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High-Deductible Health Plans Paired With Health Savings Accounts Increased Medication Cost Burden Among Individuals With Bipolar Disorder

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ABSTRACT

Objective: High-deductible health plans paired with health savings accounts (HSA-HDHPs) require substantial out-of-pocket spending for most services, including medications. We examined effects of HSA-HDHPs on medication out-of-pocket spending and use among people with bipolar disorder.

Methods: This quasi-experimental study used claims data for January 2003 through December 2014. We studied a national sample of 348 members with bipolar disorder (defined based on *International Classification of Diseases, 9th Revision*), aged 12 to 64 years, who were continuously enrolled for 1 year in a low-deductible plan (≤ $500) then 1 year in an HSA-HDHP (≥ $1,000) after an employer-mandated switch. HSA-HDHP members were matched to 4,087 contemporaneous controls who remained in low-deductible plans. Outcome measures included out-of-pocket spending and use of bipolar disorder medications, non-bipolar psychotropics, and all other medications.

Results: Mean pre-to-post out-of-pocket spending per person for bipolar disorder medications increased by 149.7% among HSA-HDHP versus control members (95% confidence interval [CI], 109.9% to 189.5%). Specifically, out-of-pocket spending increased for antipsychotics (220.9% [95% CI, 150.0% to 291.8%]) and anticonvulsants (109.6% [95% CI, 67.3% to 152.0%]). Both higher-income and lower-income HSA-HDHP members experienced increases in out-of-pocket spending for bipolar disorder medications (135.2% [95% CI, 86.4% to 184.0%] and 164.5% [95% CI, 100.9% to 228.1%], respectively). We did not detect statistically significant changes in use of bipolar disorder medications, non-bipolar psychotropics, or all other medications in this study population of HSA-HDHP members.

Conclusions: HSA-HDHP members with bipolar disorder experienced substantial increases in out-of-pocket burdens for medications essential for their functioning and well-being. Although HSA-HDHPs were not associated with detectable reductions in medication use, high out-of-pocket costs could cause financial strain for lower-income enrollees.

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High-deductible health plans (HDHPs) have become the predominant health insurance arrangement in both the employer and individual markets in the US. In 2020, 57% of workers with employer-sponsored health insurance had deductibles of ≥ $1,000, and 26% had deductibles of ≥ $2,000.[1] Almost 90% of enrollees in Affordable Care Act marketplaces had HDHPs in 2015.[2] HDHPs have lower monthly premiums than traditional health plans but require substantially higher out-of-pocket spending, with the intent to encourage cost awareness when making health care purchasing decisions. Members pay the full cost for most non-preventive care until reaching their annual deductible. After that, lower cost-sharing applies to these services. In the employer market, the annual deductible was up to $6,900 per individual or $13,800 per family in 2020. In the individual market, the average deductible in 2020 was $6,506 for bronze (lowest monthly premium but highest cost-sharing for care), $4,544 for silver, and $1,519 for gold plans.[3]

Health savings account (HSA)–eligible HDHPs are the fastest growing type of HDHP, recently accounting for about 30% of the employer-sponsored health insurance market.[1] HSA-HDHPs allow employers and members to contribute tax-free funds to special accounts that pay for medical expenses. Internal Revenue Service regulations require that HSA-HDHPs include full patient cost-sharing for almost all care (including visits, tests, procedures, and medications) before the deductible is reached except for evidence-based primary prevention services[4] and some secondary prevention services.[5] In contrast, low-deductible plans have lesser cost-sharing for all services and cover medications with a tiered copayment structure. Increased cost-sharing associated with HSA-HDHPs raises concerns about financial toxicity, which refers to the adverse impacts of out-of-pocket costs on a patient's financial burden and health outcomes. HSA-HDHPs may create financial barriers to medication access among

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Clinical Points

- High-deductible health plans paired with health savings accounts (HSA-HDHPs) require substantial out-of-pocket spending for most services, including medications. Effects of HSA-HDHPs on medication out-of-pocket spending and use among people with bipolar disorder are unknown.
- HSA-HDHP members with bipolar disorder experienced substantial and concerning increases in out-of-pocket burdens for crucial medications. Although HSA-HDHPs were not associated with detectable reductions in medication use, high out-of-pocket costs could cause financial strain for lower-income enrollees. Further research is needed to examine the broader consequences of such major increases in patient cost-sharing.

chronically ill people who require consistent access to expensive specialist care and medications.

Bipolar disorder has a 12-month prevalence of 2.8% and lifetime prevalence of 4.4% in the US.[6] It is a chronic, severe mental illness and carries a high risk of morbidity and mortality.[7,8] Evidence-based care for bipolar disorder requires medications to treat the episodic (and at times persistent) elevated and depressed mood states that are characteristic of the illness[9–11] and for ongoing maintenance to prevent relapse, hospitalization, and suicide.[12–14]

Individuals with mental illness can be especially vulnerable to the negative effects of some health insurance policies because mental illnesses may create additional obstacles to adequate self-care. For instance, they may have more challenges maintaining employment and housing, and difficulty navigating complex health insurance benefits.[15] Previous studies[16–22] have found associations between features of insurance that create financial or administrative barriers (eg, medication cost-sharing, prior authorization, capped coverage) and reduced medication adherence and subsequent increased emergency services use among individuals with mental illness. In addition, a recent study[23] demonstrated disparities in out-of-pocket spending burdens among low-income versus high-income HDHP members with bipolar disorder.

HSA-HDHP members with serious mental illness might be particularly at risk for burdensome expenses or medication underuse given their need for regular medical services and preexisting barriers to care among such enrollees. We hypothesized that employer-sponsored HSA-HDHPs would increase medication out-of-pocket spending and decrease medication use among individuals with bipolar disorder, especially in a lower-income subgroup.

METHODS

Data Source and Study Population

We drew our study population from commercially insured members in a large, nationally representative commercial (and Medicare Advantage) health insurance claims database. Data contained enrollment information and medical and pharmacy claims, including billed member out-of-pocket expenditures for these services.

The study population comprised individuals with bipolar disorder in low-deductible health plans whose employers either mandated a switch to an HSA-HDHP during our 2003–2014 study period (HSA-HDHP group) or kept their employees in low-deductible coverage (control group). Thus, our study groups were not offered a choice of deductible level; we used this design to minimize member self-selection bias. HDHPs are not a feature of Medicaid or Medicare insurance plans, so we did not include any Medicaid or Medicare beneficiaries.

As in our previous work,[24,25] we defined employers with low- and high-deductible coverage as those offering exclusively plans with annual deductibles of $0–$500 and $1,000 or more, respectively (Supplementary Appendix 1).[44–49]

Our process for identifying study groups involved first identifying eligible employers and then identifying eligible individuals with bipolar disorder at those employers. Qualifying HSA-HDHP group employers were those with at least 1 year of low-deductible–only coverage followed by at least 1 year of coverage in an HSA-eligible HDHP. We defined the index date for employers that switched to HDHPs as the beginning of the month when the switch occurred. For employers that did not switch plans, the index date was the beginning of the month when their yearly account renewed. Some members had multiple eligible index dates (eg, multiple low-to-low deductible years or both low-to-low and low-to-HDHP years). In the cases of members with both low-to-low and low-to-HDHP years, we randomly assigned enrollees to the HDHP pool or the control pool. For members assigned to the control pool who had multiple low-to-low deductible spans, we randomly selected one of their potential index dates (and their corresponding before-after enrollment years).

Study cohorts were drawn from 55 million eligible members aged 0–64 years enrolled between January 1, 2003, and December 31, 2014. As in prior research,[26–28] we used an established algorithm and outpatient and inpatient diagnosis codes for bipolar disorder as defined by *International Classification of Diseases*, *9th Revision* (*ICD-9-CM*), codes to classify members as having bipolar disorder type I, type II, or other (Supplementary Appendix 1). We identified 355,700 members with bipolar disorder.

We limited the qualifying population to a pre-match sample of 353 HSA-HDHP members and 39,953 controls with bipolar disorder who were continuously enrolled for at least 2 years in one of the aforementioned employer types, were aged 12–64 years at the time of the index date, and had their most recent bipolar disorder diagnoses occurring between 5 years and 7 months prior to the index date and whose employers did not carve out mental health benefits.

Matching Strategy and Covariates

To further minimize potential selection effects, we used coarsened exact matching[29,30] on employer- and

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Table 1. Baseline Characteristics of the HSA-HDHP and Control Groups, Before and After Coarsened Exact Matching (CEM)[a]

	Before CEM			After CEM		
Variable	HSA-HDHP Group (n = 353)	Control Group (n = 39,953)	Standardized Difference[b]	HSA-HDHP Group (n = 348)	Control Group (n = 4,087)	Standardized Difference[b]
Age > 40 y on index date	183 (51.8)	19,839 (49.7)	0.0437	178 (51.1)	2,113 (51.7)	−0.0111
Age on index date, mean (SD), y	38.3 (14.2)	38.2 (14.2)	0.0059	38.1 (14.2)	38.5 (14.5)	−0.0317
Female	211 (59.8)	24,560 (61.5)	−0.0348	208 (59.8)	2,509 (61.4)	−0.0329
Percentage of households below federal poverty level in neighborhood of residence[c]						
< 5%	125 (35.4)	10,969 (27.5)	0.1756	123 (35.3)	1,163 (28.5)	0.2306
5%–9.9%	90 (25.5)	11,698 (29.3)		88 (25.3)	1,255 (30.7)	
10%–19.9%	91 (25.8)	11,516 (28.8)		91 (26.1)	1,179 (28.8)	
≥ 20%	47 (13.3)	5,751 (14.4)		46 (13.2)	490 (12.0)	
Missing poverty data	0 (0.0)	19 (0.0)		0 (0.0)	0 (0.0)	
Percentage of persons with less than a high school education in neighborhood of residence[d]						
< 15%	286 (81.0)	30,888 (77.3)	0.2126	282 (81.0)	3,341 (81.7)	0.0484
15%–24.9%	50 (14.2)	6,470 (16.2)		49 (14.1)	581 (14.2)	
25%–39.9%	16 (4.5)	2,174 (5.4)		16 (4.6)	144 (3.5)	
≥ 40%	1 (0.3)	403 (1.0)		1 (0.3)	21 (0.5)	
Missing education data	0 (0.0)	18 (0.0)		0 (0.0)	0 (0.0)	
Race/ethnicity[e]						
Hispanic	12 (3.4)	2,277 (5.7)	0.2440	12 (3.4)	157 (3.8)	0.0807
Asian	3 (0.8)	575 (1.4)		3 (0.9)	39 (1.0)	
Black neighborhood	4 (1.1)	455 (1.1)		4 (1.1)	32 (0.8)	
Mixed neighborhood	55 (15.6)	9,212 (23.1)		53 (15.2)	685 (16.8)	
White neighborhood	279 (79.0)	27,434 (68.7)		276 (79.3)	3,174 (77.7)	
ACG score, mean (SD)[f]	2.4 (3.1)	2.3 (3.2)	0.0385	2.3 (3.0)	2.3 (3.1)	0.0046
United States region						
West	56 (15.9)	5,982 (15.0)	0.3918	56 (16.1)	701 (17.2)	0.0820
Midwest	161 (45.6)	11,726 (29.3)		159 (45.7)	1,710 (41.8)	
South	107 (30.3)	17,185 (43.0)		106 (30.5)	1,309 (32.0)	
Northeast	29 (8.2)	5,046 (12.6)		27 (7.8)	367 (9.0)	
Missing Region	0 (0.0)	14 (0.0)		0 (0.0)	0 (0.0)	
Outpatient copayment, mean (SD), $	17.5 (5.8)	16.8 (6.7)	0.1141	17.6 (5.7)	16.9 (6.1)	0.1199
Employer size, mean (SD)	896.2 (1,705.0)	8,261.7 (21,490.7)	−0.4832	896.8 (1,714.5)	1,118.5 (3,406.0)	−0.0822
Employer size						
0–99	154 (43.6)	7,780 (19.5)	0.7451	154 (44.3)	1,708 (41.8)	0.1685
100–999	132 (37.4)	12,517 (31.3)		129 (37.1)	1,809 (44.3)	
1000+	67 (19.0)	19,656 (49.2)		65 (18.7)	569 (13.9)	
Substance use disorder	52 (14.7)	7,264 (18.2)	−0.0931	51 (14.7)	770 (18.8)	−0.1124
Bipolar type						
Type 1	251 (71.1)	29,232 (73.2)	0.0867	247 (71.0)	2,978 (72.9)	0.0867
Type 2	57 (16.1)	5,097 (12.8)		56 (16.1)	528 (12.9)	
Other	45 (12.7)	5,624 (14.1)		45 (12.9)	581 (14.2)	
Rural/urban residence						
Rural	23 (6.5)	2,934 (7.3)	0.055	23 (6.6)	333 (8.1)	0.038
Urban	318 (90.1)	35,720 (89.4)		313 (89.9)	3,636 (89.0)	
Unknown	12 (3.4)	1,299 (3.3)		12 (3.4)	118 (2.9)	

[a]Values are shown as n (%) unless otherwise noted. In the health savings account–eligible high-deductible health plan (HSA-HDHP) group, individuals experienced an employer-mandated switch to an HDHP eligible to have associated health savings account; those in the matched control group remained in low-deductible plans.
[b]A lower standardized difference indicates greater similarity.
[c]Based on 2008–2012 American Community Survey data at the census tract level. High income, < 5%–9.9%; low income, 10% to < 20%.
[d]Based on 2008–2012 American Community Survey data at the census tract level. Higher education, < 25%; lower education, ≥ 25%.
[e]Definition available in the Covariates subsection in Supplementary Appendix 1.
[f]Based on Johns Hopkins Adjusted Clinical Group (ACG) software. Higher scores indicate greater morbidity burden. The mean score in the overall sample (members in and not in this cohort) was 0.62 to 0.82 from 2003 to 2014.

member-level propensity[26,28,31] to join HDHPs, year of index date, employer baseline out-of-pocket/standardized cost ratio, baseline total out-of-pocket spending, and members' baseline total standardized cost (details in Supplementary Appendix 1). Evidence suggests that matching on baseline trends of outcome measures and baseline covariates in interrupted time series studies can substantially minimize bias.[32,33] Covariates are defined in Supplementary Appendix 1. After matching, the final study sample included 348 HSA-HDHP members with bipolar disorder and 4,087 matched controls. Using the 2008–2012 American Community Survey,[34] we further classified members as residing in census tracts with below-poverty levels of < 10% (hereafter, "higher-income") or ≥ 10% ("lower-income"). The final study sample included 137 lower-income HSA-HDHP members with 1,669 matched controls and 211 higher-income HSA-HDHP members with 2,418 matched controls.

Outcome Measures

We defined and classified bipolar disorder and non–bipolar disorder psychotropic medications based on National Drug Codes from pharmacy claims linked to First

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Table 2. Adjusted Difference-In-Differences Estimates in Annual Out-of-Pocket (OOP) Spending for Medications and Utilization of Medications Among Members With Bipolar Disorder Before and After a Mandated Switch to HSA-HDHPs, Compared With Contemporaneous Matched Members With Bipolar Disorder in Low-Deductible Plans[a]

Variable	HSA-HDHP		Control		Absolute Change (95% CI), HSA-HDHP vs Control		Relative Change (95% CI), HSA-HDHP vs Control	
	Baseline	Follow-Up	Baseline	Follow-Up				
OOP Cost, Total $/Member/Year								
All health care[b]	1,605.0	2,468.4	1,665.1	1,628.3	898.9	(672.6 to 1,125.2)	**57.3%**	**(40.4% to 74.1%)**
All pharmacy services	724.8	1,130.5	743.0	729.1	419.2	(305.7 to 532.7)	**58.9%**	**(42.1% to 75.8%)**
Bipolar disorder medications[c]	175.2	406.4	188.7	175.3	243.6	(175.2 to 312.0)	**149.7%**	**(109.9% to 189.5%)**
Antipsychotics	75.7	238.9	84.7	83.3	164.4	(105.0 to 223.9)	**220.9%**	**(150.0% to 291.8%)**
Anticonvulsants	87.0	156.4	92.9	79.6	81.8	(50.1 to 113.6)	**109.6%**	**(67.3% to 152.0%)**
Lithium	13.7	16.0	12.8	12.0	3.2	(−0.6 to 7.0)	25.0%	(−5.5% to 55.4%)
Non-bipolar psychotropics	216.0	285.8	222.9	213.4	79.0	(40.6 to 117.4)	**38.2%**	**(18.8% to 57.6%)**
All other medications	352.0	418.2	341.3	354.1	53.0	(−3.3 to 109.3)	14.5%	(−1.5% to 30.5%)
Medication Use (mean number of standardized medication doses/member/month)								
Bipolar disorder medications[c]	22.0	21.1	21.0	20.4	−0.3	(−2.4 to 1.8)	−1.4%	(−11.2% to 8.4%)
Antipsychotics	9.8	8.8	8.4	8.2	−0.9	(−2.6 to 0.9)	−8.9%	(−25.5% to 7.8%)
Anticonvulsants	8.9	8.9	9.8	9.3	0.4	(−0.7 to 1.4)	4.2%	(−8.0% to 16.3%)
Lithium	3.5	3.6	2.9	2.9	0.2	(−0.3 to 0.8)	6.4%	(−10.0% to 22.8%)
Non-bipolar psychotropics	33.1	31.8	32.9	32.5	−0.8	(−3.2 to 1.5)	−2.6%	(−9.8% to 4.6%)
All other medications	43.3	45.2	41.5	42.9	0.5	(−5.0 to 5.9)	1.1%	(−11.2% to 13.4%)

[a]Boldface indicates statistical significance.
[b]Total out-of-pocket expenditure includes all medical and pharmacy claims.
[c]Bipolar medications include the following medication classes: anticonvulsants, antipsychotics and lithium.
Abbreviation: HSA-HDHP = health savings account–eligible high-deductible health plan.

Data Bank and the American Hospital Formulary Service (AHFS) therapeutic classification hierarchy, which are gold standards for therapeutic classification.

We created 3 medication categories: (1) medications for treatment of bipolar disorder—lithium, selected anticonvulsants, and selected antipsychotic medications (Supplementary Table 1); (2) non–bipolar disorder psychotropics—anxiolytics, antidepressants, dementia medications, substance abuse medications, benzodiazepines, sedative/hypnotics, and psychotropic medications used to treat attention-deficit/hyperactivity disorder; and (3) "all other medications," which included the remaining medications such as those for cardiovascular disease, diabetes, and pain relief.

Medication use was measured as the mean monthly number of standardized medication doses (SMD). We created this person-level metric of treatment intensity based on the typical dose among users in the overall population, allowing capture of change in both frequency and dose of medication use for comparison over time and between study groups (details in Supplementary Appendix 1).

To examine cost-sharing increases among HSA-HDHP members relative to controls, we estimated mean annual out-of-pocket spending per person as the sum of individuals' copayment, coinsurance, and deductible amounts for all health services (medical and pharmacy services) in a study period divided by the number of people in a given study group. We also calculated monthly and yearly out-of-pocket spending per person for the above medication categories.

Moreover, we assessed the mean of the average wholesale price (AWP; a proxy for manufacturer's suggested retail price) for 30-day drug fills per person. Fills were spread across the days covered (ie, a 30-day fill claim on January 16 would be spread to indicate that the medication was available to the member from January 16 through February 14). Reductions in this measure among HSA-HDHP members relative to controls would suggest switching to lower-price generics or branded drugs within the given medication class.

Study Design and Analysis

We used a standardized differences approach to compare baseline characteristics of our study groups.[35] We applied an interrupted time series–with–comparison series design and a pre-post with control group design to estimate the effects of being switched by employers into HSA-HDHPs.[32,33,36]

We aligned relative time for all cohort members at their index dates. We constructed controlled interrupted time series plots with monthly points adjusted for the coarsened exact weights to display trends in our matched study groups. We used generalized estimating equations to compare changes in outcomes in the year before and after the index date among HSA-HDHP members versus controls. All models used a negative binomial distribution with a log link function given that all measures were counts. The term of interest was the 2-way interaction between indicators for cohort (HSA-HDHP or control group) and study time periods (the year before or after the index date).

We then applied marginal effects methods to calculate mean out-of-pocket spending, SMD, and AWP per 30-day fill during the baseline and follow-up years as well as absolute and relative changes.[37] We adjusted all regression models for the variables used in matching to control for residual imbalance. We analyzed data with SAS (version 9.3; SAS Institute Cary, North Carolina) and Stata (version 14; StataCorp; College Station, Texas) software. The study was approved by the Harvard Pilgrim Healthcare Institutional Review Board.

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Variable	HSA-HDHP		Control		Absolute Change (95% CI), HSA-HDHP vs Control		Relative Change (95% CI), HSA-HDHP vs Control	
	Baseline	Follow-Up	Baseline	Follow-Up				
Higher-Income								
OOP Cost, Total $/Member/Year								
All health care[b]	1,532.9	2,245.4	1,704.2	1,647.9	763.2	(503.3 to 1,023.1)	**51.5%**	**(30.7% to 72.3%)**
All pharmacy services	669.2	1,096.3	755.2	732.6	447.1	(308.2 to 585.9)	**68.9%**	**(45.2% to 92.5%)**
Bipolar disorder medications[c]	174.7	379.8	192.7	178.1	218.3	(142.5 to 294.1)	**135.2%**	**(86.4% to 184.0%)**
Antipsychotics	75.1	219.0	87.4	82.5	148.0	(80.3 to 215.7)	**208.6%**	**(119.1% to 298.1%)**
Anticonvulsants	83.8	154.1	93.3	82.9	79.7	(43.3 to 116.0)	**107.0%**	**(54.3% to 159.8%)**
Lithium	15.7	16.2	14.1	12.9	1.9	(−3.5 to 7.4)	13.4%	(−25.1% to 52.0%)
Non-bipolar psychotropics	207.8	331.3	234.2	221.7	134.6	(79.4 to 189.9)	**68.5%**	**(39.0% to 97.9%)**
All other medications	297.6	362.9	339.4	345.6	59.8	(−5.0 to 124.7)	19.7%	(−3.1% to 42.6%)
Medication Use (mean number of standardized medication doses/member/month)								
Bipolar disorder medications[c]	23.0	21.2	21.2	20.3	−0.8	(−3.7 to 2.0)	−3.8%	(−16.4% to 8.7%)
Antipsychotics	10.0	8.1	8.3	8.0	−1.4	(−3.2 to 0.4)	−14.7%	(−31.1% to 1.8%)
Anticonvulsants	9.2	9.5	9.8	9.3	0.8	(−0.7 to 2.2)	8.8%	(−8.0% to 25.6%)
Lithium	4.1	3.9	3.1	3.0	0.1	(−0.6 to 0.7)	1.6%	(−15.9% to 19.1%)
Non-bipolar psychotropics	31.2	30.0	34.2	33.8	−0.7	(−3.6 to 2.2)	−2.3%	(−11.7% to 7.0%)
All other medications	35.0	34.1	41.9	40.7	0.2	(−5.8 to 6.2)	0.5%	(−17.3% to 18.3%)
Lower-Income								
OOP Cost, Total $/Member/Year								
All health care[b]	1,733.1	2,798.5	1,618.0	1,600.4	1,084.2	(680.2 to 1,488.2)	**63.2%**	**(35.9% to 90.6%)**
All pharmacy services	815.6	1,194.0	728.6	724.3	383.2	(184.6 to 581.7)	**47.3%**	**(22.4% to 72.1%)**
Bipolar disorder medications[c]	177.7	437.8	184.1	171.5	272.3	(149.6 to 394.9)	**164.5%**	**(100.9% to 228.1%)**
Antipsychotics	74.7	258.7	82.4	86.1	180.6	(78.0 to 283.1)	**231.2%**	**(124.0% to 338.4%)**
Anticonvulsants	91.5	153.7	92.5	75.2	79.4	(25.5 to 133.2)	**106.7%**	**(41.1% to 172.3%)**
Lithium	13.5	18.3	10.6	10.8	4.5	(−1.3 to 10.3)	33.0%	(−14.0% to 80.0%)
Non-bipolar psychotropics	228.8	220.6	207.7	200.6	−0.4	(−48.8 to 48.1)	−0.2%	(−22.1% to 21.7%)
All other medications	450.3	520.8	348.0	372.2	39.2	(−71.6 to 150.0)	8.1%	(−15.2% to 31.5%)
Medication Use (mean number of standardized medication doses/member/month)								
Bipolar disorder medications[c]	21.1	21.0	20.9	20.7	0.0	(−3.4 to 3.5)	0.1%	(−16.3% to 16.5%)
Antipsychotics	10.2	10.2	8.5	8.7	−0.2	(−3.7 to 3.2)	−2.2%	(−34.8% to 30.4%)
Anticonvulsants	8.4	8.0	9.8	9.3	0.0	(−1.5 to 1.5)	0.4%	(−18.3% to 19.1%)
Lithium	2.9	3.6	2.6	2.7	0.6	(−0.4 to 1.5)	18.4%	(−15.6% to 52.4%)
Non-bipolar psychotropics	36.0	34.3	31.4	30.7	−1.1	(−5.2 to 3.1)	−3.0%	(−14.5% to 8.6%)
All other medications	65.2	65.7	44.4	47.1	−3.5	(−23.4 to 16.5)	−5.0%	(−32.9% to 22.8%)

[a]Boldface indicates statistical significance.
[b]Total out-of-pocket expenditure includes all medical and pharmacy claims.
[c]Bipolar medications include the following medication classes: anticonvulsants, antipsychotics and lithium.
Abbreviation: HSA-HDHP = health savings account–eligible high-deductible health plan.

RESULTS

After matching, all standardized differences between HSA-HDHP and control group characteristics were well below 0.2, except the proportion living in low-income neighborhoods, indicating minimal baseline differences (Table 1).[35] The mean age of HSA-HDHP and control members was 38 years, and 60%–61% in each group were female. About 39%–41% lived in lower-income neighborhoods, 4%–5% lived in lower-education neighborhoods, 3%–4% were Hispanic, and the mean (SD) Adjusted Clinical Group (ACG) morbidity score was 2.3 (3.0).

In adjusted difference-in-differences analyses, pre-to-post out-of-pocket spending for all health services and pharmacy services increased by 57.3% (95% CI, 40.4% to 74.1%; Table 2) and 58.9% (95% CI, 42.1% to 75.8%), respectively, among HSA-HDHP members relative to controls. Both higher-income and lower-income HSA-HDHP members experienced significant pre-to-post increases in these outcomes (Table 3).

Figure 1 presents interrupted time series plots of monthly out-of-pocket spending for bipolar disorder medications. HSA-HDHP members experienced a 149.7% (95% CI, 109.9% to 189.5%) increase in out-of-pocket spending for bipolar disorder medications in the follow-up year compared with baseline relative to control group members. Specifically, out-of-pocket spending increased for antipsychotics (relative change: 220.9% [95% CI, 150.0% to 291.8%]) and anticonvulsants (relative change: 109.6% [95% CI, 67.3% to 152.0%]); the increase for lithium did not reach statistical significance (relative change: 25.0% [95% CI, −5.5% to 55.4%]). The HSA-HDHP group also experienced a 38.2% [95% CI, 18.8% to 57.6%]) relative pre-to-post increase in out-of-pocket spending for non-bipolar psychotropics; the increase in out-of-pocket spending for all other medications did not reach statistical significance (14.5% [95% CI, −1.5% to 30.5%]).

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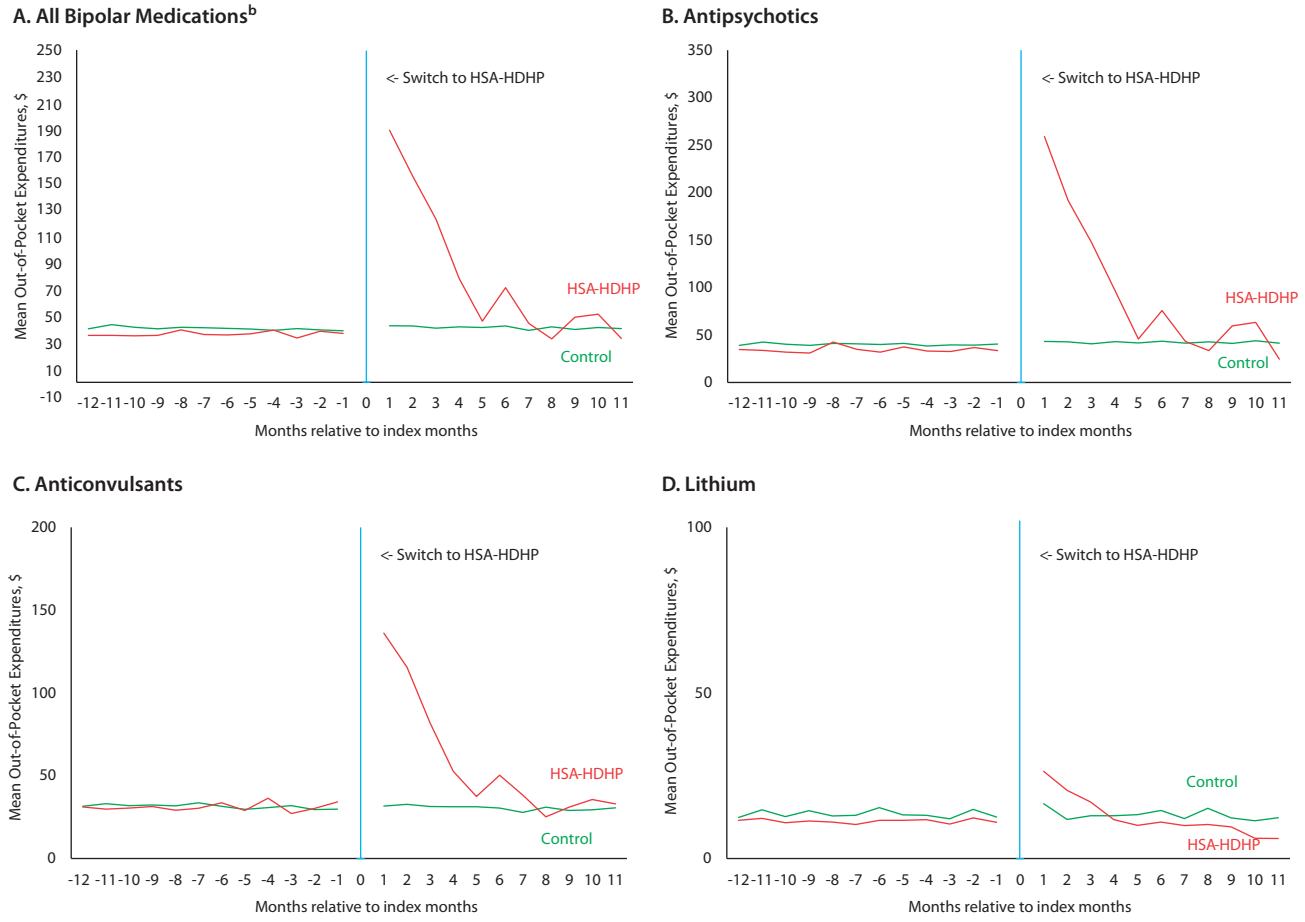
Figure 1. Monthly Out-Of-Pocket Spending for (A) All Bipolar Disorder Medications, (B) Antipsychotics, (C) Anticonvulsants, and (D) Lithium Among Members With Bipolar Disorder Before and After a Mandated Switch to HSA-HDHPs Compared With Matched Controls Who Were in Low-Deductible Plans in Both Years[a]



[a]Vertical blue lines are centered at the index month when HSA-HDHP group members were switched into HSA-HDHPs.
[b]Bipolar medications include the following medication classes: anticonvulsants, antipsychotics, and lithium.
Abbreviation: HSA-HDHP = health savings account–eligible high-deductible health plan.

In subgroup analyses, both higher-income and lower-income HSA-HDHP members experienced increases in out-of-pocket spending for bipolar disorder medications (135.2% [95% CI, 86.4% to 184.0%] and 164.5% [95% CI, 100.9% to 228.1%], respectively; Table 3).

Figure 2 presents interrupted time series plots of monthly SMD to assess intensity of medication use. In adjusted difference-in-differences analyses, we detected no statistically significant changes in use of bipolar disorder medications, non–bipolar disorder psychotropics, or all other prescription medications among all HSA-HDHP members (Table 2) as well as among higher- and lower-income HSA-HDHP members (Table 3).

In adjusted difference-in-differences analyses, we detected no statistically significant changes in AWP per 30-day fill of bipolar disorder medications, non–bipolar disorder psychotropics, and all other prescription medications among all HSA-HDHP members and higher-income HSA-HDHP members (Supplementary Table 2). Among lower-income HSA-HDHP members, we found relative reductions of 10.2% (95% CI, −19.7% to −0.7%) and 9.2% (95% CI, −17.1% to −1.3%) in AWP per 30-day fill of anticonvulsants and lithium, respectively.

DISCUSSION

This study is the first to examine effects of employer-based HSA-HDHPs on medication out-of-pocket spending and use among people with a chronic mental health condition. We used a large, nationwide sample of commercially insured individuals with bipolar disorder diverse in income, age, and geography. Our study groups were not offered a choice of health plans with different deductible levels, minimizing self-selection. We used strong longitudinal analysis methods and coarsened exact matched controls to reduce bias in estimating HSA-HDHP impacts.

We found that HSA-HDHP members with bipolar disorder faced large increases in out-of-pocket spending for all health services (57%), all pharmacy services (59%), and medically necessary antipsychotic and anticonvulsant

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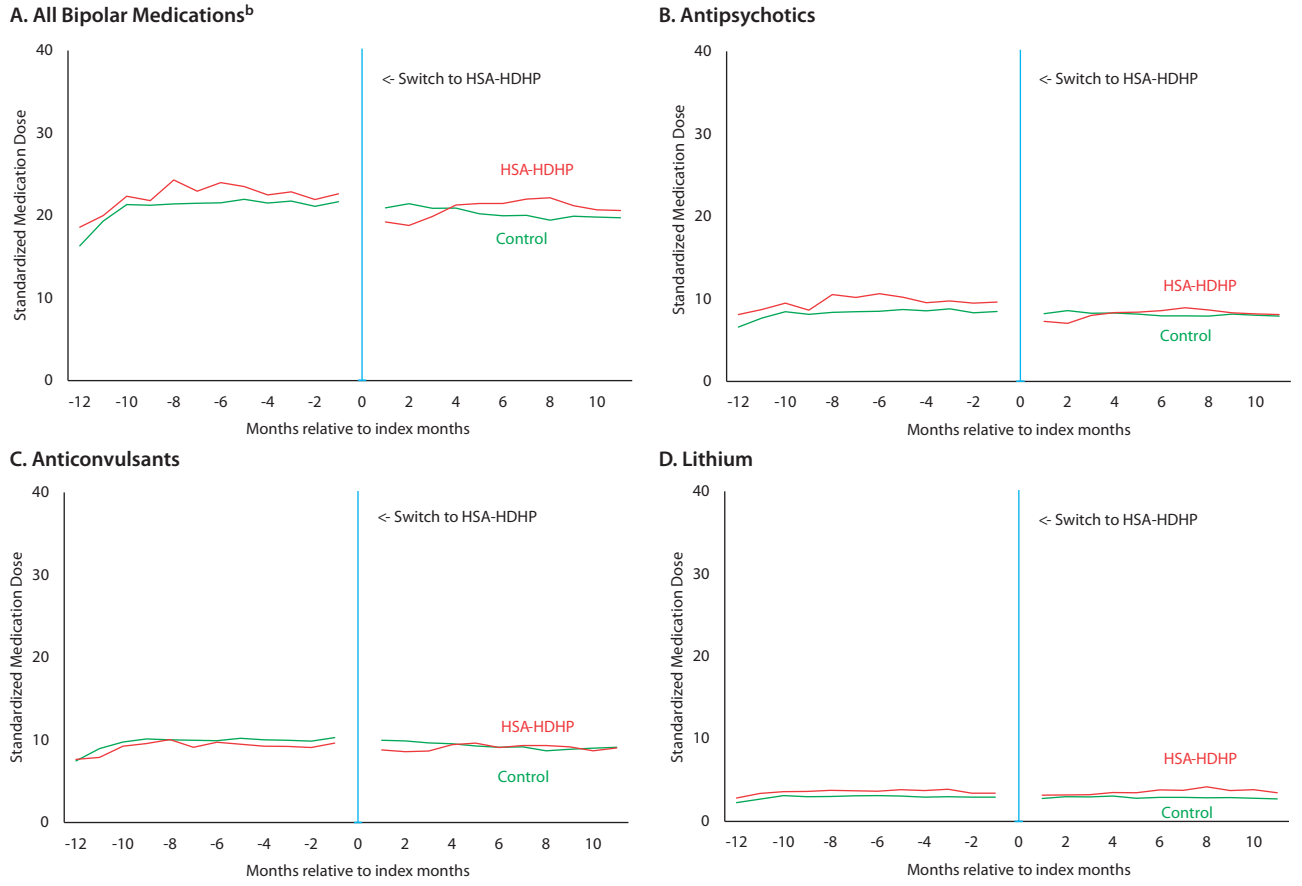
Figure 2. Mean Monthly Number of Standardized Medication Doses for (A) All Bipolar Disorder Medications, (B) Antipsychotics, (C) Anticonvulsants, and (D) Lithium Among Members With Bipolar Disorder Before and After a Mandated Switch to HSA-HDHPs Compared With Matched Controls in Low-Deductible Plans in Both Years[a]



[a]Vertical blue lines are centered at the index month when HSA-HDHP group members were switched into HSA-HDHPs.
[b]Bipolar medications include the following medication classes: anticonvulsants, antipsychotics, and lithium.
Abbreviation: HSA- HDHP = health savings account–eligible high-deductible health plan.

medications (150%), which is concerning. However, our study cannot estimate the extent to which these large increases were a financial strain for some members (eg, leading to cutting back in other essential spending areas), which could lead to unmeasured adverse outcomes. Importantly, while both higher- and lower-income HSA-HDHP members substantially increased out-of-pocket spending for bipolar disorder medications, we found that the cost burden was more pronounced among lower-income members. Negative consequences associated with increases in cost burden might be greater among vulnerable subgroups (eg, those with low income, racial/ethnic minorities, those with multimorbidity, and those with complex conditions that may require expensive medical management such as high-cost biologics), exacerbating health disparities. Moreover, increased cost burden and associated negative consequences might also be more pronounced among HDHP members in the individual market because they do not have the financial protection of HSA contributions that some employers provide and because monthly premiums are generally higher.

We also found that HSA-HDHPs were associated with larger increases in out-of-pocket spending for bipolar disorder medications than for other psychotropics and medications for somatic conditions (150%, vs 38% and 14%, respectively). Given the stable medication use that we detected, these findings suggest differences in cost-sharing increases between medications for bipolar disorder versus other medications. These increases might lead to or exacerbate health disparities in people with mental health conditions.

The 1970–1980s RAND Health Insurance Experiment[38] found that high cost-sharing reduced both appropriate and inappropriate utilization among all types of patients. Previous studies identified that higher cost-sharing among Medicaid and commercially insured enrollees with serious mental illness was associated with lower medication use and increased hospitalization and emergency mental health visits.[16–21] In contrast, we found no statistically significant changes in use of bipolar disorder and non–bipolar disorder psychotropic medications among HSA-HDHP members, including lower-income HSA-HDHP members.

Our findings might be explained by a variety of factors. First, HSA funds might have helped maintain medication use.[1] In addition, HSA-HDHP members generally pay

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lower premiums, so the premium savings from switching to these plans might partially or fully offset the increases in out-of-pocket payments. Further, HSA-HDHP members with a chronic illness might be reasonably familiar with the nuances of commercial health insurance designs and might have little incentive to cut back on medications as they might anticipate exceeding their deductibles each year and subsequently transition to lower cost-sharing (as shown in Figure 1). Another potential interpretation of these findings is that HSA-HDHP members with bipolar disorder recognize that psychotropic medications are essential for their well-being and daily functioning and were reluctant to jeopardize those by cutting back on medications. This interpretation is consistent with our previous analysis that detected no change in psychiatrist visits among HDHP members with bipolar disorder and concomitant declines in non-psychiatrist mental health outpatient visits (commonly psychotherapy).[27] Our interview study[15] indicates that people with bipolar disorder value and benefit from psychotropic medications, and psychiatrist and non-psychiatrist mental health visits but that they prioritize select care because of financial toxicity. With substantial and concerning increases in out-of-pocket burdens (110%–221%) for antipsychotic and anticonvulsant medications, people might have rationed other essential services, and such trade-offs could lead to increases in unmeasured adverse outcomes. We also observed reductions in AWP per 30-day fill of anticonvulsants and lithium among lower-income members, suggesting some people might have switched to lower-priced therapeutic alternatives to maintain medication use. However, we cannot draw definitive conclusions given the small sample size.

The unintended consequences of increased out-of-pocket spending for mental health care and medications warrant further research. In particular, in the employer market, it is important to better understand the extent to which different employee benefit structures such as contributions to premiums and HSAs modify the effects we detected and the adverse outcomes of financial toxicity among vulnerable subgroups of employees with bipolar disorder and other complex conditions. In the individual market, research should examine HDHP effects given the lack of employer assistance and higher premiums; it is plausible that these enrollees experience reduced medication adherence.

In 2013, more than 40% of large employers offered a preventive drug benefit in HSA-HDHPs, which exempt certain preventive and maintenance medications from the annual deductible[39,40] (eg, antidiabetic medications). In 2019, the Internal Revenue Service modified HSA-HDHP regulations[5] to encourage employer adoption of preventive drug lists with no drug cost-sharing for certain conditions, but not bipolar disorder. Including medically necessary bipolar disorder and non–bipolar disorder psychotropic medications under such guidance would facilitate medication access and potentially offset the negative effects of high cost-sharing in HSA-HDHPs.

Our study has several limitations. We included individuals with employer-sponsored health insurance enrolled through a single (though very large) national health plan. Our results should generalize to many people with bipolar disorder in employer-sponsored plans. HDHPs are increasingly common in commercial health insurance. However, individuals in employer-sponsored commercial plans may be at lower risk of financial toxicity compared to counterparts with less generous self-purchased commercial plans.[41] HDHPs are not seen in Medicaid or Medicare insurance plans, so our results are not generalizable to those populations. We did not have data on the employer or member HSA contributions or balances, which may affect how members make health care purchasing decisions. Members with smaller HSA balances might be affected more by the cost burden of HSA-HDHPs. Even with our large, national, commercially insured population, we identified only about 350 HSA-HDHP members with bipolar disorder. We therefore had limited power to detect changes in medication use. Nevertheless, our study offers the first data on the effects of HSA-HDHPs among individuals with bipolar disorder. Another limitation of our study is that we have insufficient power to examine the effect of HSA-HDHPs among individuals with bipolar I versus bipolar II disorder. Prior research[42,43] indicates that individuals with bipolar I disorder have higher rates of hospitalization than those with bipolar II disorder. Thus, individuals with bipolar I disorder and those with bipolar II disorder might have different sensitivities to medication expenses, but we are unable to examine this due to insufficient power for a stratified analysis. Finally, our findings may not be representative of the most vulnerable HDHP members with bipolar disorder, such as members with very high deductibles or more severe bipolar disorder and those with multimorbidities. We did not have sufficient power to examine HSA-HDHP impacts among these vulnerable subgroups.

In conclusion, our results offer early insights into HSA-HDHP effects among individuals with a chronic mental health condition requiring regular treatment. We did not detect changes in use of bipolar disorder and non–bipolar disorder psychotropic medications among HSA-HDHP members and among higher- and lower-income subgroups. However, HSA-HDHP members experienced substantial and concerning increases in out-of-pocket obligations for crucial medications, which could cause financial strain. Further research is needed to examine the broader consequences of such major increases in patient cost-sharing.

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Previous presentation: An abstract entitled "The Impact of Consumer-Directed Health Plans on Medication Use among Patients with Bipolar Disorder" was presented as a poster at the AcademyHealth Annual Research Meeting; 2018; Seattle, Washington.

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Supplementary material: Available at PSYCHIATRIST.COM

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Supplementary Material

Article Title: High-Deductible Health Plans Paired With Health-Savings Accounts Increased Medication Cost Burden Among Individuals With Bipolar Disorder

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List of Supplementary Material for the article

1. **Appendix 1** Supplementary Methods
2. **Table 1** Hierarchical ingredient code list (HICL) and generic names for medications included in analyses
3. **Table 2** Adjusted difference-in-differences estimates in average wholesale price for medications among members with bipolar disorder (BD) before and after a mandated switch to HSA-HDHPs, compared with contemporaneous matched members with bipolar disorder in low-deductible plans, by study group (all members, higher-income, and lower-income)

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Appendix 1

Annual Deductible Imputation

To estimate employer annual deductibles, we used a benefits variable available for most smaller employers (approximately ≤100 employees) and for larger employers, we imputed deductible levels using out-of-pocket costs among employees who utilized health services, an algorithm that had 96.2% sensitivity and 97.0% specificity[27,28].

Bipolar Cohort and Bipolar Type Identification Algorithm

We included individuals with diagnosis codes for bipolar I (International Classification of Diseases, 9th revision [ICD-9-CM] codes: 296.0x-296.1x, 296.4x-296.7), bipolar II (296.89), or other unspecified bipolar disorder (296.80-296.82, 301.11, 301.13), and assigned them to one of those three categories based on their earliest qualifying diagnoses of either 1 inpatient claim (with a first position diagnosis), or 2 outpatient claims (with a first or second position diagnosis) on separate days within 24 months of each other. If individuals had more than one qualifying bipolar category, bipolar I was given priority, then bipolar II. Individuals also qualified if their only diagnoses were from outpatient claims within the 2-year timeframe and on different days, but from different bipolar categories. These members were categorized as other unspecified bipolar disorder. Then we excluded members with schizophrenia or schizoaffective disorder diagnoses (ICD-9-CM: 295.0-295.95).

Medications for Treatment of Bipolar Disorder

We included the following: lithium, four guideline-recommended anticonvulsants (carbamazepine, divalproex sodium, lamotrigine, and valproic acid), and select first generation antipsychotic medications (chlorpromazine, droperidol, fluphenazine, haloperidol, loxapine, perphenazine, pimozide, prochlorperazine, thioridazine, thiothixene, trifluoperazine), and second-generation antipsychotics (aripiprazole, asenapine, clozapine, iloperidone, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, ziprasidone).

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Covariates

Using 2008-2012 American Community Survey 5-year estimates at the census tract level,[34,44,45] we classified members according to the income and education levels of their neighborhood. Income categories were based on living in neighborhoods with below poverty-levels of <5%, 5%-9.9%, 10%-19.9%, and >=20%. We categorized neighborhoods having proportions of households below the Federal Poverty Level of <9.9% as higher income and >=10% as lower income. We used a similar approach to categorize education levels (neighborhood residence with below-high-school education levels of <15%, 15%- 24.9%, 25%-39.9%, and >=40%). We classified neighborhoods having proportions of adults without a high school diploma of <25.0% as higher education and >=25.0% as lower education. We used geocoding to classify participants as living in predominantly (>75%) white, black, Hispanic, or mixed neighborhoods, and we further overwrote the classification of select participants as Hispanic or Asian using the E-Tech system (Ethnic Technologies), which analyzes full names and geographic locations of individuals.[46,47] This validated approach of combining name analysis and Census data has positive and negative predictive values of approximately 80% and 90%, respectively.[47] To estimate morbidity, we applied the ACG algorithm to members' baseline year. The algorithm uses age, sex, and diagnoses to calculate a morbidity score and the average of the reference population is 1.0. Researchers have validated this morbidity score against premature mortality.[48,49] Age categories were 12-18, 19-29, 30-39, 40-49, and 50-64 years. US regions of residence were West, Midwest, South, and Northeast. We created employer size categories of 0-99, 100-999, and 1000+ enrollees.

Matching Strategy

Coarsened exact matching tries to mimic the process of stratification by population characteristics and then randomization within the defined strata (i.e., fully blocked randomization). Coarsened exact matching is similar to exact matching but it classifies matching variables into discrete categories (e.g., 5-year age groups instead of continuous age in years). The final sample includes all members in both study groups that have common classification criteria. Coarsened exact matching software creates weights for all members in the matched strata to equalize the percentage of members in a given strata between the study groups.

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We used coarsened exact matching on the propensity (tertiles) of the employer to mandate high-deductible insurance (component variables described below), the propensity (tertiles) of individuals to work for such employers (component variables described below), year of index date, quartile for employer baseline out-of-pocket spending to standardized cost ratio, four categories of baseline total out-of-pocket spending, and quartile for a member's baseline total standardized cost. The logistic model for calculating employer propensity to join a HDHP predicted this likelihood based on employer size; proportion of women; proportions of members in each of 4 US regions and in race/ethnicity, age, education, and income categories; baseline monthly total standardized cost; the employer's mean ACG score; median copay; index month/year; and type of insurance plan (HMO, PPO, POS). We constructed the corresponding member-level propensity model to ensure contemporaneous study groups as well as to balance key characteristics, thus this model included age category, US region, employer size category, year of first qualifying diagnosis, baseline count of prescription medication categories, and baseline quarterly pharmacy out-of-pocket spending.

Standardized Medication Dose Measure Construction

We conducted several steps to create a repeated measure to examine medication use over time. First, we identified the median number of units dispensed per day (e.g., one tablet) for a specific product (e.g., lithium 600mg tablets) using data on units dispensed and days' supply in pharmacy claims among users from the entire population represented in our national database for each year during the study period. We then converted each dispensing during the year to the number of standardized medication doses (SMDs) dispensed per day. In our example, if the median number of daily units dispensed for all individuals in the population who took lithium 600mg was one tablet per day, a dispensing of two tablets per day would represent an SMD of 2.0. The value 2.0 would be assigned to each day following that particular dispensing for the number of days' supply dispensed. Finally, we estimated the average monthly and yearly numbers of SMD per person as the sum of SMD dispensed for medications of interest in 30-day time periods and in the baseline or follow-up year divided by the number of people in a given study group. Months were characterized as 30-day time periods relative to the index date.

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Supplementary Table 1. Hierarchical ingredient code list (HICL) and generic names for medications included in analyses

Drug Class	HICL Sequence Numbers	Generic Names
Guideline Anti-Convulsant	11735, 1893, 1884, 7378, 1883, 1882	Oxcarbazepine, Carbamazepine, Divalproex Sodium, Lamotrigine, Valproic Acid, Valproate Sodium
Typical Antipsychotics	1621, 1624, 1625, 1626, 1662, 1660, 1661, 1663, 1664, 1635, 1666, 1627, 13819, 1637, 1622, 1631, 1668, 1667, 1630, 1623	Chlorpromazine HCl, Fluphenazine Decanoate, Fluphenazine Enanthate, Fluphenazine HCl, Haloperidol, Haloperidol Decanoate, Haloperidol Lactate, Loxapine HCl, Loxapine Succinate, Mesoridazine Besylate, Molindone HCl, Perphenazine, Perphenazine/Amitriptyline HCl, Pimozide, Promazine HCl, Thioridazine HCl, Thiothixene, Thiothixene HCl, Trifluoperazine HCl, Triflupromazine HCl
Atypical Antipsychotics	24551, 42595, 36576, 42283, 4834, 36778, 37321, 11814, 36716, 25800, 34343, 36479, 14015, 8721, 25509, 21974, 23379	Aripiprazole, Aripiprazole Lauroxil, Asenapine Maleate, Brexpiprazole, Clozapine, Iloperidone, Lurasidone HCl, Olanzapine, Olanzapine Pamoate, Olanzapine/Fluoxetine HCl, Paliperidone, Paliperidone Palmitate, Quetiapine Fumarate, Risperidone, Risperidone Microspheres, Ziprasidone HCl, Ziprasidone Mesylate
Lithium	35133, 1669, 1670, 37605	Lithium Aspartate, Lithium Carbonate, Lithium Citrate, Lithium Citrate Tetrahydrate

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Supplementary Table 2: Adjusted difference-in-differences estimates in average wholesale price for medications among members with bipolar disorder (BD) before and after a mandated switch to HSA-HDHPs, compared with contemporaneous matched members with bipolar disorder in low-deductible plans, by study group (all members, higher-income, and lower-income)

	HSA-HDHP		Control		Absolute Change HSA-HDHP vs. Control (95% CI)		Relative Change HSA-HDHP vs. Control (95% CI)	
	Baseline	Follow-Up	Baseline	Follow-Up				
Average wholesale price (AWP), by 30-day fill equivalent								
All members								
Bipolar disorder Medications[1]	214.2	213.5	216.2	230.9	-15.3	(-32.3, 1.7)	-6.7%	(-13.8%, 0.5%)
Antipsychotics	331.2	325.6	320.7	343.9	-29.5	(-70.5, 11.4)	-8.3%	(-19.4%, 2.8%)
Anticonvulsants	184.0	185.5	192.9	201.4	-6.6	(-21.8, 8.5)	-3.4%	(-11.2%, 4.3%)
Lithium	28.5	26.4	29.2	29.4	-2.4	(-6.1, 1.3)	-8.4%	(-20.7%, 3.8%)
Non-bipolar psychotropics	108.8	102.8	112.3	114.6	-8.3	(-18.8, 2.3)	-7.4%	(-16.4%, 1.5%)
All Other Medications	147.8	156.1	150.6	166.5	-7.4	(-39.8, 25.0)	-4.5%	(-24.1%, 15.0%)
Higher-Income								
Bipolar disorder Medications[1]	211.9	206.1	218.9	230.8	-17.2	(-39.6, 5.1)	-7.7%	(-17.3%, 1.9%)
Antipsychotics	318.8	316.7	321.3	347.2	-27.7	(-83.7, 28.3)	-8.0%	(-23.8%, 7.7%)
Anticonvulsants	178.6	186.8	195.7	201.0	3.4	(-16.7, 23.5)	1.9%	(-9.2%, 12.9%)
Lithium	28.8	25.7	30.8	29.9	-2.3	(-7.6, 3.1)	-8.1%	(-26.4%, 10.1%)
Non-bipolar psychotropics	115.6	106.6	113.3	115.5	-11.2	(-27.0, 4.6)	-9.5%	(-22.0%, 3.0%)
All other medications	160.7	165.6	150.0	175.0	-22.0	(-72.8, 28.8)	-11.7%	(-37.7%, 14.3%)
Lower-Income								
Bipolar disorder Medications[1]	212.8	222.4	212.7	231.2	-8.8	(-34.1, 16.4)	-3.8%	(-14.5%, 6.9%)
Antipsychotics	347.1	336.7	320.3	339.4	-31.1	(-87.1, 25.0)	-8.4%	(-22.9%, 6.9%)
Anticonvulsants	187.1	179.4	189.0	201.7	-20.3	(-40.7, 0.0)	**-10.2%**	**(-19.7%, -0.7%)**
Lithium	27.5	26.8	26.9	28.8	-2.7	(-5.4, -0.1)	**-9.2%**	**(-17.1%, -1.3%)**
Non-bipolar psychotropics	99.0	98.4	111.0	113.3	-2.6	(-12.9, 7.6)	-2.6%	(-12.5%, 7.3%)
All other medications	134.3	143.1	149.9	151.8	7.1	(-25.1, 39.4)	5.2%	(-18.8%, 29.3%)

Abbreviations: HSA-HDHP, high-deductible health plan eligible to have associated health savings account; AWP, average wholesale price

[1]Bipolar medications include the following medication classes: anticonvulsants, antipsychotics and lithium

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