

Effect of Generic-only Drug Benefits on Seniors' Medication Use and Financial Burden

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Background: Generic-only drug benefits are a way to provide some coverage, as opposed to no coverage.

Objective: To examine how switching from brand name to generic-only drug coverage affected seniors' medication use and financial burden.

Study Design: Data are from a 2002 cross-sectional survey conducted for a separate study on benefit caps. Participants belonged to a Medicare managed care plan in one state and had \$2000 capped brand name benefits in 2001 but generic-only benefits in 2002.

Methods: Participants reported their cost-cutting strategies before and after the change to generic-only coverage, the medications affected, and their financial burden. We conducted bivariate and multivariate analyses of cost-cutting strategies and financial burden before and after implementation of generic-only benefits.

Results: Among 611 participants (63% response), rates of switching medications increased after discontinuation of brand name coverage (27% vs 8%, $P < .001$). Switches were from brand name drugs to generic equivalents (14%) (eg, Prozac to fluoxetine hydrochloride), to nonequivalent generics (26%) (eg, Paxil to fluoxetine), and to different brand name drugs (45%) (eg, Paxil to Zoloft). Ninety percent of brand name switches remained in the same therapeutic class (eg, selective serotonin reuptake inhibitors). After discontinuation of brand name coverage, participants reported higher rates of decreased medication use (28% vs 17%) and greater difficulty paying for prescriptions (65% vs 37%) ($P < .001$ for both).

Conclusions: Changing from brand name benefits to generic-only drug coverage led many participants to switch to less expensive medications but also decreased medication use and increased financial burden. Insurers need to actively help patients adjust to a discontinuation of brand name coverage.

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using limited generic-only coverage to bridge the \$2250 to \$5100 "doughnut hole" in total annual drug expenditures (ie, the gap between partial coverage up to a limit and catastrophic coverage), during which patients typically would be 100% responsible for their drug costs.^{8,9} With generic-only coverage, patients must pay for all brand name drugs out of pocket even if no generic drugs are available within the treatment class. Because 38% of Medicare beneficiaries are expected to have high enough drug expenditures to fall into the Medicare drug benefit coverage gap,¹⁰ it is important to understand how switching from brand name/generic to generic-only benefits can affect seniors.

A study by Christian-Herman et al⁵ used pharmacy claims to show that an involuntary switch from brand name to generic-only coverage led to increased out-of-pocket drug costs for patients and to decreased use of important medications (eg, angiotensin-converting enzyme inhibitors for heart failure). Our study adds to that evidence using data from patient surveys (1) to adjust for patient characteristics (eg, income and health status) and to describe which seniors may be most affected by brand name coverage discontinuation, (2) to ask about financial burden, (3) to describe whether seniors adopted other cost-cutting strategies besides decreasing medication use (eg, switching drugs and using samples), and (4) to evaluate how discontinuation of brand name coverage affected medication use for a

Policy makers and insurers increasingly view generic-only drug benefits as a way to provide at least some drug coverage, as opposed to no coverage, and to emphasize generic drugs as effective cost-saving medication choices for patients.¹⁻⁷ Before implementation of the Medicare Part D drug benefit plan, generic-only coverage comprised 60% of Medicare managed care drug coverage in 2003, compared with 18% in 2001.¹ Some Medicare drug benefit plans are

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broader range of treatment classes (eg, nonsedating antihistamines and antihypertensives).

Our data are from seniors who were surveyed in 2002 for a separate study¹¹ on the effect of benefit caps on medication use. These participants had \$2000 capped brand name drug benefits in 2001 but were involuntarily switched by their plan to unlimited generic-only benefits in 2002. We took advantage of this natural experiment to ask seniors about their cost-cutting strategies in 2001 and 2002 (ie, before and after the switch from brand name benefits to generic-only benefits), the medications affected, and their reported financial burden from drug costs.

METHODS

Design, Setting, and Participants

Participants belonged to a Medicare managed care plan in one state with 438 802 members and purchased at least 1 prescription during 2001. At the time of the single cross-sectional survey (March through July 2002), participants had recently been involuntarily switched by their plan from capped brand name benefits in 2001 to unlimited generic-only coverage in 2002. Although the survey was designed to study the effect of benefit caps, we added questions to ask participants about their cost-cutting strategies in 2001 (during brand name/generic coverage) and in 2002 (after the change to generic-only benefits). Our participants were not sampled from among all plan members but were restricted to a subset of seniors based on inclusion criteria for the study on benefit caps. Therefore, participants were sampled from among plan members (1) who had \$2000 capped brand name benefits in 2001 but who did not exceed their cap (ie, the plan's share of cost was less than \$2000) and (2) had 2001 total drug expenditures ranging from \$1277 to \$5042 (mean, \$2483). These criteria were set so that participants could act as a control group for seniors who had exceeded their caps in 2001 (\$750 or \$1200 caps for 75-120 days) by being similar in distribution of total drug expenditures. In our resulting sample, two thirds of the participants had high enough total drug expenditures in 2001 to reach the \$2250 to \$5100 coverage gap in the 2006 Medicare Part D prescription drug benefit. Our participants' drug expenditures also placed them in the highest quartile (77th-99th percentiles) of plan members with \$2000 caps in 2001, although this was not part of the sampling criteria.

Data were collected from a single cross-sectional survey conducted from March through July 2002 (3-7 months after the change from brand name/generic drug

benefits in 2001 to generic-only drug benefits in 2002). We mailed potential participants information on the study, contacted nonrefusers by telephone (≤ 3 attempts), and mailed questionnaires to those who refused telephone surveys or who could not be contacted by telephone (≤ 3 mailings). Participants were eligible if they were aged 65 years or older, not covered by Medicaid, continuously enrolled in 2001, and were plan members at the time of the 2002 survey. Participants who were cognitively impaired or were unable to complete the survey in English were ineligible for the study.

Drug Benefits

All participants had the same formulary with \$7 to \$8 generic and \$25 brand name copayments in 2001 and with \$9 generic copayments in 2002. The plan informed members in advance of the change to generic-only benefits. Brand name drugs remained available at discounted prices by mail order. All of the plan's Medicare managed care enrollees in the state were changed to generic-only coverage, so no comparison group was available in 2002.

Outcomes Variables and Statistical Analysis

We calculated each participant's 2001 total drug expenditures from pharmacy claims by summing costs paid by the patient and by the plan. We examined the availability of generic equivalents for brand name drugs in 2001 from a field in the claims indicating whether drugs were generics (eg, fluoxetine hydrochloride), brand name drugs with generic equivalents (eg, Prozac and fluoxetine), or brand name drugs without generic equivalents (eg, Zoloft). We divided the number of brand name drugs with generic equivalents by the total number of unique drugs to calculate each participant's percentage of brand name drugs with generic equivalents. For the top 10 medications affected by decreased use, we examined whether generics were available within the same treatment class in 2001.

In the survey, we asked participants if they had adopted any of 7 cost-cutting strategies during the following 2 periods: (1) in 2001, during brand name/generic coverage, and (2) in 2002 (up to the time of the survey), after the change to generic-only coverage. The 7 possible strategies were as follows: (1) switched to less expensive medications, (2) used current medications less often than wanted or prescribed, (3) stopped medications altogether, (4) did not start newly prescribed medications, (5) used free samples, (6) used others' medications, or (7) bought medications from outside of the United States. Participants were asked whether they adopted strategies only in 2001, only in 2002, or in both 2001 and 2002. We asked all participants to answer yes

only if cost was the primary reason for adopting the strategy. We defined participants as having decreased medication use if they used less medications, stopped medications, or did not start medications.

Participants reported their age, education, race/ethnicity, marital status, household size, annual household income, self-rating of health, functional independence in intermediate activities of daily living, and presence of any of 10 common medical conditions (hypertension, diabetes mellitus, heart disease, depression, stroke, cancer, peptic ulcer disease, hypercholesterolemia, osteoporosis, and bronchitis/asthma). We used the median income and household size of participants who reported their actual income (43% of the sample) to impute the incomes of participants who gave only their income ranges (42% of the sample) or who withheld their income information (15% of the sample).

To test the effect of the change from brand name/generic to generic-only coverage on adoption of cost-cutting strategies and financial burden, we conducted bivariate McNemar tests of correlated proportions to determine if participants reported higher rates of cost-cutting strategies and greater difficulty paying for medications in 2002 than in 2001. To determine which participants were most at risk for decreasing medication use after losing brand name coverage, we conducted multivariate logistic regression analyses. We included participant-level random effects (xtlogit in STATA¹²) to account for repeated measures, because time points were nested within participants (ie, patients reported cost-cutting strategies for 2 periods [2001 and 2002]). Our dependent variable was decreased medication use (ie, used less, stopped, or did not start) in 2001 vs 2002. We included a variable representing brand name/generic vs generic-only benefit (ie, benefit type) as a covariate so that we could test the effect of independent variables on cost-cutting strategies after accounting for drug benefit type. Our independent variables included patients' sex, age, race/ethnicity, education, marital status, annual household income, supplemental drug insurance coverage, self-rating of health, and functional independence in intermediate activities of daily living, as well as whether they completed a telephone or mail survey, the month they were surveyed in 2002, and the number of health conditions reported at the time of the survey. The significance level was set at 2-sided $P < .05$.

Using their 2001 medication lists, we assisted the two thirds of participants who completed telephone surveys ($n = 407$) with recalling which medications they switched or decreased use of. For these telephone participants, we described whether their brand name switches in 2002 were to generic equivalents (eg, Prozac to fluoxetine), to nonequivalent generics (eg, Zoloft to fluoxe-

tine), or to different brand name drugs (eg, Paxil to Zoloft). We also characterized whether switches remained within the same therapeutic class (eg, from one selective serotonin reuptake inhibitor to another) or went outside of the original therapeutic class (eg, from selective serotonin reuptake inhibitor to tricyclic antidepressant). We also determined which therapeutic classes were most affected by decreased medication use by classifying all unique drugs into therapeutic classes and by ranking from highest to lowest the number of times seniors reported decreased medication use in each class.

We measured participants' financial burden from drug costs before and after the change to generic-only coverage by their reported difficulty paying for medications. We also assessed whether it affected their abilities to do enjoyable activities, to pay rent or bills, and to obtain other medical care.

RESULTS

From a sample of 1172 potentially eligible participants, we excluded 199 because of death, disenrollment in 2001, self-reported illness that hindered participation, or inability to complete the survey in English. Of the remaining 973 participants, 407 completed telephone surveys and 204 completed mail surveys (overall response, 611 [63%], 222 [23%] refused to participate, and 140 [14%] could not be contacted).

Demographic Characteristics

Of the 611 respondents, patients were on average 75.8 years old, 69% were women, 89% were of white race/ethnicity, and 84% had high school degrees or higher (Table 1). Seventy-one percent had annual household incomes of \$30 000 or less. Many had hypertension (77%), hypercholesterolemia (65%), and coronary artery disease (46%), and 38% reported having fair or poor health. Participants' 2001 total drug expenditures averaged \$2484 (5th-95th percentile range, \$1599-\$3344), and out-of-pocket drug costs averaged \$865 (5th-95th percentile range, \$452-\$1428). Telephone vs mail respondents had similar 2001 total drug expenditures but were slightly younger, were more likely to be female, were more educated, had higher income, and reported more health conditions, but telephone respondents had less disability in intermediate activities of daily living and had better self-rated health. For nonrespondents, only data on age, sex, and total drug expenditures were available. Nonrespondents were slightly older (76.3 vs 75.8 years, $P < .01$) and had higher total drug expenditures (\$2568 vs \$2484, $P = .02$) than respondents but were similar in gender distribution.

Generic Availability Before Generic-only Coverage

Participants used on average 12.2 unique medications in 2001 (when they had brand name/generic coverage). Seven percent of these medications were brand names with generic equivalents, 45% were brand name drugs without generic equivalents, and 48% were generic drugs. Sixty-four percent of partici-

pants' brand name drugs that had generic equivalents available in 2001 comprised the following 6 drugs: Lanoxin (digoxin), Levothyroid (levothyroxine sodium), Tiazac (diltiazem hydrochloride slow release), Adalat CC (nifedipine slow release), Coumadin (warfarin sodium), and Synthroid (levothyroxine). More than 99% of participants had 1 or more (mean, 5.2) brand name drugs without generic equivalents.

Table 1. Characteristics Among 611 Participants*

Characteristic	Value
Age, mean, y	75.8
Female sex	69
White race/ethnicity	89
Married	50
Education	
<High school degree	16
High school degree	33
Some college	31
≥College degree	20
Annual household income	
Mean, \$	29 652
Bracket	
≤15 000	20
15 001-30 000	51
30 001-40 000	10
>40 000	19
Has supplemental drug insurance coverage	7
Health status	
Excellent	5
Very good	19
Good	38
Fair	28
Poor	10
Intermediate activities of daily living score, mean†	7.0
Prevalence of 10 measured health conditions, mean	3.7
Hypertension	77
Hypercholesterolemia	65
Coronary artery disease (chest pain, heart attack, hardening of arteries)	46
Gastroesophageal reflux disease (stomach acid/reflux/heartburn/stomach bleed)	39
Diabetes mellitus	30
Bronchitis/emphysema/asthma	28
Depression	27
Osteoporosis	24
Cancer (other than skin cancer)	18
Stroke	16
Has moderate/severe pain symptoms	44
Uses prescription pain drug most of the day/almost every day	24
2001 Drug expenditures, mean, \$	
Total	2484
Out of pocket	
Total	865
Per month	72
Telephone respondents	67

*Data are given as percentages unless otherwise indicated. The maximum number of missing values for any variable is 8 (1.3%) of 611 observations.

†Maximum score of 8 indicates no limits in function.

Cost-cutting Strategies

Based on McNemar tests, participants reported significantly higher rates of switching medications (27% vs 8%, $P < .001$) and of decreasing medication use because of cost (28% vs 17%, $P < .001$) in 2002 vs 2001 (Table 2). After discontinuation of brand name coverage, participants were more likely to use less medications (15% vs 9%, $P < .001$), stop medications (15% vs 8%, $P < .001$), not start medications (10% vs 5%, $P < .001$), and buy medications from outside of the United States (6% vs 3%, $P = .01$) in 2002 vs 2001. The frequencies of using free samples (26% vs 27%) and taking others' medications (3% vs 2%) because of cost remained similar in 2002 vs 2001.

Factors Associated With Decreased Medication Use

Based on multivariate logistic regression analyses, the participants most at risk for decreasing medication use in association with discontinuation of brand name benefits were those who were younger (9-percentage-point increase in risk with every 10-year decrease in age,

Table 2. Self-reported Strategies to Lower Medication Costs and Financial Burden of Medication Costs Before and After the Change From Brand Name to Generic-only Drug Coverage*

Variable	Brand Name Coverage in 2001	Generic-only Coverage in 2002	P [†]
7 Strategies			
■ Switched medications	8	27	<.001
■ Used less medication than prescribed/wanted to (eg, skip or use lower dose)	9	15	<.001
■ Stopped a medication	8	15	<.001
■ Did not start a new medication	5	10	<.001
Adopted ≥ 1 of the above 3 strategies that decreased medication use (used less, stopped, did not start)	17	28	<.001
■ Got free medication samples	27	26	.74
■ Took others' medications	2	3	.13
■ Bought medications outside of the United States	3	6	.01
Financial Burden			
Ease or difficulty in paying for your prescriptions			
Very easy	15	8	
Somewhat easy	23	11	
Neither easy nor difficult	24	16	
Somewhat difficult	29	37	<.001
Very difficult	8	28	
Financial effect of prescription costs			
Decide not to do enjoyable activities	34	43	<.001
Have difficulty paying rent or other bills	17	24	<.001
Decide not to get other medical care	13	15	.004
Have to borrow money or get help paying for medications	9	13	<.001

*Data are given as percentages unless otherwise indicated. The maximum number of missing values for any variable is 21 (3.4%) of 611 observations.
[†]McNemar test.

$P = .007$) and who had lower income (2–percentage-point increase in risk with every \$10 000 decrease in income, $P = .04$). Sex, education, race/ethnicity, supplemental drug insurance coverage, self-rating of health, functional independence in intermediate activities of daily living, whether they completed a telephone or mail survey, the month they were surveyed in 2002, the number of health conditions reported at the time of the survey, and 2001 total annual drug expenditures were not significant predictors of decreased medication use.

Medication Switches

Twenty-four percent (96/407) of telephone respondents reported switching to less expensive medications in 2002 after the change to generic-only coverage. Almost three fourths (73% [70/96]) named the drugs from which and to which they switched. This resulted in 96 drug-switching events, representing 51 unique drugs and 27 therapeutic classes. Forty percent of switches were from brand name to generic drugs (14% to generic equivalents and 26% to nonequivalent generics), 45%

were from brand name to different brand name drugs, and 15% were other switches (eg, generic to generic or switching from a combination pill to 2 drugs). Ninety percent (74/82) of brand name switches remained within the same therapeutic class. Almost all (43/44) brand name to brand name drug switches occurred in therapeutic classes for which no generics were available (eg, angiotensin II receptor blockers).

Decreased Medication Use

Twenty-five percent (103/407) of telephone respondents reported decreased medication use (used less, stopped, or did not start) after the change to generic-only coverage. Most telephone respondents (84% [87/103]) recalled at least 1 drug involved. This resulted in 152 drug-reducing events, representing 89 unique drugs and 47 therapeutic classes. The top 10 therapeutic classes most affected by decreased medication use included drugs for treating hyperlipidemia, ulcer or reflux, pain or inflammation, asthma or emphysema, allergies, depression, stroke, infection, hypertension,

Table 3. Top 10 Therapeutic Classes Ranked by the Number of Times Participants Reported Decreased Use Because of Cost After the Change to Generic-only Drug Coverage

Rank	Therapeutic Class	No. (%) of 152 Drug-Reducing Events	Generic Drug Available in Therapeutic Class	
			At End of 2001	In 2004
1	3-Hydroxy-3-methylglutaryl coenzyme A reductase inhibitor	23 (15)	No	Yes
2	Proton pump inhibitor	10 (7)	No	Yes
3	Cyclooxygenase-2 inhibitors	8 (5)	No	No
4	Corticosteroid inhaler	8 (5)	No	No
5	Nonsedating antihistamine	7 (5)	No	Yes
6	Selective serotonin reuptake inhibitor	5 (3)	Yes	Yes
7	Antiplatelet	4 (3)	No	No
8	Bacterial antibiotic	4 (3)	Yes	Yes
9	Calcium channel blocker	4 (3)	Yes	Yes
10	Female hormone therapy	4 (3)	No	Yes

of the study by Christian-Herman et al⁵ (using claims data) that discontinuation of brand name benefits affects the use of “essential” drugs for treating diseases with significant mortality or morbidity (hypertension, heart disease, and asthma). Our study found that patients decreased the use of potentially “nonessential” medications such as nonsedating antihistamines and proton pump inhibitors, which are often used to treat non-life-

and osteoporosis or hormone therapy (Table 3). Half of the drug-reducing events fell into these top 10 classes. In 2001, 7 of these top 10 therapeutic classes had no generics within the class. By 2004, only 3 of these 10 classes had no generics within the class.

Financial Burden

McNemar tests indicated that participants were more likely to report that it was somewhat or very difficult to pay for medications (65% in 2002 vs 37% in 2001, $P < .001$) (Table 2) after switching to generic-only coverage. Medication costs also affected their ability to do enjoyable activities (43% vs 34%, $P < .001$), pay rent or other bills (24% vs 17%, $P < .001$), get other medical care (15% vs 13%, $P = .004$), and borrow money or get help paying for medications (13% vs 9%, $P < .001$) in 2002 vs 2001.

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DISCUSSION

To our knowledge, this is the first study based on seniors’ self-reports of how an involuntary switch from brand name/generic to generic-only drug coverage affected their adoption of cost-cutting strategies and financial burden. One in 4 seniors in our study switched medications, and 1 in 4 decreased medication use after their benefits were changed to generic-only coverage. Two thirds of seniors reported financial burden from drug costs. Patients decreased the use of antihyperlipidemia and antihypertensive drugs, confirming findings

and threatening symptoms. In our examination of cost-cutting strategies that cannot be easily evaluated from claims data, we found that rates of switching medications increased but that rates of using free medication samples, taking others’ medications, and buying medications outside of the United States did not change substantially.

These high rates of switching and decreasing medication use have important implications for health plans that are considering generic-only benefits as a way to bridge the coverage gap in the Medicare drug benefit. For the 4 in 10 Medicare beneficiaries expected to fall into the coverage gap, having generic-only benefits is better than no coverage. However, because patients who lose brand name coverage frequently engage in cost-cutting strategies that affect the use of essential and potentially nonessential drugs, insurers and physicians need to actively help patients with generic-only coverage choose the best strategies to trade off cost with health benefits. We did not measure the health effects of the change to generic-only drug coverage, but others found an association with increased hospitalization rates.⁵

In our study, younger and lower-income seniors were at greatest risk for decreasing medication use. However, higher total annual drug expenditures and not having supplemental drug insurance were not significant predictors of decreasing medication use. This may be because most of our seniors had high annual drug expenditures (mean, \$2483) and because few (7%) had

supplemental drug insurance. Discontinuation of brand name coverage led to significant financial burden, with two thirds of participants reporting difficulty paying for medications. It is surprising that seniors reported this high financial burden, despite adopting cost-cutting strategies, but it may be because many drug classes in 2001 did not have generics within the same treatment class. For example, 45% of switches were to brand name drugs, which may be less expensive than brand name drugs previously used by the patient but still would not be covered by generic-only benefits. Physicians must be aware that even patients with drug coverage may have significant out-of-pocket costs or, as in the case of the Medicare drug benefit, may have coverage gaps. Even when the participants in our study had brand name coverage in 2001, 37% reported financial burden from drug costs.

Our study adds to the current literature by examining the types of medication switching that seniors made. Forty percent of brand name switches were to generic drugs. Fourteen percent of these switches were from brand name to direct generic equivalents and theoretically should not negatively affect health. However, many brand name switches were made to nonequivalent generics (26%) and to different brand name drugs (45%). We do not know how participants and their physicians chose which drugs to switch to, but 90% of these switches were conservative, with treatment kept within the same therapeutic class. In addition, 98% of switches to brand name drugs were made when no generics existed within the same treatment class. Although we did not examine how many participants had brand name drugs with no generics within the same class at baseline, 7 of 10 medications most affected by decreased use because of cost were in classes without generic drugs. Brand name drugs that have no generics within the same treatment class pose financial and clinical difficulties for patients who must pay out of pocket, forgo medications, or switch to another class.

We assume, but cannot confirm, that medication switches were to lower-cost drugs, because we asked patients to report only those medication changes made because of cost. Such switches could potentially be positive if patients chose lower-cost but potentially equally effective medications. Many therapeutic classes (angiotensin-converting enzyme inhibitors, proton pump inhibitors, and nonsedating antihistamines) have several drugs within the class that are clinically similar but can differ in cost.¹³⁻¹⁷ For other classes such as statins, generic drugs (eg, lovastatin vs atorvastatin calcium) are less potent than brand name drugs without generics available but can still help patients reach their clinical goals (eg, cholesterol reduction).¹⁸ For these

classes, switching to less expensive medications within the class makes sense with appropriate patient education and follow-up laboratory testing when necessary.

In our study, only 7% of medications before the benefit change were brand name drugs with existing generic equivalents. This may be because, while physicians prescribe generic drugs by name only 45% to 50% of the time,¹⁹ all states allow pharmacies to substitute brand name prescriptions with generic equivalents unless "no substitution" is indicated.² Now, 84% to 93% of brand name drugs with generic equivalents are filled as generics, compared with 41% in 1994 and 22% in 1987.^{2,20} The 7% of brand name drugs in our study with existing generic equivalents were concentrated among drugs (eg, Synthroid and Coumadin) that physicians may be reluctant to switch because of perceived differences in bioavailability or efficacy among manufacturers and narrow therapeutic indexes.^{3,19} Physicians need to consider initiating therapy with generic drugs (eg, levothyroxine and warfarin) to avoid the need for switching or laboratory tests to reevaluate therapeutic adequacy after switching.

Continuous evaluation of potential cost savings from generic drugs is important. Many frequently prescribed brand name drugs have gone off patent since 2001 (eg, Glucophage [metformin hydrochloride]). Generic drugs are now available in many important drug classes, so patients may not face as great a financial burden with generic-only drug benefits as they did in 2002 when we conducted our survey. In addition, patients show greater acceptance of generics: 95% of seniors know about generics,^{21,22} 90% would consider generics if recommended by their physicians,² and 64% to 80% believe that no difference exists between brand name and generic drugs.^{2,21} Similarly, physicians are increasingly comfortable choosing generic drugs.^{22,23} Raising physicians' awareness of generic-only benefits and of the coverage gap in the Medicare drug benefit may increase their prescribing of generic medications when appropriate. This in turn may decrease the number of beneficiaries who fall into the coverage gap in the Medicare drug benefit or help to lessen the financial burden of beneficiaries once they reach the doughnut hole and have no coverage or only limited generic drug coverage.

Limitations to this study are that we studied Medicare beneficiaries from a single health plan in one state. In addition, participants were sampled to study the effect of exceeding the cap on medication use and cannot be generalized to all Medicare beneficiaries or plan members. However, two thirds of our seniors had high enough drug expenditures to place them at risk of falling into the coverage gap, during which insurers are considering providing limited generic-only drug bene-

fits. We also did not have a control group with brand name drug benefits similar to our participants' benefits in 2001 and who continued to have brand name drug coverage (eg, with the same copayments and deductibles) in 2002. Therefore because we cannot control for secular trends, we may have a biased estimate of the change in rates of cost-cutting strategies and financial burden from drug costs attributable to a discontinuation of brand name drug coverage. However, we were able to adjust for several patient characteristics that are likely to influence the use of cost-cutting strategies (eg, income and supplemental drug insurance coverage) and to confirm that discontinuation of brand name drug benefits remained a significant independent predictor of decreasing and switching medications. Our findings on the types of medication switches and on the medications most affected by decreased use are also likely to be valid without requiring a control group.

We surveyed participants in March through July of 2002, when they had experienced generic-only drug benefits for 3 to 7 months and did not anticipate their brand name drug coverage being restored. Medicare beneficiaries who are without brand name coverage for fewer months or who expect to have their brand name drug coverage renewed the following year (eg, with Medicare Part D) may not switch medications or decrease medication use as much as our participants did. Our participants may also have reported higher rates of cost-cutting strategies in 2002 vs 2001 because of greater recall of more recent events. We were unable to evaluate actual medication use, expenditures, or savings from cost-cutting strategies in 2002 because pharmacies did not always submit claims to the plan when patients were required to pay for the entire cost of their brand name drugs out of pocket. A \$1 to \$2 increase in 2002 generic copayments may also have affected cost-cutting strategies and financial burden.^{24,25} The strengths of this study are that we examined wider ranges of cost-cutting strategies (such as medication switching) and described more classes of medications affected by these strategies (essential and potentially nonessential drugs) than previously reported.⁵

Our study found that discontinuation of brand name coverage among Medicare beneficiaries increased their rates of switching medications, decreased their medication use, and led to greater financial burden. Because generic equivalents were often unavailable and not all therapeutic classes had generics, health providers and policy makers must examine how to help patients make use of generic-only benefits to maximize their health and to ensure access to necessary medications.

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