

# Utilization Management for Smoking Cessation Pharmacotherapy: Varenicline Rejected Claims Analysis

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Smoking is a serious health problem associated with significant mortality, morbidity, and costs. It is known to be a cause of many deadly diseases such as cancer, stroke, heart diseases, and lung diseases.<sup>1</sup> The Centers for Disease Control and Prevention estimated that smoking or exposure to smoking led to 443,000 premature deaths annually from 2000 to 2004 in the United States. Three leading causes of smoking-related death were lung cancer, ischemic heart disease, and chronic obstructive pulmonary disease. The total annual economic burden of smoking was \$193 billion per year in the United States during 2001 to 2004, with \$96 billion for direct healthcare costs and \$97 billion for productivity losses.<sup>2</sup> It was estimated that if all smokers covered by Medicaid stopped smoking, Medicaid could save \$9.7 billion every year after 5 years.<sup>3</sup> Further, at a global level, the World Bank has estimated that smoking accounts for about 6% to 15% of total health expenditures in developed countries.<sup>4</sup>

Although smoking cessation (SC) is extremely beneficial, it is known to be difficult. Among all of the untreated smokers who try to quit smoking, only 4% to 7% are likely to be successful.<sup>5</sup> Current clinical guidelines call for aggressive treatment of tobacco dependence through a combination of clinical counseling and medication interventions to improve the success rates.<sup>5</sup> Seven medications have been identified as first-line treatment for smoking, including bupropion SR, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, nicotine patch, and varenicline.<sup>5</sup>

Unfortunately, SC treatments have been severely underused. The National Health Interview Survey shows that of smokers attempting to quit smoking in 2000, only 21.7% used any pharmacotherapy and only 1.3% used behavioral counseling.<sup>6</sup> Clinical guidelines call for coverage of tobacco dependence treatments to improve the use of SC treatments and cessation rates.<sup>5</sup>

Research on the impact of benefit design on SC medication is limited. Existing studies generally focused on the effects of copayments on SC medication use.<sup>7-9</sup> The impact of utilization management methods such as prior authorization, step therapy, restrictive formulary, and quantity limits is not well understood. Previous research on rejected claims in other therapeutic areas showed that some patients did not fill prescriptions

**Objective:** To evaluate the impact of utilization management methods on use of smoking cessation medication.

**Study Design:** Retrospective cohort analysis of pharmacy claims data.

**Methods:** The study population included patients at least 18 years of age, naive to varenicline, and with a rejected varenicline claim between January 2007 and April 2008 because of 1 of 4 utilization management restrictions: drug not covered, prior authorization, step therapy, or quantity limits. The outcome variable was whether patients used any smoking cessation medication including varenicline, bupropion, and nicotine replacement therapy (prescribed and over-the-counter) within 6 months of the rejected varenicline claim. Multivariable logistic regression was conducted to evaluate the probability of filling a prescription for any smoking cessation medication.

**Results:** A total of 15,597 patients were identified. Within 6 months after the rejected claims, 8393 (53.8%) patients filled at least 1 smoking cessation medication, 7864 (93.7%) of whom filled varenicline. Compared with quantity limits, the odds ratios for filling any smoking cessation medication after the rejected varenicline claim were 0.01 (95% confidence interval [CI], 0.01-0.02) for varenicline not covered, 0.07 (95% CI, 0.06-0.09) for step therapy, and 0.18 (95% CI, 0.16-0.20) for prior authorization. Higher out-of-pocket expense was associated with a lower probability of filling any smoking cessation medication.

**Conclusion:** About half of the patients in this study did not fill any smoking cessation medication following a rejected varenicline claim. It is important to address this treatment gap in support of patients seeking smoking cessation therapy.

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### Take-Away Points

This research examines the use of smoking cessation medication among patients whose varenicline claims were rejected because of 1 of 4 utilization management restrictions (drug not covered, prior authorization, step therapy, or quantity limits). Six months after the rejected varenicline claim:

- Only 53.8% of patients filled a prescription for any smoking cessation medication.
- Of patients who did fill a prescription, 93.7% received varenicline and 6.3% received other smoking cessation medication without getting varenicline.
- Higher out-of-pocket expense was associated with a lower filling rate for any smoking cessation medication.

cally around 10% to 15%, and the claim is recorded in the data set.

The target study population included patients who attempted to fill prescriptions for varenicline that were rejected because of utilization management. The study population met the following inclusion criteria:

after their claims were rejected. For example, research on step-therapy restrictions on angiotensin-receptor blockers showed that 12 months after a claim for an angiotensin-receptor blocker was rejected because of step therapy, 7% of patients did not have any antihypertensive medication claims.<sup>10</sup> Another study showed that up to 70% of patients did not try to overcome a prior-authorization restriction after having a rejected claim for a cyclooxygenase-2 inhibitor.<sup>11</sup> If a large percentage of patients did not fill any SC medication after being denied an SC medication claim, such an observation should raise concerns for health plans and policy makers. In the long run, decreased use of SC medication could lead to worse health outcomes and higher healthcare costs.

We investigated the relationship between utilization management for varenicline and the initiation of therapy with SC medication. Specifically, this study reports the proportion of patients who actually used SC medication 6 months after a varenicline claim rejection and examines factors that influenced patients' decision to use SC medication. We focused on varenicline because utilization management of SC medication generally focuses on this drug, as it is the only newly approved SC medication in over a decade. In this study, 94.3% of the patients whose claims for SC medication were rejected because of utilization management had prescriptions for varenicline. Sensitivity analysis was performed to include patients whose claims for other prescribed SC medication were rejected.

- At least 1 rejected varenicline claim from January 2007 to April 2008 because of 1 of 4 utilization management restrictions: drug not covered, prior authorization, step therapy, or quantity limits.
- No approved or rejected varenicline claims before the identification period.
- Continuously enrolled in the same health plan 1 year before and at least 183 days after the initial rejected varenicline claim.
- Had coverage for over-the-counter (OTC) SC medication.
- Age 18 years or older at the time of attempting to fill a varenicline claim.

### Utilization Management

This research focused on patients whose varenicline claims were rejected because of 1 of 4 utilization management restrictions: drug not covered, prior authorization, step therapy, or quantity limits. These 4 restrictions accounted for approximately 80.9% (140,228 of 173,314) of the total number of rejected varenicline claims (Table 1). The remaining varenicline claims were turned down for reasons unrelated to benefit design such as member benefit expired, incorrect spelling, not a network pharmacy, etc.

Patients whose claims for varenicline were rejected because the drug was not covered had a closed formulary in which medications not listed in the formulary were excluded from coverage. Closed formularies are commonly used by health plans to control costs.<sup>12</sup> Patients who had an open formulary, in which medications not in the preferred formulary were covered with a higher copayment, were not included in this analysis because their varenicline claims were not rejected.

Patients whose claims were rejected because of prior authorization usually were required to enroll in an approved counseling and behavior-modification program. Both clinical guidelines and the prescribing information for varenicline recommend the use of clinical counseling along with varenicline to improve cessation rates.<sup>5,13</sup> For this reason, many health plans require patients to enroll in a clinical counseling program before varenicline can be dispensed. Upon enroll-

## METHODS

### Data Source and Subject Selection

A retrospective cohort data analysis was conducted based on MedImpact's claims database. MedImpact is a large private national pharmacy benefits management company. The claims database contains detailed information of the adjudication process, including rejected, reversed, and approved claims. If a patient decides to pay cash to purchase a medication after a claim is rejected because of utilization management, he or she receives a network discount, typi-

ment in such a program, patients receive a certificate of enrollment that they then can fax to health plans to meet the prior-authorization requirement and obtain varenicline. Prescribing physicians also can certify this enrollment on behalf of patients to help them obtain the drug.

The step-therapy restriction typically requires patients to try bupropion or nicotine replacement therapy before trying varenicline. Health plans usually impose the step-therapy requirement to encourage patients to use a low-cost alternative. If a significant portion of patients can be diverted to low-cost alternatives, health plans can save on medication costs.<sup>14,15</sup>

Finally, the quantity-limit restriction usually restricts days of supply of the initial varenicline claim to fewer than 21 to 34 days, depending on the health plan. Health plans usually put a quantity limit on SC medication to avoid waste. For example, some patients may stop using varenicline, like other SC medication, after several days. In that case, the rest of the medication could be wasted if a large quantity of varenicline were dispensed.

**Outcome Measure**

The outcome variable was whether patients used any SC medication within 6 months of the rejected varenicline claim. In general, the intent of utilization management is to encourage patient compliance with clinical guidelines or to channel patients to use cheaper alternatives, rather than to deter patients from initiating SC pharmacotherapy treatment altogether. For this reason, the percentage of patients using any SC medication was used as a measure of success for these tools. The SC medication considered in this research included any form of bupropion, prescribed and OTC nicotine replacement therapy, and varenicline.

**Price Index for Smoking Cessation Medication**

When a patient’s claim for an SC medication is rejected, he or she may consider alternative medications. The health plan’s generosity in covering SC medication may be an important factor in the patient’s decision. We constructed a price index to quantify health plan’s coverage of SC medication.<sup>16,17</sup> A price index is the average out-of-pocket (OOP) cost for SC medication weighted by the number of claims. It can be interpreted as the OOP cost for a market basket of SC medication. The

**Table 1. Data Construction Process**

Selection Criteria	No.
All rejected varenicline claims between January 2007 and April 2008	173,314
Claims rejected because of 4 benefit restrictions	140,228
Unique number of patients	56,594
Continuous enrollment in the same health plan 1 year before and 183 days after the first rejected claim	23,283
Naïve to varenicline 1 year before the first rejected claim	17,897
Had coverage of over-the-counter smoking cessation medication	15,642
Age 18 years or older	15,597

**eAppendix** (available at [www.ajmc.com](http://www.ajmc.com)) provides the technical details about the price index.

**Statistical Analysis**

Multivariable logistic regression modeling was done to examine factors that could influence patient response to a rejected varenicline claim. The covariates included age, sex, type of insurance, geographic locations, comorbidities, type of benefit restrictions, price index, and history of use of bupropion or nicotine replacement therapy before the rejected varenicline claim. Comorbidities were measured by RxRisk, a method to determine a patient’s risk profile based on pharmacy data only.<sup>18</sup> Only comorbidities that influenced more than 5% of the population were included in the final regression analysis.

**RESULTS**

Table 1 illustrates the data construction process. A total of 15,597 patients from 70 health plans were identified as meeting the inclusion criteria. **Table 2** provides the descriptive statistics for this population. The mean (SD) age of patients was 47.3 (11.9) years, and 56% were female. Most patients were located in the Midwest (81.1%) and belonged to commercial health maintenance organizations (85.2%). Drug not covered, prior authorization, quantity limits, and step therapy accounted for 34.9%, 30.4%, 28.3%, and 6.4% of the rejected claims, respectively. About 8.9% of patients had used bupropion or nicotine replacement therapy before having a rejected varenicline claim. The remaining 91.1% of patients were naïve to SC medication.

Of the 15,597 patients, 8393 (53.8%) patients filled at least 1 SC medication and 7204 (46.2%) patients did not fill any SC medication during the 6 months after the rejected varenicline claim. The filling rate differed substantially by utilization management method. Quantity limits appeared to be a mild restriction, with a filling rate of 92.3%. The filling rates were 63.9% for prior authorization and 46.0% for

■ **Table 2.** Characteristics of the Overall Study Population and of Those Filling Any Smoking Cessation Medication<sup>a</sup>

Characteristic	All Patients With Rejected Varenicline Claim	Patients Who Filled Any Smoking Cessation Medication Within 183 Days of Rejection of Varenicline Claim
<b>No. of patients</b>	15,597 (100)	8393 (53.8)
<b>Age, mean (SD), y</b>	47.3 (11.9)	47.6 (12.0)
<b>Age group, y</b>		
18-39	4009 (25.7)	2161 (53.9)
40-49	4745 (30.4)	2469 (52.0)
50-64	5746 (36.8)	3100 (54.0)
≥65	1097 (7.0)	663 (60.4)
<b>Sex</b>		
Female	8734 (56.0)	4833 (55.3)
Male	6863 (44.0)	3560 (51.9)
<b>Type of insurance</b>		
Commercial HMO	13,282 (85.2)	7148 (53.8)
Medicaid	1263 (8.1)	616 (48.8)
Medicare Part D	898 (5.8)	534 (59.5)
Self-insured	154 (1.0)	95 (61.7)
<b>Geographic location</b>		
Northeast	558 (3.6)	353 (63.3)
Midwest	12,645 (81.1)	7111 (56.2)
South	513 (3.3)	177 (34.5)
West	1881 (12.1)	752 (40.0)
<b>Comorbidities as measured by RxRisk</b>		
Anxiety and tension	3307 (21.2)	1816 (54.9)
Coronary/peripheral vascular disease	867 (5.6)	491 (56.6)
Cystic fibrosis	2528 (16.2)	1394 (55.1)
Depression	5010 (32.1)	2995 (59.8)
Diabetes	1242 (8.0)	663 (53.4)
Epilepsy	1524 (9.8)	859 (56.4)
Gastric acid disorder	2962 (19.0)	1695 (57.2)
Heart disease/hypertension	3093 (19.8)	1720 (55.6)
Hyperlipidemia	3956 (25.4)	2277 (57.6)
Hypertension	3919 (25.1)	2183 (55.7)
Irritable bowel syndrome	1841 (11.8)	1024 (55.6)
Thyroid disorder	1184 (7.6)	657 (55.5)
<b>Reason for rejected claim</b>		
Varenicline not covered	5440 (34.9)	831 (15.3)
Quantity limits	4409 (28.3)	4069 (92.3)
Step therapy	1003 (6.4)	461 (46.0)
Prior authorization	4745 (30.4)	3032 (63.9)
<b>Price index for SC medication, mean (SD)</b>	\$28.3 (\$20.2)	\$26.4 (\$21.0)
<b>Price index for SC medication group</b>		
\$0-\$5	1888 (12.1)	980 (51.9)
\$6-\$20	3563 (22.8)	2314 (65.0)
\$21-\$30	3178 (20.4)	1759 (55.4)
\$31-\$40	4946 (31.7)	2546 (51.5)
\$41-\$60	1297 (8.32)	517 (40.0)
>\$60	725 (4.7)	277 (38.2)
<b>Used bupropion or NRT in previous 12 months</b>		
Yes	1381 (8.9)	936 (67.8)
No	14,216 (91.1)	7457 (52.5)

HMO indicates health maintenance organization; NRT, nicotine replacement therapy; SC, smoking cessation.

<sup>a</sup>Values are number (percentage) unless indicated otherwise.

**Table 3.** Distribution of Filling Rate of Smoking Cessation Medication Among Patients Who Filled a Prescription for at Least 1 Smoking Cessation Medication

Type of Prescription Filled	No. (%)				
	Overall	Drug Not Covered	Step Therapy	Prior Authorization	Quantity Limits
Any smoking cessation claim	8393 (100.0)	831 (100.0)	461 (100.0)	3032 (100.0)	4069 (100.0)
Any varenicline <sup>a</sup>	7864 (93.7)	488 (58.7)	437 (94.8)	2907 (95.9)	4042 (99.3)
Any bupropion <sup>a</sup>	860 (10.2)	345 (41.5)	46 (10.0)	236 (7.8)	233 (5.7)
Any prescribed NRT <sup>a</sup>	33 (0.4)	3 (0.4)	1 (0.2)	11 (0.4)	18 (0.4)
Any OTC NRT <sup>a</sup>	156 (1.9)	56 (6.7)	5 (1.1)	43 (1.4)	52 (1.3)
Other smoking cessation medication without filling varenicline <sup>a</sup>	529 (6.3)	343 (41.3)	24 (5.2)	125 (4.1)	27 (0.7)

NRT indicates nicotine replacement therapy; OTC, over-the-counter.

<sup>a</sup>Note that the figures are not mutually exclusive because patients could fill more than 1 medication during the 6-month follow-up period.

step therapy. Drug not covered had the lowest filling rate (15.3%).

High OOP cost generally was associated with a lower filling rate. The filling rates for the price indexes \$0 to \$5 and \$6 to \$20 were 51.9% and 65.0%, respectively. These rates decreased to 40.0% and 38.2% for patients with price indexes of \$41-\$60 and more than \$60, respectively. Patients completely naïve to SC medication had a lower filling rate (52.5%) than those patients who previously used other SC medication (67.8%).

**Table 3** shows the filling patterns for the 8393 patients who filled at least 1 SC medication. Note that the numbers in the table are not mutually exclusive because patients could fill prescriptions for more than 1 medication during the 6-month follow-up period. Among patients who filled prescriptions for any SC medication, an overwhelming majority (93.7%) filled prescriptions for varenicline, followed by bupropion (10.2%), OTC nicotine replacement therapy (1.9%), and prescribed nicotine replacement therapy (0.4%). Only a small proportion of patients (6.3%) filled prescriptions for SC medication without filling varenicline. The varenicline filling rates differed substantially by utilization management methods. For patients rejected by step therapy, prior authorization, and quantity limits, the varenicline filling rates among patients who filled SC medication were 94.8%, 95.9% and 99.3% respectively. In contrast, for patients whose claims were rejected because varenicline was not covered, the varenicline filling rate was only 58.7%. Patients whose claims were rejected because the drug was not covered could not attain varenicline at a favorable price. This forced many patients to use other SC medication.

**Table 4** reports odds ratios (ORs) and confidence intervals (CIs) from the logistic regression models. Compared with claims rejected because of quantity limits, the ORs for filling any SC medication after rejection for prior authoriza-

tion, step therapy, and drug not covered were 0.18 (95% CI, 0.16-0.20), 0.07 (95% CI, 0.06-0.09), and 0.01 (95% CI, 0.01-0.02), respectively ( $P < .0001$  for all comparisons). The OOP cost was another important factor. The OR of filling any SC medication decreased as the OOP cost increased. Compared with an OOP cost of \$0 to \$5, the ORs were 0.58 (95% CI, 0.47-0.71) for an OOP cost of \$6 to \$20; 0.55 (95% CI, 0.44-0.68) for an OOP cost of \$21 to \$30; 0.42 (95% CI, 0.34-0.52) for an OOP cost of \$31 to \$40; 0.33 (95% CI, 0.26-0.42) for an OOP cost of \$41 to \$60; and 0.32 (95% CI, 0.24-0.42) for an OOP cost of more than \$60. All ORs for OOP cost groups were statistically significant at  $P < .0001$ .

Patient demographics, type of insurance, and most comorbidities were generally insignificant in predicting the probability of filling SC medication. Patients who had previously used bupropion or nicotine replacement therapy were significantly more likely to fill SC medication (OR = 2.08, 95% CI, 1.78-2.43;  $P < .0001$ ).

To assess the robustness of the results, we performed a sensitivity analysis by including patients whose claims for other prescribed SC medication were rejected. When the population was expanded to all patients with rejected claims for prescribed SC medication, the total number of patients increased by 935 from 15,597 to 16,532. Patients with rejected varenicline claims accounted for 94.3% of the 16,532 patients. Of the 935 patients whose claims for bupropion and prescribed nicotine replacement therapy were rejected, 71.0% (664) filled at least 1 SC medication, higher than the filling rate for patients whose claims for varenicline were rejected (53.8%). The higher filling rate may be partially explained by the higher rate of rejection because of quantity limits (47.5% vs 28.3%, see Table 2) and lower rate of rejection because the drug was not covered (24.6% vs 34.9%, see Table 2) for these 935 patients. Similar to patients whose

■ **Table 4.** Multivariable Logistic Model Results: Filled Any Smoking Cessation Medication Within 183 Days

Explanatory Variable	Odds Ratio (95% CI)	Two-Sided P
<b>Age group, y</b>		
18-39 <sup>a</sup>	1.00	
40-49	0.98 (0.87-1.09)	.69
50-64	0.98 (0.87-1.10)	.67
≥65	0.89 (0.72-1.10)	.28
<b>Female</b>	1.05 (0.96-1.15)	.28
<b>Business type</b>		
Commercial HMO <sup>a</sup>	1.00	
Medicaid	1.06 (0.80-1.40)	.70
Medicare Part D	1.17 (0.93-1.46)	.18
Self-insured	0.91 (0.56-1.51)	.72
<b>Geographic location</b>		
Midwest <sup>a</sup>	1.00	
South	0.24 (0.18-0.31)	<.0001
Northeast	1.00 (0.75-1.35)	.98
West	0.83 (0.67-1.02)	.08
<b>Price index for smoking cessation medication groups</b>		
\$0-\$5 <sup>a</sup>	1.00	
\$6-\$20	0.58 (0.47-0.71)	<.0001
\$21-\$30	0.55 (0.44-0.68)	<.0001
\$31-\$40	0.42 (0.34-0.52)	<.0001
\$41-\$60	0.33 (0.26-0.42)	<.0001
>\$60	0.32 (0.24-0.42)	<.0001
<b>Comorbidities as measured by RxRisk</b>		
Anxiety and tension	0.98 (0.88-1.09)	.73
Coronary/peripheral vascular disease	0.97 (0.80-1.18)	.78
Cystic fibrosis	0.99 (0.88-1.11)	.85
Depression	1.55 (1.40-1.71)	<.0001
Diabetes	0.90 (0.76-1.06)	.19
Epilepsy	0.98 (0.84-1.13)	.74
Gastric acid disorder	1.11 (0.99-1.24)	.07
Heart disease/hypertension	0.89 (0.79-1.00)	.05
Hyperlipidemia	1.20 (1.07-1.34)	.00
Hypertension	1.01 (0.90-1.13)	.84
Irritable bowel syndrome	1.06 (0.93-1.21)	.40
Thyroid disorder	0.91 (0.78-1.07)	.26
<b>Reasons for rejected claim</b>		
Quantity limits <sup>a</sup>	1.00	
Prior authorization	0.18 (0.16-0.20)	<.0001
Step therapy	0.07 (0.06-0.09)	<.0001
Varenicline not covered	0.01 (0.01-0.02)	<.0001
<b>Used bupropion or NRT in previous 12 months</b>		
No <sup>a</sup>	1.00	
Yes	2.08 (1.78-2.43)	<.0001

CI indicates confidence interval; HMO, health maintenance organization; NRT, nicotine replacement therapy.  
<sup>a</sup>Reference group.

varenicline claims were rejected, patients whose claims for bupropion and prescribed nicotine replacement therapy were rejected strongly preferred to fill the rejected medication. Of the 664 patients who filled at least 1 SC medication, 608 (91.6%) filled the rejected medication; the comparable figure for patients whose claim for varenicline was rejected was 93.7% (Table 3). Results in Table 4 were similar after the inclusion of these 935 patients.

### DISCUSSION

In this study, about half of all patients did not use any SC medication within 6 months of a rejected varenicline claim. The finding is particularly troublesome given that the patients we studied were likely motivated quitters. These are patients who went through the process of visiting their physicians, obtaining prescriptions, and going to the pharmacy to fill their prescriptions. They all needed SC pharmacotherapy, according to their physicians. However, they were stopped short of starting therapy because of the placement of utilization management.

Consistent with the clinical guidelines,<sup>5</sup> the implications of this research underscore the importance of covering SC medication. Patients who did not have any coverage of varenicline (drug not covered) had the lowest filling rate (15.3%). In addition, we found that a high OOP cost was associated with decreased use of SC therapy once patients had a rejected claim. Offering full coverage of SC medication should help improve the use of SC medication.<sup>7,8</sup>

In addition, this research showed that only a small number of patients used SC medication other than varenicline after having a claim for varenicline rejected by step therapy. When step therapy is successful, a large percentage of patients switch to alternative medications following a rejected claim. In this study, only 24 (2.4%) of the 1003 patients with rejected varenicline claims because of the step-therapy requirement used other SC medication (Table 3). More than half (54.0%, see Table 2) of the patients did not use any SC medication after their claims were rejected because of step therapy.

The findings in this analysis showed that many patients (36.1%) discontinued their effort to fill an SC prescription after their varenicline claim was rejected because of prior authorization. These patients usually are required to enroll in an approved-counseling and behavior-modification program. As counseling is a critical component of the SC therapy, the rate of therapy discontinuation is cause for concern and identifies a need to optimize integration of the counseling and pharmacotherapy components of SC therapy. Health plans need to follow up with these patients to encourage the initiation of this therapy.

Although the study had an adequate sample size to examine the distribution of patients over time, several limitations should be acknowledged. First, this research was a retrospective claims analysis. Important information such as a patient's smoking history or the actual SC outcome was not available. It is possible that patients quit smoking without any treatment. Some researchers have argued that unaided cessation is the most common method used by successful former smokers.<sup>19</sup> Second, although many health plans do cover OTC SC medication, some patients may not be aware of this benefit and fill prescriptions for OTC SC medication without using their insurance cards. In this case, the use of SC medication in this research may be underestimated. Third, our knowledge of previous SC medication use is limited and based on data from 1 year before the index claim. Fourth, this research only identifies a treatment gap in SC therapy after rejected claims because of utilization management. It is not a comprehensive cost-effectiveness analysis of utilization management. Decision makers need to evaluate advantages and disadvantages carefully in deciding whether to implement utilization management for SC medication. Finally, we used data from a national pharmacy benefits management data set, and the findings may not be necessarily generalizable to patients in other health plans.

### CONCLUSION

Smoking cessation is a high-priority issue for policy makers and healthcare providers. This study identified a treatment gap in the use of SC medication in the presence of 4 commonly used utilization management methods. About half of all patients whose varenicline claims were rejected by these utilization management methods did not use any SC medication within 6 months of the rejected varenicline claim.

Our findings have important implications for health plans and policy makers. The recently passed healthcare reform act mandates that health plans cover SC medication with zero copayment.<sup>20</sup> Although this reform addresses the issue of formulary coverage, it is silent on other utilization management methods including prior authorization and step therapy for SC medication. Addressing the treatment gap associated with utilization management is important to improving SC therapy in the United States.

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**Authorship Information:** Concept and design (FZ, CC, VM, KHZ, JH); acquisition of data (FZ); analysis and interpretation of data (FZ, CC, VM, KHZ, JH, BVP); drafting of the manuscript (FZ, CC, KHZ); critical revision of the manuscript for important intellectual content (FZ, CC, VM, KHZ, JH); statistical analysis (FZ); obtaining funding (FZ, CC, BVP); administrative, technical, or logistic support (FZ, CC, JH); and supervision (FZ, CC, VM, BVP).

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