Effect of Medicare Part D Benzodiazepine Exclusion on Psychotropic Use Among Benzodiazepine Users

Michael K. Ong, MD, PhD[1], **Haiyong Xu, PhD**[1], **Lily Zhang, MS**[1], **Francisca Azocar, PhD**[2], and **Susan L. Ettner, PhD**[1]

[1]University of California, Los Angeles; Los Angeles, CA

[2]OptumHealth Behavioral Solutions; San Francisco, CA

Abstract

Background/Objectives—The Medicare Modernization Act (MMA) created prescription drug coverage through Medicare Part D starting in 2006, but specifically excluded benzodiazepines from coverage. This study evaluated the effect of the Medicare benzodiazepine coverage exclusion on psychotropic use among benzodiazepine users.

Design—Pre/post design with concurrent control group.

Setting—General community.

Participants—Intervention and comparison cohorts of patients drawn from the same insurer who were prescribed benzodiazepines through the end of 2005. The intervention patients (N = 19,339) were elderly individuals from a large, national Medicare Advantage (MA) plan subject to the MMA benzodiazepine exclusion. The comparison patients (N = 3,488) were near-elderly individuals enrolled in a managed care plan not subject to the MMA benzodiazepine exclusion.

Measurements—Any psychotropic drug use and expenditures.

Results—Among the intervention cohort, any benzodiazepine use and expenditures significantly declined from 100% and $134 in 2005 to 74.8% and $59 in 2007. Any non-benzodiazepine psychotropic drug use and expenditures significantly increased from 35.8% and $163 in 2005 to 39.5% and $207 in 2007. Among the comparison cohort, any benzodiazepine use and expenditures also significantly declined from 100% and $173 in 2005 and 57.5% and $105 in 2007. However,

any non-benzodiazepine psychotropic drug use and expenditures significantly declined from 55.4% and $647 in 2005 to 45.1% and $572 in 2007. Changes in non-benzodiazepine psychotropic drugs were primarily due to antidepressants and anxiolytics in both cohorts.

Conclusion—Any use of benzodiazepines continued among the elderly despite negative financial incentives, possibly due to the low costs of such medication. While some substitution occurred with antidepressants and anxiolytics, the magnitude of this increase does not fully offset the reduction in benzodiazepine any use.

Keywords

benzodiazepine; Medicare Part D; psychotropic use; psychotropic expenditures

BACKGROUND

The Medicare Modernization Act (MMA) created prescription drug coverage through Medicare Part D starting in 2006, but specifically excluded benzodiazepines (BZDs) from Medicare Part D coverage. Only patients with supplemental drug insurance, such as through Medicaid or private secondary insurance, have access to BZD coverage. The MMA's BZD exclusion from Medicare Part D plans was eliminated in the Patient Protection and Affordable Care Act, but this change will not take effect until 2013. However, California's state auditor recently recommended that BZDs be excluded from Medicaid coverage in an effort to reduce budget costs.[1] Consequently, the effect of BZD exclusion remains a policy concern.

The MMA's BZD exclusion was based on studies showing that BZD use in the elderly increases the risk of falls and hip fractures and worsens conditions such as emphysema, urinary incontinence, and depression.[2] However, BZDs are an effective, low-cost treatment for anxiety. A major concern regarding MMA's BZD exclusion was potential adverse effects on patients with anxiety disorders.[3]

Our study examines any psychotropic drug use and costs among two cohorts of older benzodiazepine users, elderly Medicare Advantage patients and near-elderly patients with managed care insurance over a three year period, before and after the Medicare Part D BZD exclusion. Prior to Medicare Part D in 2005, Medicare Advantage plans were one of the few options available to Medicare-eligible patients that provided prescription drug coverage, including BZD coverage; similarly, all near-elderly patients with managed care insurance had BZD coverage in 2005. In 2006 and 2007, all Medicare Advantage plans were subject to the categorical exclusion of BZDs under Part D. However, all near-elderly patients with managed care insurance continued to have BZD coverage in 2006 and 2007. We hypothesized that the BZD exclusion would reduce any BZD use and increase any non-BZD psychotropic drug use among elderly Medicare Advantage patients in 2006 and 2007, when compared to 2005.

METHODS

Data Sources

Our study used medical and pharmaceutical claims linked with eligibility files from a large national health plan. We developed an intervention cohort of non-Medicaid elderly (age 65+) individuals drawn from one of this health plan's national Medicare Advantage (MA) plans. We developed a comparison cohort of near-elderly (age 60-64) individuals from one of this health plan's national managed care plans. Both cohorts had prescription drug coverage before and after MMA implementation, but BZD coverage was excluded for the intervention cohort after MMA implementation. Patients were included if the total days supply of their BZD prescriptions in 2005 were enough to provide them BZDs from the first fill date in 2005 through December 31, 2005. Patients were then excluded if they did not have continuous medical, behavioral and pharmaceutical insurance coverage from 2005 through 2007. The final intervention cohort had 19,339 individuals and the final comparison cohort had 3,488 individuals.

Measures

Our main outcomes were any use (covered and uncovered use), days supply, and total expenditures (patient deductible and copayment plus plan reimbursement) for psychotropic medications, both overall and for psychotropic medication classes. Psychotropic medications were subclassified as BZDs, antidepressants, other anxiolytics, and other psychotropic medications using American Hospital Formulary System classifications.[4]

For covariates, we used age and gender from the eligibility files. We also included an indicator for the year of analysis (2005, 2006, and 2007, with 2006 and 2007 representing post-Part D). We additionally used ICD-9-CM diagnoses from encounter claims to create indicators for psychiatric comorbidities (substance abuse, depression and psychotic disorder) and medical comorbidities (arthritis, anemia, asthma, congestive heart failure, chronic obstructive pulmonary disease, diabetes, ulcer or liver problems, hypertension, malignant cancer, paralysis or other neurological disorders, obesity, peripheral vascular disease, pulmonary circulation disease, renal failure, valvular disease, and weight loss).[5, 6]

Statistical Analyses

Three sets of models were estimated for statistical analyses of our main outcomes.[7, 8] Logistic regression models were estimated for the probability of any use of psychotropic medications and specified subclasses. Two-part models were estimated for each of the non-BZD psychotropic medication expenditure and days supply outcomes, with logistic regression used to predict any use and zero-truncated negative binomial regression to predict expenditures (or days supply) given any use. BZD expenditure and days supply outcomes were estimated with non-zero truncated negative binomial regression models, since all individuals had been users in 2005. All regression models were adjusted for the following covariates: age, age squared, gender, year, and psychiatric / medical comorbidities. Significance was determined as $p < 0.05$.

To facilitate interpretation of the estimates we present in Table 2 the predicted probabilities and utilization for each outcome, using the underlying covariates for each individual observation, along with 95% bias-corrected empirical confidence intervals generated by the bootstrap technique using 2000 replicate samples.[6] SAS 9.1.3 was used for data management and Stata 11 was used for all statistical analyses. This study was approved by the University of California, Los Angeles institutional review board (IRB) as being exempt from IRB review.

RESULTS

Table 1 shows characteristics of both cohorts. Due to the differences in age restrictions we placed on each cohort, the intervention cohort is significantly older than the comparison cohort (77.8 years vs. 62.8 years) and hence had higher rates of being female (71.7% vs. 64.3%) and having any medical comorbidity (excluding hypertension, 72.57% vs. 65.3%), but significantly lower rates of having any psychiatric comorbidity (20.9% vs. 24.3%). The differences in psychiatric comorbidities were due primarily to differences in psychoses, while the differences in medical comorbidities were in nearly all comorbidities except diabetes, obesity, chronic pulmonary and pulmonary circulation diseases, and valvular diseases.

Post-Part D Changes Among the Intervention Cohort

Significant differences in any predicted psychotropic medication use occurred over time for the intervention cohort (Table 2). Significantly lower rates of any BZD use occurred in 2006 (54.2%) and 2007 (74.8%). Non-BZD psychotropic medication claims among the intervention cohort significantly increased from 35.9% in 2005 to 38.3% in 2006 and 39.5% in 2007. More specifically, significant increases occurred for antidepressants (34.0% in 2005, to 36.5% in 2006 and 37.7% in 2007) and anxiolytics (8.0% in 2005, to 11.1% in 2006 and 12.3% in 2007).

Significant differences in predicted days supply of psychotropic drugs also occurred over time for the intervention cohort. BZD days supply significantly declined from 240.5 days in 2005 to 121.7 days in 2006 and 176.5 days in 2007. Non-BZD days supply significantly increased from 101.3 days in 2005, to 121.9 days in 2006 and 135.1 days in 2007. These significant increases also occurred specifically for antidepressants (82.2 days in 2005, to 97.8 days in 2006 and 104.9 days in 2007) and anxiolytics (8.3 days in 2005, to 14.2 days in 2006 and 19.2 days in 2007).

Significant differences in predicted expenditures for psychotropic drugs also occurred over time for the intervention cohort. Annual expenditures for all psychotropic drugs significantly declined from $307 in 2005 to $271 in 2006 and $262 in 2007. Expenditures for BZDs significantly declined from $134 in 2005 to $64 in 2006 and $59 in 2007. Non-BZD expenditures significantly increased from $163 in 2005 to $211 in 2006 and $207 in 2007. These significant increases also occurred specifically for antidepressants ($105 in 2005, $128 in 2006 and $114 in 2007) and anxiolytics ($24 in 2005, $43 in 2006 and $45 in 2007).

Post-Part D Changes Among the Comparison Cohort

For the comparison cohort, significant declines also occurred for any use of BZDs, to 81.9% in 2006 and 57.5% in 2007. However, there were also significant declines in any non-BZD psychotropic use, from 55.4% in 2005 to 53.7% in 2006 to 45.1% in 2007. Similarly, there were significant declines in BZD days supply (266.6 days in 2005 to 219.1 days in 2006 and 168.4 days in 2007) Non-BZD days supply significantly declined from 242.0 days in 2005, to 226.2 days in 2006 and 202.6 days in 2007. This pattern was also seen with antidepressants (179.9 days in 2005, 168.7 days in 2006, 149.2 days in 2007) and anxiolytics (38.0 days in 2005, 34.9 days in 2006, 29.7 days in 2007).

Total expenditures also declined for all psychotropic drugs ($894 in 2005 to $783 in 2006 and $618 in 2007). While BZD expenditures also declined over time ($173 in 2005 to $132 in 2006 and $104 in 2007), non-BZD expenditures also declined from $647 in 2005; this was a non-significant decline in 2006 to $631 and a significant decline in 2007 to $571. This same pattern was also seen for antidepressants ($400 in 2005 to $375 in 2006 and $322 in 2007) and anxiolytics ($115 in 2005 to $114 in 2006 and $89 in 2007).

DISCUSSION

In our study of elderly benzodiazepine users enrolled in Medicare Advantage, the BZD exclusion implemented in MMA resulted in declines in any BZD use and days supply, even when out of pocket use is included. There are few studies that have examined the effect of the MMA BZD exclusion since its implementation. One study examined BZD use among nursing home residents across states with varying supplemental Medicaid BZD coverage and found that BZD use declined but hip fracture rates increased in the one state without supplemental Medicaid BZD coverage.[9] However, nursing home residents are a small proportion of BZD users and effects among them may not be generalizable. Another study of psychotropic prescriptions in a national retail pharmacy chain one year before and after MMA BZD exclusion found that BZD filled prescriptions fell by 5% immediately, while antidepressants and antipsychotics increased by 7% and 18%, respectively.[10] However, this study does not use a control cohort and cannot account for BZD users who may have switched pharmacies.

Prior studies on drugs and out-of-pocket payments (i.e., co-payments) show that individuals faced with higher levels of co-payment reduce their general utilization of drugs,[11] although individuals with a chronic condition are less likely to reduce a drug for their condition than other drugs.[12] Population-level analyses have also not always observed reductions in psychotropic drug utilization with higher copayments, possibly due to other competing factors.[13] Nonetheless, prior experiences with BZD regulation suggest that many individuals who use BZDs go without treatment when restrictions are imposed. When New York's Medicaid system implemented triplicates for BZDs in 1989, BZD use was reduced by 50% and was only partially offset (10%) by substitute anxiolytic drugs.[14-16] Eighteen months after a temporary ban on triazolam was implemented in the U.K., 45% of chronic and 66% of intermittent users stopped using BZDs altogether, even though other BZDs were available by prescription.[17] In the case of the MMA BZD exclusion, nearly half of BZD users stopped using BZDs, a much greater decline than what was seen in the comparison cohort. However,

in the second year, BZD use actually increased while further declines were seen in the comparison cohort. Essentially, three-quarters of BZD users in our intervention cohort were willing to purchase BZDs out-of-pocket after the MMA BZD exclusion, a substantial offset to the intended effect of the MMA BZD exclusion. While declines in BZD use among both cohorts could be related to a combination of discontinuation due to resolution of acute problems and improved awareness of potential problems with BZDs in older populations, the pattern of sharp decline and subsequent rebound in the intervention cohort suggests that forced switching or discontinuation did not result in similar levels of resolution of acute problems as seen in the comparison cohort.

Overall psychotropic medication expenditures declined for both groups. However, the intervention group had an increase in medication expenditures for non-BZD psychotropics which mitigated potential savings from reductions in any BZD use. This mitigation was due to increased any use and days supply of non-benzodiazepine psychotropic medications among elderly BZD users subject to the MMA BZD exclusion, despite trends in the opposite direction among the comparison cohort. Of note, an insurer perspective instead of the societal perspective would have seen larger declines in medication expenditures for the BZD users subject to the MMA BZD exclusion since the BZD spending would not have been accrued to the insurer. From the patient perspective, BZD users subject to the MMA BZD exclusion preferred to accept a larger out of pocket burden than to discontinue using BZDs.

There are several limitations to this study. Our study does not have clinical data to determine whether treatment outcomes changed as a result of Part D implementation. Additional studies could help elucidate this issue. Our study also does not have behavioral health data and it is possible that there may have been substitution of behavioral health care for declines in any BZD use. However, we separately analyzed behavioral health visits for elderly patients with new anxiety disorders before and after the Medicare Part D benzodiazepine exclusion using data from a different plan and found no changes in behavioral health care use.[18] We examined patients with Medicare Advantage insurance, and it is possible that our findings may not generalize to the Medicare fee-for-service population. However, Medicare fee-for-service patients had little prescription drug coverage prior to Medicare Part D, which makes it difficult to study this issue in the larger Medicare fee-for-service population. Similarly, our findings also may not generalize to dual-eligibles, who generally retained benzodiazepine coverage if they were enrolled in Medicaid, or low-income subsidy Medicare beneficiaries, who may have different responses due to income restraints. Our control cohort was smaller than our intervention cohort, which made it more difficult to detect significant differences. However, the point estimates for the comparison cohort suggest that rates and amounts of any use were generally stable over time which suggests that the lack of significance is not due to low power. Our comparison cohort also had more use of any psychotropic drugs than our intervention cohort, which raises the concern of whether secular time trends would have been the same. However, the comparison cohort did not significantly differ from our intervention cohort on rates of depression or substance abuse. The only difference occurred in rates of psychosis diagnoses, which were likely due to the age differences.

The MMA's BZD exclusion resulted in lower overall prescription costs among prior BZD users through reductions in any BZD use, although these cost reductions were partially offset cost by increases in non-BZD psychotropic drugs, particularly antidepressants and anxiolytics. These findings suggest that states seeking to reduce budget costs through restrictions of BZDs[1] may not realize expected savings. It will be important to evaluate whether these changes persist after BZDs are made available through Medicare Part D in 2013; the data from this study can provide a baseline for measuring future changes after BZD coverage in Medicare Part D is implemented

Acknowledgments

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Table 1

Patient Characteristics of Both Cohorts

Characteristics	Intervention (N=19,339) % (N)	Comparison (N=3,488) % (N)	*P*-value
Age, Mean (± SD)	77.79 (6.7)	62.8 (1.3)	<0.001
Female	71.7 (13,856)	64.3 (2,242)	<0.001
Any comorbidity	90.4 (17,481)	85.2 (2,971)	<0.001
Comorbidity, excluding hypertension			<0.001
None	22.9 (4,437)	27.9 (972)	
psychiatric condition only	4.6 (881)	6.8 (237)	
medical condition only	56.2 (10,869)	48.0 (1,674)	
Both	16.3 (3,152)	18.4 (605)	
Any psychiatric condition	20.9 (4,033)	24.1 (842)	<0.001
Substance abuse	1.7 (317)	1.6 (55)	0.79
Depression	15.3 (2,950)	14.8 (515)	0.46
Psychoses	7.8 (1,502)	12.5 (437)	<0.001
Any medical condition, excluding hypertension	72.5 (14,021)	65.3 (2,279)	<0.001
Anemias	15.4 (2,968)	13.3 (462)	0.001
Rheumatoid arthritis/collagen vascular disease	5.0 (962)	5.4 (187)	0.014
Congestive heart failure	12.4 (2,388)	5.5 (193)	<0.001
Chronic pulmonary disease	21.9 (4,228)	20.8 (726)	0.17
Diabetes	21.0 (4,058)	21.0 (732)	0.997
Hypertension	71.3 (13,784)	60.2 (2,099)	<0.001
Hypothyroidism	19.7 (3,807)	17.0 (592)	<0.001
Ulcer/Liver problem	1.7 (319)	2.7 (94)	<0.001
Lymphoma/Tumor/Metastatic cancer	12.6 (2,437)	11.8 (412)	0.19
Paralysis/Other neurological disorders	8.3 (1,600)	4.6 (160)	<0.001
Obesity	3.2 (616)	3.8 (131)	0.08
Peripheral vascular disease	12.0 (2,328)	7.4 (259)	<0.001
Pulmonary circulation disease	1.9 (372)	1.5 (51)	0.06
Renal failure	3.6 (689)	1.9 (67)	<0.001
Valvular disease	9.5 (1,838)	10.4 (364)	0.09
Weight loss	4.1 (789)	2.9 (101)	0.001

Intervention cohort refers to group of elderly Medicare Advantage patients (subject to Medicare Part D BZD exclusion), and comparison cohort refers to group of near-elderly patients with managed care insurance (not subject to Medicare Part D BZD exclusion).

Table 2

Comparison of Predicted Drug Any Use and Expenditure Outcomes Between the Two Cohorts

	Intervention			Comparison		
	2005 (N = 19,339)	2006 (N = 19,339)	2007 (N = 19,339)	2005 (N = 3,488)	2006 (N = 3,488)	2007 (N = 3,488)
Any use of Psychotropic Drugs (%)						
Any psychotropic drugs	100	73.1‡	86.4‡	100	86.3‡	62.7‡
Any non-BZD psychotropic drugs	35.9 (0.3)	38.3 (0.3)‡	39.5 (0.3)‡	55.4 (0.9)	53.7 (0.88)*	45.1 (0.9)‡
Benzodiazepines	100	54.2‡	74.8‡	100	81.9‡	57.5‡
Antidepressants	34.0 (0.2)	36.5 (0.3)‡	37.7 (0.3)‡	47.1 (0.9)	46.1 (0.8)	39.2 (0.9)‡
Anxiolytics	8.0 (0.2)	11.1 (0.2)‡	12.3 (0.2)‡	18.4 (0.7)	17.1 (0.6)	14.7 (0.7)‡
Number of days supply (days)						
Any psychotropic drugs	345.4 (1.9)	241.3 (1.9)‡	310.8 (1.9)‡	528.3 (10.5)	450.5 (8.5)‡	351.8 (9.3)‡
Any non-BZD psychotropic drugs	101.3 (1.3)	121.9 (1.4)‡	135.1 (1.5)‡	242.0 (7.5)	226.2 (6.0)†	202.6 (6.9)‡
Benzodiazepines	240 (1.1)	122 (1.1)‡	176 (1.2)‡	266.6 (4.0)	219.1 (3.6)‡	168.4 (4.2)‡
Antidepressants	82.2 (1.1)	97.8 (1.2)‡	104.9 (1.2)‡	179.9 (5.3)	168.7 (4.6)*	149.3 (5.3)‡
Anxiolytics	8.3 (0.3)	14.2 (0.4)‡	19.2 (0.5)‡	38.0 (2.5)	34.9 (1.9)	29.7 (2.1)*
Psychotropic drug total expenditures ($)						
Any psychotropic drugs	307.1 (3.8)	270.5 (4.1)‡	262.2 (4.0)*†	893.7 (33.9)	782.6 (27.5)‡	618.1 (32.2)‡
Any non-BZD psychotropic drugs	163.1 (3.3)	210.8 (3.8)‡	207.2 (4.0)‡	647.2 (27.6)	631.3 (23.8)	571.5 (32.8)*
Benzodiazepines	134.4 (1.1)	63.6 (0.8)‡	58.5 (0.7)‡	173.22 (6.9)	132.3 (4.6)‡	104.5 (5.0)‡
Antidepressants	105.0 (1.9)	127.9 (2.1)‡	114.1 (2.2)‡	400.0 (15.4)	375.5 (13.0)	322.0 (15.6)‡
Anxiolytics	24.0 (1.0)	43.1 (1.3)‡	45.4 (1.4)‡	114.8 (7.9)	114.4 (6.5)	89.3 (6.9)*

Intervention cohort refers to group of elderly Medicare Advantage patients (subject to Medicare Part D BZD exclusion), and comparison cohort refers to group of near-elderly patients with managed care insurance (not subject to Medicare Part D BZD exclusion). Medicare Part D BZD exclusion was active in 2006 and 2007 but not 2005.

*
p < 0.05,

†
p < 0.01,

[‡] p < 0.001 when compared with 2005 within cohort. Logistic regression models were estimated for medication any use outcomes. Two-part regression models (logistic for occurrence and zero-truncated negative binomial for amounts) were estimated for expenditure and days supply outcomes. Regressions controlled for a constant, gender, age, age squared, and psychiatric/medical comorbidities. 95% confidence intervals were calculated using bias-corrected empirical bootstrapping with 2,000 replicate samples.