had told them why the medication was not covered, 63% indicated that it was still not clear to them why their medication was not covered.

TABLE 3 Distribution of Patient-Reported Outcome From Step-Therapy Edit: PPI, NSAID, and Total

| | PPI N = 105 (%) | NSAID N = 96 (%) | Total N = 201 (%) |
|--|-----------------------|------------------------|-------------------------|
| You filled the prescription for a different medication that was covered by your plan | 43.1 | 45.3 | 44.2 |
| Your pharmacy or physician's office got permission for you to get the same medication for your regular copay | 18.6 | 11.6 | 15.2 |
| You did not fill the prescription at all and you received no other similar medication | 12.7 | 9.5 | 11.2 |
| You filled the prescription for the same medication and paid the total cost yourself | 7.8 | 14.7 | 11.2 |
| You did not fill the prescription at all and you got an over-the-counter medication instead | 6.9 | 9.5 | 8.1 |
| You obtained samples from physician | 3.9 | 3.2 | 3.6 |
| Other | 4.9 | 5.3 | 5.1 |
| Don't know/don't remember | 2.0 | 1.1 | 1.5 |
| Total | 100 | 100 | 100 |

PPI = proton pump inhibitor; NSAID = nonsteroidal anti-inflammatory drug.

TABLE 4 Time From Step Edit to Receipt of Medication

| | Same Day (%) | 1-2 Days (%) | 3-4 Days (%) | 5 or More Days (%) | Don't Know or Don't Remember (%) |
|---|-----------------|-----------------|-----------------|-----------------------|-------------------------------------|
| You filled the prescription for a different medication that was covered by your plan (n = 87) | 20.7 | 26.4 | 12.6 | 37.9 | 2.3 |
| Your pharmacy or physician's office got permission for you to get the same medication for your regular copay (n = 28) | 3.6 | 17.9 | 17.9 | 53.6 | 7.1 |
| You filled the prescription for the same medication and paid the total cost yourself (n = 21) | 66.7 | 19.0 | 4.8 | 9.5 | 0.0 |

Finally, 43% of respondents reported spending less than an hour trying to resolve the coverage issue, 30% spent 1 to 2 hours, 12% spent 3 to 4 hours, and 16% spent more than 4 hours trying to resolve the coverage issue.

Outcomes

Members were asked to indicate which outcome best described the result of the step-therapy edit (Table 3). Overall, 44% indicated that they obtained a different medication than was originally prescribed (i.e., first-line drug), 15% indicated that they got permission for the brand (target) drug and paid their regular brand-drug copay (i.e., PA brand), 11% received no medication, and 11% paid the full price for the brand (target) drug out of pocket. Eight percent received an OTC medication, and 4% received samples from their physician. Five percent indicated something other than the response categories listed (e.g., using a spouse's or other family member's insurance). Chi-square tests of independence were performed to evaluate differences in the distribution of outcomes (i.e., drug selected) across the PPIs and NSAIDs and across income categories, recategorized as lower (i.e., ≤\$39,999) and higher (i.e., ≥\$40,000). No statistically significant differences were found at the $\alpha = 0.05$ level.

Members who received a medication were asked approximately how long it took to receive a medication, starting from the time that they were told the medication was not covered. More than half of those who obtained a PA for the brand target drug indicated that it took 5 or more days, while approximately half of those who received another covered medication indicated that they received it within 2 days, with 38% indicating that it took 5 or more days (Table 4). Among those who paid out of pocket for the target drug, 67% did so the same day and 10% paid out of pocket 5 or more days after the step edit. Those who obtained a PA for the target drug were significantly more likely to indicate that it took 5 or more days, compared with those who obtained the first-line drug or paid out of pocket ($\chi^2 = 5.40, P = 0.02$).

The likelihood of receiving a generic or first-line drug was significantly influenced by whether the members or their pharmacists contacted their physician (Table 5). Logistic regression found that when the members contacted their physician, they were approximately 3 times more likely to obtain a first-line drug. When the pharmacist contacted the physician, members were 2.5 times more likely to receive a first-line drug. Similarly, the likelihood of receiving any covered medication (i.e., brand PA or first-line drug) was significantly influenced by whether the member (OR = 6.5; 95% confidence interval, 2.76-15.12) or their pharmacy (OR = 0.6; 95% CI, 1.96-10.60) contacted their physician (Table 5).

Satisfaction With Medication Received and Pharmacy Benefit

Among those who reported receiving a medication (i.e., samples, OTC, covered medication, or paid out of pocket), members were asked how satisfied they were with the medication they received. Compared with those who obtained the brand drug (i.e., received coverage authorization for brand or paid 100% out of pocket), members who obtained a differ-

ent medication that was covered by their health plan were significantly less satisfied with the medication they received ($\chi^2 = 13.62, P < 0.001$).

Although there were differences in satisfaction with the medication received based upon outcome, the outcome of the step-therapy edit did not significantly influence members' overall satisfaction with their pharmacy benefit (Table 6). The only factor influencing overall satisfaction with the pharmacy benefit was income, with those in the income category from \$40,000 to \$59,999 3 times more likely to be satisfied with their pharmacy benefit than those in the lowest income group.

Follow-up Telephone Survey

A second telephone survey explored reasons why members received no medication after the step edit. A total of 1,056 adult members had a step-therapy edit from January 1, 2003, through April 25, 2003; 439 were excluded due to our inability to obtain valid telephone numbers, leaving a sampling pool of 617 members. Of the telephone attempts made, 56 (9%) members refused, 198 (32%) members were unavailable when telephone attempts were made, and 101 (16%) had disconnected or wrong telephone numbers. An addition 57 (9%) members were excluded due to other issues, including language barriers, more than 1 member with a step edit within a household, and those indicating that the event did not happen, leaving 205 completed surveys, for a 33% response rate.

When asked the outcome, in terms of medication received, 87% (n = 178) of respondents indicated receiving a medication, either through payment out of pocket, obtaining a PA for the brand medication, or that their doctor switched them to another medication. Twelve percent (n = 25) of respondents indicated that they received no medication. Using an open-ended question, these respondents were probed further as to the reason they did not receive any medication. The most common response (32%) was that some type of medication was actually received for their condition (Table 7). One member indicated that the original medication was approved, while others indicated that they had other medication on hand, used an OTC drug, or were trying vitamin or herbal remedies for their condition. The next most frequent comment related to issues of affordability of the branded medication (28%). The cost of the brand drug was mentioned by 16% of respondents, although not in terms of affordability but more a matter of "willingness to pay." Sixteen percent of those who received nothing indicated that they did not pursue coverage because they did not need the medication or the issue resolved itself. Some responses indicated respondent misunderstanding of the benefit or hassles and delays in trying to obtain coverage as reasons why no medication was received (i.e., misunderstood the benefit [16%], attempts for coverage made but as yet no remedy [8%], and inconvenience [8%]). Finally, 8% of members indicated that, while they understood the requirement of trying other drugs

TABLE 5 Factors Influencing the Likelihood of Obtaining First-Line Drug (n = 142) or Any Covered Medication (n = 143)

| | First-Line Drug | | | Any Covered Medication | | |
|--------------------------------|-----------------|-------------------------|-------|------------------------|-------------------------|-------|
| | Odds Ratio | 95% Confidence Interval | | Odds Ratio | 95% Confidence Interval | |
| | | Lower | Upper | | Lower | Upper |
| Female | 0.91 | 0.44 | 1.86 | 0.59 | 0.27 | 1.33 |
| Age group | | | | | | |
| 18 to 34 years (reference) | | | | | | |
| 35 to 54 years | 0.93 | 0.27 | 3.23 | 0.56 | 0.14 | 2.27 |
| 55 years and older | 0.81 | 0.21 | 3.20 | 0.41 | 0.09 | 1.89 |
| Income category | | | | | | |
| \$39,999 and below (reference) | | | | | | |
| \$40,000 to \$59,999 | 1.17 | 0.48 | 2.82 | 0.90 | 0.34 | 2.39 |
| \$60,000 and above | 1.27 | 0.52 | 3.07 | 0.52 | 0.19 | 1.37 |
| Health status | | | | | | |
| Excellent/good (reference) | | | | | | |
| Fair/poor | 2.41 | 0.88 | 6.61 | 2.64 | 0.78 | 8.90 |
| Member contacts MD | 2.91 | 1.33 | 6.35 | 6.46 | 2.76 | 15.12 |
| Pharmacy contacts MD | 2.52 | 1.21 | 5.24 | 4.56 | 1.96 | 10.60 |
| Therapy class | | | | | | |
| NSAID (reference) | | | | | | |
| PPI | 0.72 | 0.35 | 1.50 | 0.96 | 0.43 | 2.16 |

MD = physician; NSAID = nonsteroidal anti-inflammatory drug; PPI = proton pump inhibitor.

TABLE 6 Member Satisfaction With Their Pharmacy Benefit (N = 134)

| | Odds Ratio | 95% Confidence Interval | |
|--------------------------------|------------|-------------------------|-------|
| | | Lower | Upper |
| | Female | 1.56 | 0.72 |
| Age group | | | |
| 18 to 34 years (reference) | | | |
| 35 to 54 years | 0.87 | 0.23 | 3.30 |
| 55 years and older | 2.49 | 0.61 | 10.11 |
| Income category | | | |
| \$39,999 and below (reference) | | | |
| \$40,000 to \$59,999 | 2.98 | 1.23 | 7.24 |
| \$60,000 and above | 0.72 | 0.26 | 1.95 |
| Health status | | | |
| Excellent/good (reference) | | | |
| Fair/poor | 0.68 | 0.23 | 2.04 |
| Medication received | | | |
| First-line (reference) | | | |
| PA brand | 1.78 | 0.61 | 5.17 |
| OOP | 0.74 | 0.21 | 2.65 |
| Nothing | 0.68 | 0.22 | 2.09 |

PA = prior authorization; OOP = out of pocket.

TABLE 7 Reasons for Receiving No Medication: Follow-up Survey Results* (N = 25)

| Reason | N (%) |
|--|--------|
| Received a medication (e.g., original medication approved/OTC/stockpile/vitamin) | 8 (32) |
| Could not afford branded medication | 7 (28) |
| Unclear | 5 (20) |
| Cost: not willing to pay | 4 (16) |
| Did not need | 4 (16) |
| Misunderstood the benefit | 4 (16) |
| Authorization or change in medication attempted but no action | 2 (8) |
| Inconvenience | 2 (8) |
| Other first-line medications did not work | 2 (8) |

* Responses are not mutually exclusive.

OTC = over the counter.

first, they had tried them and found them to be ineffective or they experienced side effects.

Limitations

Limitations of the study should be considered. These results reflect the experience of 1 health plan that had step therapy in place for more than 1 year. Differences in outcomes and processes would be expected due to patient, provider, and other plan-specific factors.

The fact that 13% of survey respondents did not remember experiencing denial of coverage may be related to poor recall, given the time lag between the step edit and survey administration (an average of 2.5 months). However, no significant relationship was found between the month of the step edit and member recollection of the edit. Some members may not have remembered the event because they never went to pick up the prescription or didn't realize their physician had called in a prescription. This is not an uncommon practice, particularly among those new to therapy.¹⁶

This study relied heavily upon patient recall to respond accurately to questions about the step-therapy process. However, response categories included a "don't know" or "don't remember" option that members could select when applicable. The highest percentage selecting "don't know" or "don't remember" was for the question relating to whether their pharmacist contacted their physician (10%). This higher rate of uncertainty is not unexpected due to the fact that, for many reasons, members may not have been aware of actions taken by their pharmacist on their behalf.

Caution in interpreting results is warranted, given evidence of response bias. The fact that those with prescription claims subsequent to the edit were more likely to respond suggests that these results may not fully represent the true distribution of out-

comes in the population of those who experience a step-therapy edit. Finally, the response rate could have been increased by providing a nominal incentive to respond or by sending a second survey to nonresponders.

Discussion

The results of this survey suggest that members are taking an active role in obtaining coverage for either the first- or second-line drug. More than half of respondents who contacted their physician's office made multiple attempts, and 28% reported spending 3 or more hours trying to remedy the situation.

Only 40% of respondents indicated that their pharmacist contacted their physician on their behalf to remedy the coverage issue. This rate is likely underreported, given that some members may have been unaware that action was taken on their behalf. Research has shown that when patients voice concerns about the price of their medication, 56% of pharmacists called the prescribing physician to see if a less-expensive medication could be prescribed.¹⁷ Additionally, community pharmacists' attitudes toward therapeutic recommendations indicate that they more strongly agreed that they should make recommendations for cost reasons than for clinical reasons.¹⁸

Several factors could be contributing to the lower-than-expected rate of pharmacist involvement. First, pharmacy computer systems may not effectively show the electronic message transmitted by the PBM; even if the message is viewed, the pharmacist may not understand the rationale for coverage denial and therefore not know to assist with alternative therapy. Additionally, prescription-order entry may be handled by the pharmacy technician, and messages related to rejected claims may not be viewed by the pharmacist. If the PBM messaging is viewed by pharmacists and understood, how this is communicated to members remains unknown. Although more than 60% of respondents indicated that their pharmacist told them why the medication was not covered, they may have been told only that "this medication is not covered by your plan."

Another factor precluding effective pharmacist involvement in resolution of step-therapy rejections is the limited time that pharmacists have for these types of activities, given the growing administrative and professional demands placed on pharmacists. A 1991 survey of community pharmacists indicated that pharmacists made recommendations to physicians to change to a less expensive product 5 times a week when prescriptions were phoned in and 3 times a week when they initiated contact with the physician.¹⁹

The outcome of the combined efforts to obtain coverage was that approximately 60% of members new to therapy received a covered medication, strongly influenced by whether they or their pharmacy contacted their physician. While contact with the physician is necessary to obtain a covered medication, a review of the literature on pharmacists' influence on prescribing indicates that, in a majority of cases, physicians accept the

pharmacists' suggestions for therapy change.²⁰

While making contact was a significant factor influencing receipt of a covered medication, it did not guarantee coverage. More than half of those who did not obtain a covered medication (i.e., received an OTC drug, paid out of pocket, or did not receive any medication) did make some contact with either their physician or health plan. Whether these members did not want to pursue the PA process or whether they were seeking clarity on the issue is unclear. However, ability to pay did not appear to be a major factor between those paying 100% out of pocket and those not receiving medication since a greater percentage of lower-income respondents paid out of pocket than higher-income respondents (even though this difference was not statistically significant).

The follow-up survey provides some insight into the reasons why members reported that they did not receive a medication. First, when members were probed further as to why they did not receive a medication, 30% reported that they actually did obtain a medication for their condition. This is possibly a limitation of the original survey's design. Among those who truly did not receive a medication, some noted the "hassle" factor associated with obtaining coverage (i.e., some members did not want to pursue it or found the medication unnecessary). However, some indicated that they could not afford to pay 100% for the brand medication, which could suggest that they were unaware that other lower-cost options were available or recommended. In addition, members who indicated that they had tried first-line drugs in the past but had either experienced side effects or lack of effectiveness may have been unaware of the PA process for medical exceptions.

The time from the step-therapy edit to receiving medication was longer for those who obtained the PA for the brand drug, compared with those who obtained first-line drug coverage. This is to be expected given that the PA process involves more than writing a new prescription. Whether these are system delays at the physician office and/or the PBM is uncertain. However, delays greater than 5 days should be explored further. The reason for some members paying out of pocket days after the edit also merits further research. It is not known whether this behavior represents a lack of knowledge on the part of members or physicians as to first-line drug coverage options, refusal of first-line drug options, or a decision to reduce time spent dealing with the issue.

Conclusions

While many members do receive coverage for the first-line drug in a timely manner, these findings suggest a need for better communication of program objectives to assist members, physicians, and pharmacists in understanding these more complex point-of-service edits. These improvements may help increase the percentage of members receiving a covered medication and reduce the time delay in obtaining medication. Future research

should examine the clinical outcomes and related health care costs associated with step-therapy programs to ensure that these and other cost-containment programs are achieving their intended objective without unintended consequences.

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