Assessing the Relationship Between Copay Adjustment Program Exposure and Household Income Levels in a Cohort of Patients With Schizophrenia

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BACKGROUND

Copay adjustment programs (CAPs), including Accumulator and Maximizer programs, shift copay adjustment assistance away from patients, which may impose additional copayment burden to patients due to delays in reaching annual deductibles[1-6]

Copayment burden is associated with poorer medication adherence and treatment outcomes in patients with schizophrenia[7]

Overall CAP exposure and how it varies by household income (HHI) level in commercially insured patients with schizophrenia are unknown

OBJECTIVES

- To describe patient demographic and geographic characteristics by copay card usage among commercially insured patients classified within the schizophrenia therapeutic area
- To assess the prevalence of copay card usage across different HHI levels among commercially insured patients classified within the schizophrenia therapeutic area
- To assess the prevalence of CAP exposure (as Accumulators and Maximizers) across different HHI levels among commercially insured patients classified within the schizophrenia therapeutic area

METHODS

Study Design

- A retrospective, cross-sectional study was conducted using IQVIA Longitudinal Access and Adjudication Data (LAAD) linked to Experian™ Marketing Solutions, LLC, consumer data (referred to as consumer marketing attributes data) between January 1, 2019, and September 30, 2021 (study period)
- Unique patients who were covered by commercial insurance, had ≥1 pharmacy claim with reliable payer information for treatment classified within the schizophrenia therapeutic area, had ≥1 active pharmacy claim in all 3 years during the study period, and had matched consumer marketing attributes data were identified
  - Pharmacy claims included branded, generic, and biosimilar treatments for schizophrenia
- Patients included in this study were required to have full demographic (i.e., age, sex, race/ethnicity, state of residence, HHI), pharmacy benefit manager (PBM), state-level CAP policy, and overall drug cost data
- Patients designated as copay card users were classified into 3 cohorts following prespecified CAP classification rules (**Table 1**)

Table 1. Patient CAP Classification

CAP analysis cohort[a]	Description
Accumulators[b]	• Patients with ≥3 prescriptions with a high patient cost exposure that are >50% of a treatment's WAC price • Patients with high annual cumulative patient cost exposures (e.g., >$10,000 in a given year) across ≥3 prescriptions of the same treatment • Patients with unsuccessful mitigation by the manufacturer, shown as ≥2 prescriptions with equal and high copay card buydown amounts but with minimal decreases in patient cost exposures over time • Patients with ≥3 prescriptions with high patient cost exposure that are decreasing by copay card program PALA amounts
Maximizers	• Patients with ≥3 prescriptions at the same high initial patient cost exposure for a product within a therapeutic area
Neither	• Patients not meeting the above criteria

CAP, copay adjustment program; WAC, wholesale acquisition cost; PALA, pay-as-little-as.
[a]All patients were first identified as commercial copay card users with activity every year from January 1, 2019, to September 30, 2021, with valid payer information of PALA amounts; all categories were mutually exclusive.
[b]Patients meeting any of these criteria were classified as Accumulators.

Outcome Measures

- Prevalence of copay card usage was assessed at the patient level by flagging commercial claims with ≥1 copay card claim classified within the schizophrenia therapeutic area
- Prevalence of CAP exposure was assessed at the patient level by flagging commercial patients with ≥1 copay card claim classified within the schizophrenia therapeutic area as Accumulators and Maximizers among patients with sufficient and complete cost data (**Table 1**)

Statistical Analyses

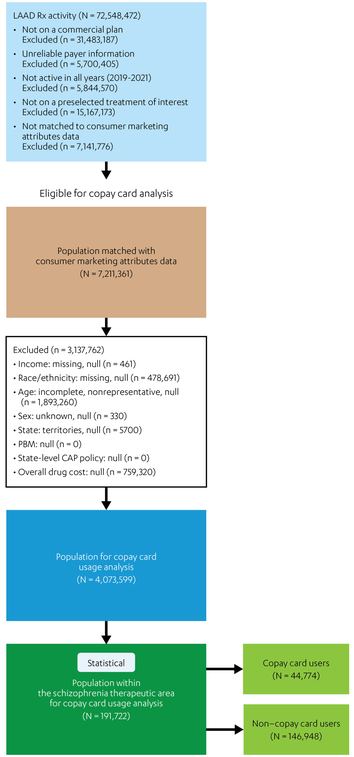
- All categorical variables were summarized with frequencies and percentages
- All continuous variables were summarized with measures of central tendency (mean, median, standard deviation, interquartile range, minimum, and maximum)
- Multivariable logistic regression and multinomial regression were conducted to examine the association of HHI with copay card usage and CAP prevalence, respectively, adjusting for age, sex, race/ethnicity, state of residence, PBM, state-level CAP policy, and overall drug cost
  - HHI was defined as the income levels derived for households or families; it was grouped into 6 categories, including <$25,000, $25,000 to $49,999, $50,000 to $74,999, $75,000 to $99,999, $100,000 to $149,999, and ≥$150,000; the HHI level of ≥$150,000 was used as the reference category
- All analyses were conducted assuming a 2-tailed test of significance and an alpha level set *a priori* at 0.05 using R Release 4.0.3 (R Foundation for Statistical Computing)

RESULTS

Patients

- A total of 191,722 unique patients were included in the copay card analysis for patients with claims classified within the schizophrenia therapeutic area (**Figure 1**)
- A total of 44,774 (23.4%) patients classified within the schizophrenia therapeutic area were identified as copay card users and 146,948 (76.6%) were non–copay card users
- The demographic characteristics of patients classified within the schizophrenia therapeutic area are listed in **Table 2**

Figure 1. Flowchart of patient selection.



LAAD, Longitudinal Access and Adjudication Data; Rx, pharmacy; PBM, pharmacy benefit manager; CAP, copay adjustment program.

Table 2. Demographic Characteristics of Commercially Insured Patients Classified Within the Schizophrenia Therapeutic Area

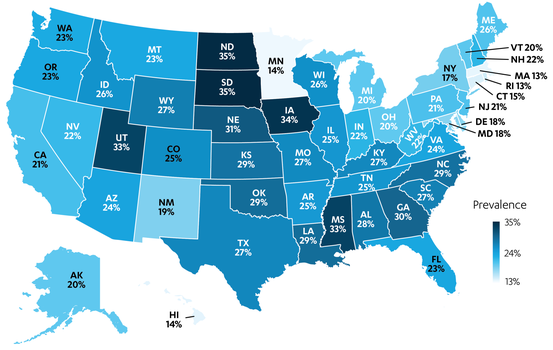
Demographic characteristic, n (%)		Copay card users (N = 44,774)	Non–copay card users (N = 146,948)
Age group	<18 years	141 (0.3)	544 (0.4)
	18-34 years	12,120 (27.1)	42,423 (29.0)
	35-44 years	10,557 (23.6)	33,989 (23.1)
	45-54 years	12,175 (27.2)	37,936 (25.8)
	55-64 years	9781 (21.8)	31,856 (21.7)
Sex	Female	31,367 (70.1)	101,866 (69.3)
	Male	13,407 (29.9)	45,082 (30.7)
Race/ethnicity	White	39,722 (88.7)	128,113 (87.2)
	Non-White[a]	5052 (11.3)	18,835 (12.8)
PBM	1	10,643 (23.8)	42,195 (28.7)
	2	9390 (21.0)	34,625 (23.6)
	3	5131 (11.5)	12,424 (8.5)
	4	8818 (19.7)	27,479 (18.7)
	Other	10,792 (24.1)	30,225 (20.6)
State-level CAP policy status	Yes	13,082 (29.2)	37,643 (25.6)
	No	31,692 (70.8)	109,305 (74.4)

PBM, pharmacy benefit manager; CAP, copay adjustment program.
[a]Non-White included African American, Hispanic, Native American, Southeast Asian, Central and Southwest Asian, Far Eastern Polynesian, and other.

Copay Card Usage

- Copay card usage in the schizophrenia therapeutic area varied by state, ranging from 13% in Rhode Island (RI) and Massachusetts (MA) to 35% in North Dakota (ND) and South Dakota (SD) (**Figure 2**)

Figure 2. Prevalence of copay card usage by state in the schizophrenia therapeutic area.



- In an adjusted analysis of 191,722 patients classified within the schizophrenia therapeutic area, there were no significant differences in the use of copay cards between any of the lower income categories and the reference HHI level of ≥$150,000 (**Table 3**; **Figure 3A**)

Table 3. Copay Card Usage and CAP Exposure, by HHI level, of Commercially Insured Patients Classified Within the Schizophrenia Therapeutic Area

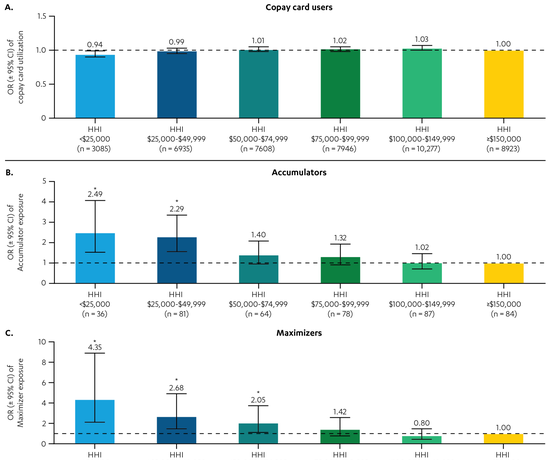
HHI level, n (%)	Copay card users (N = 44,774)	Non–copay card users (N = 146,948)	CAP analysis cohort		
			Accumulators (n = 430)	Maximizers (n = 181)	Neither (n = 6682)
<$25,000	3085 (20.8)	11,728 (79.2)	36 (8.2)	22 (5.0)	380 (86.8)
$25,000-$49,999	6935 (22.5)	23,929 (77.5)	81 (7.7)	33 (3.1)	939 (89.2)
$50,000-$74,999	7608 (23.5)	24,722 (76.5)	64 (5.3)	32 (2.7)	1104 (92.0)
$75,000-$99,999	7946 (23.9)	25,337 (76.1)	78 (5.7)	31 (2.3)	1248 (92.0)
$100,000-$149,999	10,277 (24.1)	32,402 (75.9)	87 (5.0)	28 (1.6)	1621 (93.4)
≥$150,000	8923 (23.6)	28,830 (76.4)	84 (5.6)	35 (2.3)	1390 (92.1)

CAP, copay adjustment program; HHI, household income.

CAP Prevalence

- Among the copay card users, 7293 (16.3%) met inclusion criteria for the CAP analysis (430 [5.9%] were Accumulators, 181 [2.5%] were Maximizers, and 6682 [91.6%] were Neither; **Table 3**)
- Compared to patients with an HHI level of ≥$150,000 (n = 1509), patients with an HHI level of <$25,000 (n = 438) and of $25,000 to $49,999 (n = 1053) were significantly more likely to be exposed to Accumulators (odds ratio [OR] 2.49; 95% confidence interval [CI] = 1.53-4.07 and OR 2.29; 95% CI = 1.56-3.35, respectively; **Figure 3B**) and Maximizers (OR 4.35; 95% CI = 2.12-8.90 and OR 2.68; 95% CI = 1.47-4.91, respectively; **Figure 3C**)
- Patients with an HHI level of $50,000 to $74,999 (n = 1200) were significantly more likely to be exposed to Maximizers (OR 2.05; 95% CI = 1.12-3.74) than patients with an HHI level of ≥$150,000 (**Figure 3C**)

Figure 3. Likelihood of (A) copay usage, (B) CAP prevalence as Accumulators, and (C) CAP prevalence as Maximizers between lower HHI levels and the highest HHI level (≥$150,000; reference) within the schizophrenia therapeutic area.



CAP, copay adjustment program; HHI, household income; OR, odds ratio; CI, confidence interval.
*P <0.05 versus ≥$150,000 HHI reference.

LIMITATIONS

- The study did not confirm schizophrenia diagnosis using medical claims and may have included patients without schizophrenia
- These results may not be generalizable beyond the schizophrenia therapeutic area
- This study evaluated socioeconomic-level data according to household values for income; however, it should be noted that many patients with schizophrenia are unemployed[8]
- This is a study of commercially insured patients eligible for copay cards; therefore, it excluded patients ≥65 years of age and patients with lower income who do not qualify for Medicare/Medicaid
- Study results may be affected by confounders (e.g., disease severity, comorbidities) that were not explicitly evaluated in the study, although prior year drug expense was included as a covariate in the model
- CAP flagging requires an estimation based on visibility into a minimum number of claims within the IQVIA LAAD, potentially underrepresenting their prevalence, although we found no clear indication that there is systematic underrepresentation in one population of interest versus the other
- Compiled consumer marketing attributes data may lead to some misclassification

CONCLUSIONS

- Among this selected sample of patients classified within the schizophrenia therapeutic area in a commercially insured patient population, there was no relationship between HHI and copay card utilization; however, households with lower HHIs appear to be at a higher risk of CAP exposure
- This higher risk of CAP exposure may therefore create additional disproportionate financial barriers to accessing medication and treatment in commercially insured patients using schizophrenia medication

DISCLOSURES

MI, JS, and KS are employees of Janssen Scientific Affairs, LLC. XZ is an employee of IQVIA.

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