

The Effect of a Closed Formulary in the Face of Real-Life Enrollment and Disenrollment Patterns

by Brenda Motheral, Thomas A. Delate,
James W. Shaw, and Rochelle Henderson

OBJECTIVE: To evaluate the effect of a closed formulary on pharmaceutical utilization and expenditures in a non-continuously eligible population.

DESIGN: A pretest–post-test design was used to compare changes in pharmaceutical utilization and expenditures between the formulary and a nonformulary group in the nine months before formulary implementation and the nine months after.

SETTING: Two government employer plans in the eastern United States.

PARTICIPANTS: Noncontinuously eligible individual plan members were included in the study if they had been enrolled in their plan for at least one month in both the pre- and the post-periods.

MAIN OUTCOME MEASURES: Mean pharmaceutical utilization and expen-

ditures per member per month (PMPM).

RESULTS: Formulary cases (n=1,542) were matched on age and baseline pharmaceutical utilization with controls who were not in a formulary group plan. These cases had a higher generic fill rate, lower mean total claims PMPM, and lower mean brand claims PMPM in the post-period, controlling for age, sex, chronic disease score, and utilization in the pre-period.

CONCLUSIONS: Formularies can significantly reduce pharmaceutical utilization in a noncontinuously eligible population. Future research should examine the effect of a closed formulary within therapy classes.

KEYWORDS: formulary, pharmaceutical utilization

J Managed Care Pharm 2000; 293-97

Authors

BRENDA MOTHERAL, R.Ph., M.B.A., Ph.D., is Senior Director of Outcomes Research, Express Scripts, Inc., Maryland Heights, MO, and faculty member at the University of Arizona College of Pharmacy, Tucson, AZ; THOMAS A. DELATE, M.S., is Graduate Research Assistant, and JAMES W. SHAW, Pharm.D., is a graduate student, Department of Pharmacy Practice and Science, College of Pharmacy, University of Arizona, Tucson, AZ; ROCHELLE HENDERSON, M.P.A., is Research Analyst, Express Scripts, Inc., Bloomington, MN.

AUTHOR CORRESPONDENCE: Brenda Motheral, Ph.D., Senior Director of Outcomes Research, Express Scripts, Inc., 13900 Riverport Dr., Maryland Heights, MO 63043; Tel: 314-770-1666, x 67753; Fax: 314-702-7077; E-mail: bmotheral@express-scripts.com.

Copyright© 2000 Academy of Managed Care Pharmacy, Inc. All rights reserved.

The mean annual increase in U.S. prescription drug expenditures between 1980 and 1990 was 12.2%.¹ This rate slowed to 8.5% between 1990 and 1993, presumably because of the influence of managed care.¹ However, in 1998 drug expenditures grew by 17.6%.² Faced with unrelenting cost increases, health plans have evolved a variety of techniques to curb growth in pharmaceutical utilization and associated expenditures. One of the most controversial of these cost containment mechanisms is the closed formulary, a list of drugs for which a health plan will pay.

A primary objective of a closed formulary is to reduce unit drug costs by promoting use of generic and less expensive brand medications. In addition, a closed formulary may help to reduce medication overutilization. Closed formularies among health maintenance organizations (HMOs) slowly increased between 1996 and 1997—25% of HMOs reported using a closed formulary in 1996; 31.8% did so in 1997—but they are increasingly being supplanted by three-tier copayments.³

In the 1990s, interest in evaluating the outcomes of formulary restrictiveness—particularly its effect on health care resource utilization—has grown. Numerous studies have assessed the benefit of formularies.⁴⁻¹⁵ Most of these investigations were conducted among Medicaid populations, examined only one or two therapy classes, or suffered from inadequate study design.^{16,17} The Managed Care Outcomes Project, a multicenter observational investigation, is one of only two studies that have evaluated the outcomes of formulary restrictions using data derived from a non-Medicaid population.⁹⁻¹¹ However, this study has been criticized for methodological and analytical flaws.^{18,19}

The most recent study to examine closed formularies used a pre-/post- with control group design and examined a continuously eligible population of commercial enrollees within a pharmacy benefit management company.²⁰ The investigators found that the closed formulary was associated with significantly lower utilization of brand medications, significantly lower drug expenditures, and a higher prior authorization rate. However, patients with a closed formulary had a reduced rate of continuation with chronic medications in the nine months following formulary implementation compared to patients without a closed formulary. The study raised questions about the reasons for discontinuation of therapy and whether a prior authorization system is an efficient approach to drug coverage.

This study did not consider noncontinuously eligible

patients, who represent a significant portion of most health plans' enrollment base. Similar cost savings may not be observed in a noncontinuously eligible population. For example, a new plan enrollee may have a pent-up demand, particularly if the person did not previously have a prescription benefit. A person exiting a plan may attempt to stockpile medications (although this will be tempered somewhat by quantity limits). If these factors overshadow the incentives created by a closed formulary, the implications for decision makers are substantial, as the potential savings from a closed formulary will depend on turnover in the enrollee population. Accordingly, the objective of this investigation was to examine how a closed formulary affected pharmaceutical utilization and expenditures in a noncontinuously eligible population.

In light of consumer demand and the latest research, this study hypothesized that decreased use of nonformulary medications would not be offset by an increase in the use of formulary medications, and hence, brand utilization and total expenditures would decrease. It was also hypothesized that generic utilization would increase because generics, when available, would be viewed as substitutes for brand medications.

Methods

Study design. This study used a retrospective cohort of two government employer groups in the eastern United States. The intervention group's health plan implemented a closed formulary on July 1, 1997. The control group's health plan had no formulary restrictions in 1996 or 1997. In selecting the cohort, the investigators made sure that no other plan design changes that could have affected the results occurred during the study period. Noncontinuously eligible individual plan members were included in the study if they had been enrolled in their plan for at least one month in both the pre- and post- periods.

A substantially higher number of formulary group subjects (n=6,583) were eligible for inclusion compared with control group subjects (n=1,664). These groups differed in mean age and mean baseline utilization of pharmaceutical resources. Because of the potential confounding effects of these differences, each formulary subject was matched with a randomly selected control subject based on age and baseline utilization. No age- and baseline utilization-matched control group subject existed for 122 of the formulary subjects.

A pretest-post-test design was used to compare the changes in the dependent variables between groups from the pre- to post-periods. The investigation period spanned 18 months—9 months in the pre-study period and 9 months in the post-period. The pre-period began July 1, 1996, and ended March 31, 1997. The post-period began July 1, 1997 and ended March 31, 1998.

The formulary covered approximately 520 single-source brand pharmaceuticals. The market share of nonformulary products ranged from 3.5% to 20.6% before the formulary was implemented for the intervention group. A prior authorization

system allowed plan members to request coverage for a nonformulary product. Excluded from the analysis *a priori* were all claims for cancer, organ transplantation, growth hormone, injectable fertility, and anti-HIV therapy medications because the formulary did not restrict coverage for these medications, which are very costly and used by a small proportion of patients. Claims for these medications could have substantially affected the results of this study for reasons unrelated to the closed formulary.

Study variables. Because subjects had varying lengths of eligibility over the study period, total claims and expenditures were calculated per month of subject eligibility. Dependent variables used in the analyses included the following.

- *Participation*, equal to 1 if the subject had one or more claims in the period. This variable was calculated separately for brand and generic utilization.
- *Mean total claims per subject*, the total number of claims in the period divided by the total number of months of eligibility during the period, calculated separately for both brand and generic claims. Mail-order prescriptions for 90- or 60-day supplies were converted to 30-day equivalents. The study did not include over-the-counter or nonformulary medications that were not given prior authorization.
- *Mean total cost per subject*, the sum of all ingredient costs across all claims in the period divided by the number of months of eligibility during the period, calculated separately for both brand and generic ingredient costs. Ingredient cost was calculated as average wholesale price (AWP) as of July 1997 for brand products and 65% of AWP for generic products. The discount of 35% for generics mirrors the usual AWP price difference between brand and generic products for third-party payers.²¹
- *Mean cost per prescription per subject*, the sum of ingredient costs for all claims in the period divided by the number of claims during the period. This variable is shown only for subjects who had at least one claim in the pre- and post- periods.
- *Mean generic fill rate per subject*, the total number of generic claims divided by the total number of claims. This variable is shown only for subjects who had at least one claim in the pre- and post-periods.
- *Mean number of prior authorizations per subject*, the total number of prior authorizations divided by number of months of eligibility during the period.

Independent variables included in every regression were: formulary (formulary intervention vs. control), age as of July 1, 1997, gender, chronic disease score (CDS), months eligible in the pre-period, months eligible in the post-period, and pre-period variable (pre-period equivalent of the dependent variable). CDS is a pharmacy claims-based measure of chronic disease status that has been shown to predict hospitalizations and mortality.²² Higher CDS scores indicate a greater number of chronic illnesses for a subject.

The Effect of a Closed Formulary in the Face of Real-Life Enrollment and Disenrollment Patterns

Statistical analysis. Nonparametric Mann-Whitney U tests were performed in the bivariate analysis to compare changes in the continuous dependent variables from the pre- to post- period between formulary and control groups. Multivariate regression analyses examined brand and generic participation using logistic regression. The remaining variables, except prior authorization (which violated the regression model assumptions), were analyzed using linear regression. Statistically significant results ($p < .05$) are discussed.

Results

Study sample. After matching, the final sample size was 1,542 for each group. Age and baseline-utilization matching of formulary and control subjects resulted in matched groups that did not significantly differ from each other in mean age, percentage of females, and mean baseline utilization of pharmaceutical resources (Table 1). The fact that mean CDS score (0.21 versus 0.31, $p < 0.05$) was higher for the formulary group was statistically significant but clinically inconsequential. As months of eligibility in the pre- and the post- periods were associated with expenditure changes (data not shown) and varied across groups, multivariate analysis was necessary to control for differences in months of eligibility.

Bivariate results. Total claims, brand claims, brand cost, and cost per prescription increased less in the formulary group than in the control group between the pre- and post-periods (Table 2). With the implementation of the formulary, that group had a greater increase in the mean number of prior authorizations per member per month (PMPM) ($p < .001$).

TABLE 1 Study Sample

Variable	Control (n=1,542)	Formulary (n=1,542)
Age (mean)	24.5	24.5
Gender (% female)	52.3	50.5
CDS (mean) ^a	0.31	0.21
Months preformulary eligibility (mean) ^b	6.5	3.5
Months post-formulary eligibility (mean) ^b	6.7	8.5
Baseline utilization per month (mean)	0.38	0.40

Note: CDS is chronic disease score.

^aRank-sum test of differences between control and formulary groups ($p \leq 0.05$).

^bRank-sum test of differences between control and formulary groups ($p \leq 0.001$).

Multivariate regression results. Consistent with the bivariate results, the closed formulary was associated with statistically significant lower total claims PMPM ($p < .01$) and total brand claims PMPM ($p < .05$), after controlling for other factors associated with prescription drug use (Table 3). Lower total

TABLE 2 Utilization and Expenditures by Group

Variable	Control (n=1,542)			Formulary (n=1,542)			Mann-Whitney U Test ^a
	Pre	Post	Change	Pre	Post	Change	p-value
Mean total cost/month	12.90	20.00	7.10	12.50	16.20	3.70	0.115
Mean generic cost/month	2.40	3.70	1.30	2.60	3.30	0.70	0.058
Mean brand cost/month	10.50	16.30	5.80	9.90	12.90	3.00	0.068
Mean total claims/month	0.37	0.56	0.19	0.40	0.50	0.10	0.026
Mean generic claims/month	0.16	0.24	0.08	0.18	0.23	0.05	0.433
Mean brand claims/month	0.21	0.32	0.11	0.22	0.27	0.05	0.008
Mean cost/claim (n=1,080)	29.16	32.42	3.26	29.20	29.23	0.03	0.023
Mean generic fill rate (n=1,080)	0.46	0.44	-0.02	0.49	0.52	0.03	0.123
Mean prior authorizations/month	0.003	0.006	0.003	0.004	0.01	0.006	0.000

^aRank-sum test of between-group differences.

The Effect of a Closed Formulary in the Face of Real-Life Enrollment and Disenrollment Patterns

TABLE 3 Regression Analyses

Dependent Variable ^a	N	Predictor								Adjusted R ²
		Formulary	Age	CDS	Female	Preperiod Variable ^e	Month Eligible Preperiod	Months Eligible Preperiod	Total Claims Preperiod	
Total	3,084	-2.57	0.0320***	9.80***	3.52**	0.591***	-0.106	-0.206	—	0.42
Total brand cost	3,084	-1.66	0.284***	9.04***	3.53**	0.538***	0.006	-0.324	—	0.37
Total generic cost	3,084	-0.851*	0.057***	1.85***	0.294	0.512***	-0.115	0.114	—	0.34
Total claims	3,084	-0.093**	0.006***	0.185***	0.122***	0.615***	-0.009	0.004	—	0.48
Total brand claims	3,084	-0.050*	0.004***	0.130***	0.093***	0.601***	-0.004	-0.004	—	0.46
Total generic claims	3,084	-0.037*	0.002***	0.088***	0.039**	0.475***	-0.005	0.008*	—	0.29
Cost/claim ^b	1,080	-1.45	0.190***	0.660	-2.84*	0.438***	0.029	-0.776	—	0.25
Generic fill rate ^b	1,080	0.055*	-0.002**	-0.003	-0.051*	0.265***	0.006	0.016**	—	0.13
Brand participation ^c	3,084	0.697***	1.01***	1.05	1.61***	3.86***	0.901***	1.22***	1.13***	—
Generic participation ^d	3,084	0.963	0.997	1.16*	1.37***	1.98***	0.963	1.32***	1.08***	—

Note: CDS is chronic disease score.

^aAll dependent variables represent the post-period on a per month basis except as noted. Coefficients were determined with linear regression except as noted.

^bOnly those subjects with a claim in both the pre- and post-periods were included in this regression.

^cLogistic regression of brand participation. Brand participation was coded as 1 if the subject had one or more brand product claims in the post-period and 0 otherwise. Coefficient is presented as an exponentiated beta coefficient.

^dLogistic regression of generic participation. Generic participation was coded as 1 if the subject had one or more generic product claims in the post-period and 0 otherwise. Coefficient is presented as an exponentiated beta coefficient.

^ePreperiod variable refers to the preperiod equivalent of the dependent variable.

* $p \leq 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$

generic cost PMPM ($p < .05$) and total generic claims ($p < .05$), and greater generic fill rate ($p < .05$) were also observed in the closed formulary group. With few exceptions, increasing age, higher CDS, female gender, and higher preperiod value were associated with a higher post-period value for each of the dependent variables.

The likelihood of receiving one or more brand prescriptions (brand participation) in the post-period was statistically significantly lower for closed formulary subjects ($\text{Exp}\beta = 0.70$, $p < .0001$). All other independent variables except CDS were statistically significant for having one or more brand claims in the post-period.

Discussion

This study provides evidence that closed formularies mitigate continued increases in pharmaceutical utilization, even given

real-life enrollment and disenrollment patterns. In this and our previous research, as hypothesized, closed formularies were associated with reductions in the utilization of brand medications. These findings suggest that while pent-up demand or stockpiling may occur when enrollees enter or exit a plan, such factors do not negate the effect of a closed formulary. These results cannot be compared to those of previous studies of closed formularies given the significant differences in study populations, research design, and formulary content.

The fact that generic utilization increased more in the control group than in the formulary group, although the generic fill rate went up in the formulary group, was surprising. In addition, unlike our previous work within a continuously eligible population, utilization reductions were not associated with statistically significant reductions in pharmaceutical expenditures.

The Effect of a Closed Formulary in the Face of Real-Life Enrollment and Disenrollment Patterns

This may be explained by the large variation in costs relative to utilization, combined with the relatively small sample size in this study, which reduced the statistical power (only 47%) to detect differences.

Soumerai et al. have recommended at least two years of follow-up to examine whether subjects learn to bypass formulary policy changes over time.¹⁶ If patients learn to circumvent policy changes beyond the first nine months after a formulary is introduced, the observed reduction in utilization would lessen over time. Soumerai et al. recommend a time-series approach to more appropriately elucidate underlying trends.¹⁶ Insufficient data were available in this investigation for such an analysis, which would require data over three to four years.

The cost estimates in this study do not reflect negotiated rebates or discounts. Nor were out-of-pocket pharmaceutical expenditures captured and, if substantial, these would lessen the reported differences in utilization between groups. Because the study groups both represented government health plans with relatively high utilization, a closed formulary would be expected to have a much smaller effect in a plan with more typical utilization. This study examined the experience of only one plan that had a growing enrollment. How this group's enrollment and disenrollment rates compare with other plans is beyond the scope of this investigation. However, we cannot rule out the possibility that the experience of a plan with a large disenrollment rate may differ from that found in this investigation.

The issue of compliance was not addressed. In our previous study, we found lower compliance among formulary group subjects who had been prescribed nonformulary medications in the preperiod.²⁰ Accordingly, while a closed formulary can substantially reduce pharmaceutical utilization even in a noncontinuously eligible population, decision makers should be vigilant in assessing possible unintended consequences. Further research is needed to assess whether decreased compliance rates compromise health status or increase other medical expenditures.

Utilization and expenditures were not broken down by therapeutic class due to the small number of subjects in many therapeutic classes. With a larger sample size, future research may be able to discern whether reductions in utilization and expenditures are consistent across therapy classes.

Formulary impact need not necessarily account for enrollee turnover, because turnover does not appear to mediate the effect of a closed formulary. Future research could add strength to these findings by replicating this work in larger populations with varying enrollment patterns.

References

1. Health and Injury Chart Book, United States, 1996-1997. Hyattsville, MD: National Center for Statistics, 1997.
2. IMS Health Web site: http://www.imshealth.com/html/news_arc/07_21_1999_238.htm; and http://www.imshealth.com/html/news_arc/08_13_1998_81.htm.
3. Novartis pharmacy benefit report. Trends & forecasts, 1998 edition. East Hanover, NJ: Novartis Pharmaceuticals Corporation, 1998.
4. Hammel RW. Insights into public assistance medical care expenditures. *JAMA* 1972; 219: 1740-44.
5. Hefner DL. Cost-effectiveness of a restrictive drug formulary—Louisiana vs. Texas. Reston, VA: National Pharmaceutical Council, 1980.
6. Kozma CM, Reeder CE, Lingle EW. Expanding Medicaid drug formulary coverage: effects on utilization of related services. *Medical Care* 1990; 28: 963-77.
7. Smith DM, McKercher PL. The elimination of selected drug products from the Michigan Medicaid formulary: a case study. *Hospital Formulary* 1977; 12: 36-41.
8. Soumerai SB, Ross-Degnan D, Gortmaker S, Avorn J. Withdrawing payment for non-scientific drug therapy: intended and unexpected effects of a large-scale natural experiment. *JAMA* 1990; 263: 831-39.
9. Horn SD, Sharkey PD, Gassaway J. Managed Care Outcomes Project: study design, baseline patient characteristics, and outcome measures. *Am J Managed Care* 1996; 2: 237-47.
10. Horn SD, et al. Intended and unintended consequences of HMO cost-containment strategies: results from the Managed Care Outcomes Project. *Am J Managed Care* 1996; 2: 253-64.
11. Horn SD, Sharkey PD, Phillips-Harris C. Formulary limitations and the elderly: results from the Managed Care Outcomes Project. *Am J Managed Care* 1998; 4(8): 1105-13.
12. Bloom BS, Jacobs J. Cost effects of restricting cost-effective therapy. *Medical Care* 1985; 23: 872-80.
13. Dranove D. Medicaid drug formulary restrictions. *J Law and Economics* 1989; 32: 143-62.
14. Kreling DH, Knocke DJ, Hammel RW. The effects of an internal analgesic formulary restriction on Medicaid drug expenditures in Wisconsin. *Medical Care* 1989; 27: 34-44.
15. Smith MC, MacLayton DW. The effect of closing a Medicaid formulary on the prescription of analgesic drugs. *Hosp Formulary* 1977; 12: 36-41.
16. Soumerai SB, et al. A critical analysis of studies of state drug reimbursement policies: research in need of discipline. *Milbank Quar* 1993; 71(2): 217-52.
17. Schweitzer SO, Shilta SR. Access and cost implications of state limitations on Medicaid reimbursement for pharmaceuticals. *Annual Rev Pub Health* 1992; 13: 399-410.
18. Fairman K, Teitelbaum F, Motheral B, et al. [letter]. *Am J Managed Care* 1996; 2: 588-92.
19. Kravitz RL, Romano PS. Managed care cost containment and the law of unintended consequences. *Am J Managed Care* 1996; 2: 323-24.
20. Motheral BR, Henderson R. The effect of a closed formulary on prescription drug utilization and costs. *Inquiry* 1999-00, Winter; 36(4): 481-91.
21. The Wyeth-Ayerst prescription drug benefit cost and plan design survey report: 1998 edition. Albuquerque, NM: PMBI Inc., and Wellman Publishing, Inc., 1998.
22. Von Korff M, Wagner EH, Saunders K. A chronic disease score from automated pharmacy data. *J Clin Epidemiol* 1992; 45(2): 197-203.