

Impact of Cost-Sharing on Treatment Augmentation in Patients With Depression

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Depression is among the most common psychiatric disorders in the United States. Using data from the US National Comorbidity Survey Replication conducted from February 2001 through April 2002, Kessler et al (2005) found the 12-month prevalence of major depressive disorder to be 6.7 percent.¹ Consistent with the high rate of depression in the population, antidepressants are among the most frequently prescribed medication classes in the United States.²

Patients with depression may not respond to first-line antidepressant therapy; even adequate trials of antidepressants often fail to achieve remission of symptoms. The Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study reported a remission rate for first-line therapy (citalopram) of up to 32.9%, depending on the definition of remission.³ For patients who do not respond to first-line antidepressant therapy, treatment options include remaining on a single antidepressant (monotherapy) or augmenting antidepressant treatment with another concurrent treatment such as a second antidepressant, a stimulant, a mood stabilizer, or a second-generation antipsychotic (SGA).

While treatment decisions are primarily based on clinical considerations, patient cost-sharing (ie, the price to the patient) may also be a consideration when deciding which treatment course to pursue. Previous research has demonstrated that higher patient prescription drug cost-sharing amounts are associated with lower levels of prescription drug utilization and expenditures.^{4,5} While one rationale behind imposing higher prescription drug cost-sharing is to steer patients away from low-value drugs and preventing medication overuse, previous studies have shown that higher cost-sharing amounts are also associated with lower initiation rates of high-value medication therapies for chronic illnesses.⁶

The largest financial impact on the patient in the decision to remain on a single therapy, or to attempt augmentation, is the choice of continuing to pay 1 cost-sharing amount or to bear an additional cost-sharing amount when adding a treatment. To our knowledge, no studies have addressed the effects of cost-sharing on treatment augmentation patterns in patients on antidepressant therapy.

The objective of this study was to examine the relationship between patient cost-sharing and the use of augmentation strategies among a large sample of commercially insured patients with depression on antidepressant therapy. We examined the effects of cost-sharing on any augmentation with a mood

Objectives: Many patients with depression do not respond to first-line antidepressant therapy and may require augmentation with another concurrent treatment such as a second antidepressant, a stimulant, a mood stabilizer, or a second-generation antipsychotic (SGA). The objective of this study was to examine the relationship between patient cost-sharing and the use of augmentation among a sample of commercially insured patients.

Study Design: Retrospective observational study of adult patients diagnosed with depression and receiving antidepressant therapy (n = 48,807).

Methods: Logistic regression models estimated the likelihood of augmentation as a function of patient cost-sharing amounts. An alternative-specific conditional logit model of the likelihood of each augmentation class, varying the cost-sharing prices faced for each class, was also estimated. All models controlled for sociodemographic characteristics, physical and mental comorbidities, health plan type, and year of index antidepressant therapy initiation.

Results: The range of mean copayments paid by patients for augmentation therapy was from \$27.05 (antidepressant) to \$38.81 (SGA). A \$10-higher cost-sharing index for all augmentation classes was associated with lower odds of augmentation (adjusted odds ratio = 0.85; 95% confidence interval 0.79-0.91). Doubling the cost-sharing amount for each augmentation class was associated with a smaller percentage of patients utilizing each class of augmentation therapy.

Conclusions: Employers and payers should consider the relationship between cost-sharing and medication utilization patterns of patients with depression.

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Take-Away Points

In a sample of adult patients with depression who were undergoing antidepressant therapy, higher patient cost-sharing is associated with a lower likelihood of antidepressant treatment augmentation. Higher cost-sharing amounts for each augmentation class were associated with a smaller percentage of patients utilizing each class of augmentation therapy.

- Our findings add to the evidence that cost-sharing not only impacts treatment decisions for depression from the time of initial therapy but also follow-on treatment pathways for those not achieving remission.
- Employers and payers should consider the implications of higher cost sharing on the utilization patterns of patients with depression.

We selected patients who were 18 to 64 years of age at the time of the first antidepressant prescription claim and had at least 2 medical claims (outpatient or inpatient services) with a depression diagnosis (*International Classification of Diseases, Ninth Revision, Clinical Modification* [ICD-9-CM]: 296.2x, 296.3x, 300.4, 309.0, 311) during the study period, which

consisted of the year preceding the initial antidepressant claim and the 16 months following. Patients were excluded from the study if a prescription for one of the augmentation classes appeared prior to the index date (n = 5672) or if they had evidence of electroconvulsive therapy (n = 5) or a prescription claim for clozapine or a fixed-dose combination of antidepressants and SGA (n = 135). After these exclusion criteria were applied, patients were also excluded if they had a medical claim with another diagnosis wherein one of the augmentation strategies might be indicated. These included dementia, schizophrenia, delusional disorder, psychoses, pervasive development disorder, mental retardation, cerebral degenerations, Parkinson's disease, senility, manic depression, bipolar disorder, or major depressive disorder with psychotic features (n = 688). Patients were also excluded if the first augmentation prescription did not overlap with an antidepressant prescription for at least 30 days (allowing 6 gap days) or if prescriptions for medications within 2 different augmentation classes appeared on the date of the first augmentation (n = 4823). We found 48,807 patients meeting the study criteria of antidepressant medication treatment and fulfilling the diagnostic and other criteria.

stabilizer, SGA, stimulant, or antidepressant. In addition, we estimated the relationship between changes in cost-sharing within each class on the share, or percentage, of patients utilizing each augmentation class.

METHODS

Data Source

This retrospective analysis used data from the Thomson Reuters MarketScan Commercial Claims and Encounters (CCAE) Database, which contains the healthcare experience of tens of millions of individuals annually who have commercial health insurance provided primarily by large self-insured employers. The CCAE Database includes detailed spending and utilization data for healthcare services performed in both inpatient and outpatient settings, covered by a variety of plan designs, including preferred provider organizations (PPOs), point of service plans, indemnity plans, and health maintenance organizations (HMOs). Medical claims are linked to outpatient pharmacy claims and enrollment data using unique enrollee identifiers. No institutional review board approval was required, because the database meets criteria for a limited-use data set in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Study Population

Patients were selected from the database by finding the first antidepressant claim for each patient during the study time frame (January 1, 2005, through December 31, 2008) with a 1-year period of continuous enrollment prior to the antidepressant fill (**Figure 1**). Augmentation of antidepressant treatment is typically not recommended for patients for at least 8 weeks after initiation of antidepressant therapy.⁷ Conservatively, to allow for partial response, augmentation was required to be at least 4 months (16 weeks) after the initial antidepressant, allowing two 8-week antidepressant trials.⁷ The index date was established as the date 4 months after the initial antidepressant, and each patient had a minimum follow-up period of 1 year (52 weeks) following the index date.

MEASURES

Outcomes

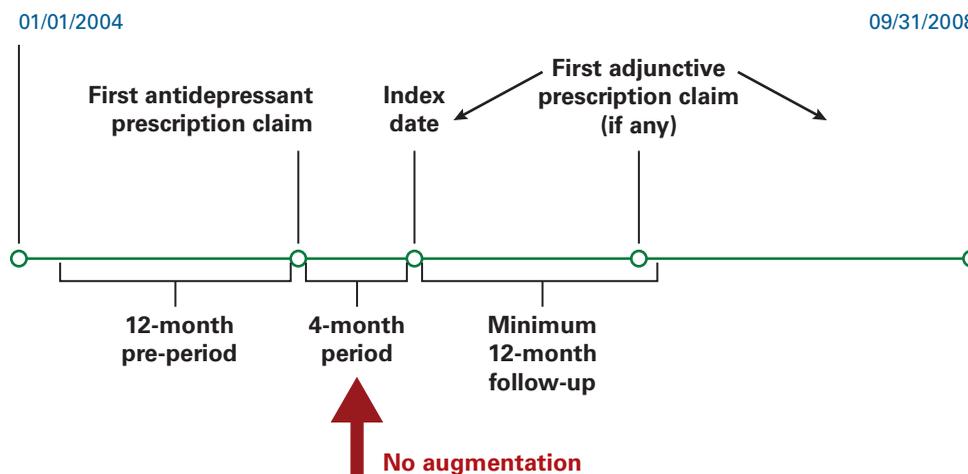
Any Augmentation

The first outcome measure was the use of any augmentation therapy in the post-index time frame, and any augmentation was recorded as a yes/no indicator variable in the year following the index date. Augmentation of the initial antidepressant therapy was defined as at least 30 days overlap (with a 6-day gap) post-index with any 1 of the following classes: SGA, mood stabilizer, stimulant, or a second antidepressant.

Augmentation Class

The first class of augmentation (SGA, mood stabilizer, stimulant, concomitant antidepressant, or antidepressant monotherapy [no augmentation]) that the patient filled in the year following the index date was recorded.

■ **Figure 1. Study Time Frame**



Cost-Sharing Measures

The key explanatory variable was the patient prescription drug cost-sharing index⁸ representing the prices faced by each patient within each employer/health plan combination for a fill within each augmentation class, regardless of whether they augmented or not. Cost-sharing is represented by a price index calculated as a weighted average of the prices of each medication, as patients are likely to respond to the prices of each medication alternative they face, even if they do not fill a prescription within that class. Class-specific (eg, mood stabilizer or SGA medication), plan-level cost-sharing amounts were calculated as a weighted average of brand-name and generic copayments (p) with weights based on overall utilization (a market-basket approach), $p_{ci} = w_{cb} * p_{cbi} + w_{cg} * p_{cgi}$ where c is class, b/g are brand and generic, i is plan, and the weights sum to 1, $w_{cb} + w_{cg} = 1$. In the case of SGA medications, no generic medications existed at the time, so the class-specific index was equal to the brand-name cost-sharing amount. In addition to the class-specific measure, a plan-level index combined a weighted average of the brand and generic cost-sharing amounts for all classes (with the utilization weights summing to 1).

Other Explanatory Variables

Other explanatory variables included sociodemographic characteristics consisting of age, gender, employee status (vs spouse or dependent), rural (vs urban) residence, United States Census region, and median household income by zip code of residence (from the US Census). Type of health plan (eg, HMO, PPO) was also included. Health status variables were measured during the year prior to the index date. The Charlson Comorbidity Index (CCI) is an aggregate measure based on diagnoses associated with 19 conditions.⁹ Because the CCI does not capture mental health conditions, the num-

ber of Psychiatric Diagnostic Groupings (PDGs)¹⁰ was also included. The PDGs are identified by ICD-9-CM diagnosis codes and include comorbid mental health conditions such as alcohol use disorders and other substance use disorders. A dichotomous flag indicating medication switching when at least 2 different antidepressant monotherapies were filled during the 4-month period following the initial antidepressant prescription was included, which may signal treatment resistance to the initial antidepressants. Also included were indicator variables denoting the year the first observed antidepressant was filled.

Statistical Analysis

Two sets of models were estimated for the outcome of any augmentation. First, a logistic regression was used to model the odds of any augmentation over a 1-year period after the index date. Based on the model results, we calculated the effects of higher cost-sharing on the likelihood of any augmentation and the price elasticity of the probability of augmentation. Models included cost-sharing variables, sociodemographic characteristics, health plan type, health status variables, and time. We also included a fixed effect for each employer (firm) to account for all time-invariant employer-specific confounders in the analysis.¹¹

For the analysis of the outcome on augmentation class, we estimated an alternative-specific conditional logit model (McFadden's choice logit) of the type of augmentation (augmentation class) utilized within 12 months of the index date.¹² The alternatives in this model were the 5 augmentation strategies (none, SGA, mood stabilizer, stimulant, antidepressant). This model is similar to the multinomial logit; however, in the alternative-specific conditional logit model, the cost-sharing amounts were varied with each augmentation class (alternative-specific characteristics). Other covariates remained the

■ **Table 1.** Patient Characteristics

	Augmentation Within 1 Year of Index Date				No Augmentation
	SGA	Mood Stabilizer	Stimulant	Antidepressant Polypharmacy	Antidepressant Monotherapy
Cohort size	292	627	274	3791	43,823
Total sample, %	0.6	1.3	0.6	7.8	89.8
Age, mean	38.38	42.34	38.90	41.52	40.74
Female, %	54.1	67.1	56.2	66.6	66.1
Relationship to employee					
Employee, %	50.3	56.8	52.6	57.6	60.4
Spouse or dependent, %	49.7	43.2	47.4	42.4	39.6
Median household income in zip code, mean, \$	49,143	49,077	51,944	50,661	50,006
Urban residence, %	87.3	86.0	88.3	86.3	85.6
US Census region, %					
South	33.9	33.2	32.8	31.9	33.0
North Central	28.4	33.7	35.4	27.4	30.2
North East	15.8	10.8	13.9	13.2	12.6
West	21.9	22.3	17.9	27.6	24.2
Plan type, %					
PPO	50.0	44.5	47.4	46.7	46.6
Comprehensive	11.6	10.7	12.0	8.3	9.1
High deductible	2.1	3.8	2.9	3.5	3.4
HMO	23.3	22.6	20.4	25.2	24.5
POS	13.0	17.4	16.4	15.9	15.9
Year of initial antidepressant, %					
2005	40.1	37.0	43.4	38.5	40.2
2006	38.7	42.4	35.8	41.8	40.6
2007	21.2	20.6	20.8	19.7	19.2
Health status					
Charlson Comorbidity Index, mean	0.29	0.37	0.31	0.22	0.20
No. PDGs, mean	0.79	0.74	0.79	0.70	0.80
≥2 AD agents, %	19.2	16.3	15.0	15.3	10.1
Cost-sharing information^a					
Mean, \$	38.81	30.51	34.21	27.05	27.05
Range	(\$0-\$130.42)	(\$0-\$78.20)	(\$0-\$188.04)	(\$0-\$67.20)	(\$0-\$67.20)

AD indicates antidepressant drug; HMO, health maintenance organization; PDG, psychiatric diagnosis grouping; PPO, preferred provider organization; POS, point of service; SGA, second-generation antipsychotic.

^aAugmentation cost-sharing amounts would be in addition to the amount expended for antidepressant monotherapy.

same with each augmentation class (ie, sociodemographic, health plan, health status, time, and firm fixed effect). Based on the model results, we calculated the effects of higher cost-sharing for each augmentation alternative on the probability that each augmentation alternative is selected.¹³ Using results from the alternative-specific conditional logit model, we es-

timated the effects of a change in the cost-sharing index for each augmentation class, varying the prices 1 class at a time, on the share of patients using the class. Using this information, we calculated the own price elasticity of share (ie, the percent change in the share of patients using the class/percent change in cost-sharing for the class).

RESULTS

Of the 48,807 patients meeting the study criteria, 10.2% (4984) augmented therapy within 1 year of the index date (ie, 4 months after the first antidepressant fill). Most augmented with an antidepressant (7.8%), followed by a mood stabilizer (1.3%), and then SGAs and stimulants (both 0.6%).

Patient characteristics by augmentation class are displayed in **Table 1**. The average age in each cohort was about 40 years, although patients augmenting with SGAs were the youngest on average (38.4 years), and patients augmenting with a mood stabilizer were oldest (42.3 years). Patients augmenting with a mood stabilizer were also most likely to be female (67.1%) and patients augmenting with an SGA were most likely to be male. About 40% of patients had an initial antidepressant fill in 2005, another 40% had an initial fill in 2006, and the remainder had an initial fill in 2007.

Health status varied across the cohorts, with patients augmenting with mood stabilizers having the highest CCI score (0.37) and the lowest number of PDGs (0.74). Conversely, patients on antidepressant monotherapy had the lowest CCI (0.20) and the highest number of PDGs (0.80). Almost one-fifth of patients augmenting with SGAs had 2 or more antidepressant agents in the 4 months after the initial antidepressant fill, while half that amount (10.1%) of patients on antidepressant monotherapy filled a prescription for 2 or more antidepressant agents during the same time.

The mean cost-sharing index varied with the medication class (Table 1) and the smallest amount was for antidepressants, at \$27.05 per fill; SGAs were the highest, at \$38.81 per fill. The overall cost-sharing index, combining all classes as a weighted average, was \$28.67 per fill.

Results from the logit model of any augmentation showed that as the cost-sharing index rose, the likelihood of any augmentation decreased (**Table 2**). A \$10-higher cost-sharing index for all augmentation classes was associated with 15% lower odds of augmentation (adjusted odds ratio [OR] = 0.85, 95%

Table 2. Likelihood of Any Augmentation

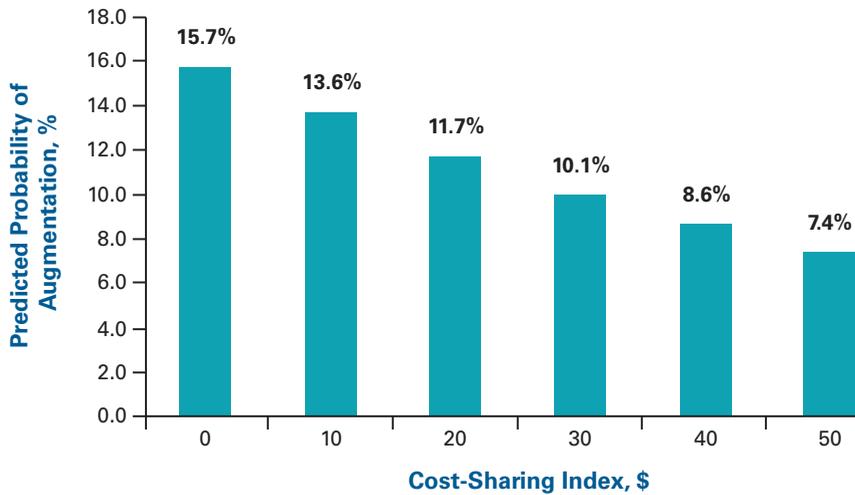
	Any Augmentation Within 1 Year	
	Adjusted OR	95% CI OR
Cost-sharing index (\$10s)	0.85 ^a	(0.79, 0.91)
Age	1.00 ^a	(1.00, 1.01)
Female	0.94	(0.88, 1.00)
Employee ^b	0.82 ^a	(0.77, 0.88)
Income	1.00	(1.00, 1.00)
Urban residence	1.05	(0.95, 1.16)
US Census region		
Reference = South		
North Central	0.92	(0.82, 1.01)
North East	1.03	(0.91, 1.16)
West	1.06	(0.93, 1.20)
Plan type		
Reference = PPO		
Comprehensive	0.96	(0.84, 1.10)
High deductible	0.91	(0.70, 1.16)
HMO	0.94	(0.85, 1.04)
POS	1.00	(0.89, 1.13)
Year of initial antidepressant		
Reference = 2005		
2006	1.07	(1.00, 1.14)
2007	1.02	(0.93, 1.11)
Health status		
CCI	1.10 ^a	(1.05, 1.14)
PDG	0.87 ^a	(0.84, 0.90)
≥2 AD	1.66 ^a	(1.52, 1.80)

AD indicates antidepressant drug; CCI, Charlson Comorbidity Index; CI, confidence interval; HMO, health maintenance organization; OR, odds ratio; PDG, psychiatric diagnostic grouping; PPO, preferred provider organization; POS, point of service.
^aP < .001.
^bReference = spouse or dependent.
 Models also include a fixed effect for each employer.

confidence interval [CI] 0.79-0.91) (Table 2). When converted into the effects on the probability of any augmentation, a \$10-higher cost-sharing index was also associated with 1.5-percentage-point lower (*P* < .01) probability of any augmentation. This translates to a price elasticity of the probability of any augmentation of -0.44. **Figure 2** displays the predicted probability of any augmentation at various cost-sharing levels.

Results from the alternative specific conditional logit model showed that higher cost-sharing was associated with lower odds of augmentation (**Table 3**). While prices for each augmentation class were entered separately into the model, a single marginal effect of cost-sharing was obtained, representing the association between cost-sharing and augmentation. We found that higher cost-sharing was associated with lower odds

■ **Figure 2. Cost-Sharing and the Probability of Any Antidepressant Augmentation^a**



^aAugmentation is measured within 1 year of the index date.

of augmentation (adjusted OR = 0.85, 95% CI 0.75-0.91).

We found that a doubling in the price, or 100% higher price, of antidepressants was associated with a 41% smaller share of patients utilizing antidepressants as an augmentation class (elasticity estimate of -0.41). Also, a doubling in the price of SGAs led to a 63% smaller share of patients utilizing SGAs (elasticity estimate -0.63); a doubling in the price of mood stabilizers or stimulants was associated with a slightly smaller share of patients utilizing mood stabilizers (49% smaller, elasticity -0.49) or stimulants (55% smaller, elasticity -0.55), respectively.

DISCUSSION

This study contributes new evidence to the literature regarding the impact of patient cost-sharing on utilization of medications to augment antidepressant therapy among patients with depression. Among a population of adults with depression who have employer-sponsored health insurance, higher cost-sharing was linked to lower rates of utilization of classes of medication used to augment antidepressant therapy. Specifically, higher prescription drug cost-sharing was associated with lower rates of any augmentation. Importantly, higher cost-sharing amounts for each augmentation class were associated with a smaller percentage of patients utilizing each class of augmentation therapy.

Augmentation of antidepressant monotherapy with other pharmacologic therapies has been shown to be an effective means to manage depression for many patients who do not achieve full remission of symptoms.^{7,14} Augmentation decisions made by providers and their patients must balance the ben-

efits of augmentation in terms of remission of symptoms and averted medical utilization and costs with the costs of augmentation in terms of the potential for increased side effects (and related costs) and the cost of the augmentation therapy. Clinical evidence reveals that up to one-third of patients do not achieve full remission of symptoms³; however, we found slightly more than 10% of our sample augmented therapy within 1 year. While the number augmenting therapy might have been higher if the length of time followed had been extended,

our results demonstrate that rates of augmentation in the first year are lower in plans with higher cost-sharing.

While previous studies have demonstrated lower levels of antidepressant use with higher levels of cost-sharing among commercially insured patients,^{5,8} this is the first study to our knowledge that builds upon this work and examines the relationship between cost-sharing and augmentation. Our findings add to the evidence that cost-sharing not only impacts treatment decisions for depression from initial therapy, but also follow-on treatment pathways for those not achieving remission. We found that the estimated price elasticity of any augmentation was -0.44 , and the price elasticity of shares to the various augmentation classes were similar or higher. These augmentation estimates exceed price elasticity of demand estimates for antidepressants alone among adult commercially insured enrollees (-0.26) and among the subgroup of enrollees with a medical claim containing a diagnosis for depression (-0.08).⁵

The economic burden of depression is considerable in terms of direct medical and indirect absence and disability costs,¹⁵ and in lost productivity time.¹⁶ As such, employers and payers may want to encourage improvements to treatment of enrollees with depression, including first-line and augmentation therapies. These findings show that benefit plan provisions, such as cost-sharing, can affect the timing and type of decisions made to augment therapy in patients with depression.

This study has several limitations. The study utilizes health-care administrative claims with the assumption that a patient's filling pattern for an antidepressant or augmentation therapy corresponds to their consumption pattern for the medication.

Cost-Sharing and Treatment Augmentation

■ **Table 3.** Conditional Logit of Augmentation Class

Alternative-Specific Variables				
Cost-sharing	0.85 ^a	95% CI (0.75-0.91)		
Case/Individual-Specific Variables (Relative to No Augmentation)				
	SGA	Mood Stabilizer	Stimulant	Antidepressant Polytherapy
Age	0.98 ^b	1.01 ^b	0.99	1.01 ^a
Female	0.54 ^a	1.03	0.61 ^a	1.01
Employee	0.61 ^a	0.79 ^b	0.69 ^b	0.86 ^a
Income	0.99	1.00	1.00	1.00
Urban residence	1.35	1.10	1.23	1.01
US Census region				
Reference = South				
North Central	0.75	1.06	0.91	0.90
North East	1.11	0.85	1.02	1.05
West	1.06	0.88	0.88	1.11
Plan type				
Reference = PPO				
Comprehensive	1.25	1.02	0.99	0.92
High deductible	0.33	1.13	0.97	0.92
HMO	0.88	0.93	0.78	0.96
POS	0.89	1.25	0.91	0.98
Year of initial antidepressant				
Reference = 2005				
2006	1.02	1.16	0.82	1.08 ^c
2007	1.13	1.12	0.84	1.00
Health status				
CCI	1.17 ^b	1.24 ^a	1.21 ^b	1.05
PDG	0.95	0.91	0.95	0.85 ^a
≥ 2 AD	2.17 ^a	1.75 ^a	1.51 ^c	1.62 ^a
Price Elasticity of Share	-0.63 ^a	-0.49 ^a	-0.55 ^a	-0.41 ^a

AD indicates antidepressant drug; CCI, Charlson Comorbidity Index; CI, confidence interval; HMO, health maintenance organization; PDG, psychiatric diagnosis grouping; PPO, preferred provider organization; POS, point of service; SGA, second-generation antipsychotic.

^a*P* < .001.
^b*P* < .01.
^c*P* < .001.

Models also include a fixed effect for each employer. Augmentation is measured within 1 year of the index date.

We also utilize a sample of patients with commercial insurance from large and medium-sized firms where income is likely to be higher than in the general population. To the extent that choice may exist between prescription drug plans, and patients who expect higher prescription use and expenditures choose a health plan with lower prescription drug cost-sharing, the results could be biased upward. However, it is likely that this type of bias is minimized, since the majority of employers tend to offer a standard prescription benefit across relevant medical plans.¹⁸ Also, our study measures the first augmentation strategy

utilized by the patient and does not encompass the subsequent course of treatment. Future studies may address more complex augmentation patterns. In addition, our study only examined the influence of cost-sharing for antidepressants and other augmentation strategies on the likelihood of augmentation. We considered including a measure for the cost-sharing for other medications being used; however, we did not include it in the models, as we found it to be highly collinear with the out-of-pocket costs for antidepressants and other augmentation strategies we modeled.

We included an indicator of antidepressant medication switching (measured as the use of 2 or more antidepressant agents) in the first 4 months following antidepressant initiation as a proxy for treatment resistance. While we find that this measure is highly associated with augmentation, it is a simple dichotomous measure, with only 10.6% of patients switching within 16 weeks. Since one-half to three-fourths of patients with depression on antidepressant treatment are likely to achieve remission,^{3,7} those who switch early in the course of treatment are not the full set of those at higher risk of augmentation long-term. Access to clinical information to create a clinically derived measure might have improved our ability to risk adjust for augmentation. When we estimated the multivariate models with the subset of patients who switched in the first 16 weeks as a sensitivity analysis, the direction and magnitude of the findings were similar, although we lost statistical power due to the small sample size.

Prescription cost-sharing strategies are likely to continue as payers struggle to control growing prescription drug expenditures. Balancing underuse of high-value medications and overuse of low-value medications will be a continuing challenge within the healthcare system. Our study highlights the need for employers and payers to consider the role that cost-sharing may play in meeting treatment goals and the relationship between cost-sharing and the utilization patterns of vulnerable patient groups, such as those with depression.

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YJ, ZC, JAB, TH); critical revision of the manuscript for important intellectual content (TBG, YJ, JAB, TH, RAF, JAD); statistical analysis (TBG, YJ, ZC, JAB); provision of study materials or patients (TBG); obtaining funding (TBG); administrative, technical, or logistic support (TBG, YJ, JAB, JEB, TH); and supervision (TBG, YJ, TH).

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