INTRODUCTION

- Copay assistance helps to offset the cost of prescriptions to patients by reducing their cost-sharing requirements
- Copay accumulator adjustment programs (CAAPs) have been employed by commercial payers in the US to encourage patients to choose lower-cost drug options by restricting the amount of copay assistance that can count toward a patient's annual cost-sharing limit.
- In response to the proliferation of these programs, some states have enacted legislation banning the use of CAAPs.

OBJECTIVE

• This study assessed whether there is an association between the implementation of CAAP bans and patient liability and treatment adherence and persistence.

METHODS

Study design

- This was a retrospective cohort study using administrative claims from the IQVIA Pharmetrics Plus database for patients with fully insured commercial plans receiving autoimmune or multiple sclerosis drugs between January 1, 2017 and December 31, 2021.
- This study compared patient liability and treatment adherence and persistence in states that implemented a CAAP ban during the study period (Arizona, Georgia, Illinois, Virginia, West Virginia) with those in states that did not, for before and after the date of ban. For states not implementing a CAAP ban, a pseudopolicy effective date was set to January 1, 2020.
- Patients were required to have at least 1 year of continuous enrollment in medical and pharmacy benefits before the index date (defined below).

Patient liability

- Patient liability was defined as the difference in allowed and paid amounts, including both out-of-pocket costs and copay assistance.
- Previously treated patients were included in the patient liability analyses to minimize any potential imbalance in the amount of costs already contributed toward a deductible as a result of patients initiating treatment at various points during the calendar year (Figure 1A).
- First and last drug use had to cover January of any calendar year within the study period (2017–2021), with January 1 after first drug use defined as the index date.
- Patients had to have at least 1 month of drug use between the index date and the end of continuous enrollment.

Treatment adherence and persistence

- Because time since treatment initiation for previously treated patients could bias adherence and persistence results, newly treated patients were used for these analyses, with drug initiation during the study period defined as the index date (Figure 1B).
- Treatment adherence was measured as the proportion of days covered (defined as the number of days with drug on hand) over a 1-year continuous enrollment period after the index date.
- Treatment persistence was defined as the time from treatment initiation to discontinuation (defined as a period of 60 days without supply of treatment); patients had to be continuously enrolled for at least 3 months after the index date.

PLAIN LANGUAGE SUMMARY

What is this about?

- Copay accumulator adjustment programs (CAAPs) have been set up by commercial insurance companies to encourage patients to choose lower-cost drug options. This is done by limiting the amount of copay assistance that can count toward a patient's annual cost-sharing limit.
- This study compared patient liability, treatment adherence, and treatment persistence between US states that allow or have banned CAAPs.

What were the results?

Patient liability decreased, and treatment adherence and persistence improved, in states that have banned CAAPs compared with states that allow CAAPs.

What do the results of the study mean?

The results show that CAAP bans have worked as intended, and therefore other states looking to protect their patients from the impacts of CAAPs may consider similar policies.

Patient Liability and Treatment Adherence/Persistence Associated with **State Bans on Copay Accumulator Programs**

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Statistical methods

- To assess differences in patient liability between states with and without a CAAP ban, multivariate difference-in-difference models, with year-month as the unit of analysis, were fitted to mean monthly patient liability, weighted by the number of patients with drug claims per year-month.
- Mean monthly patient liability was modeled using a log-linked gamma generalized linear model with a four-way interaction between drug, calendar month, CAAP status, and before versus after the effective policy date.
- One-year adherence (defined as proportion of days covered ≥ 0.8) was assessed using propensity-scoreweighted logistic regression. The patients' policy periods were determined by whether the index dates were before or after the effective policy date.
- Persistence was assessed as time to treatment discontinuation using propensity-score-weighted Kaplan-Meier methods. Patients initiating treatment before the policy effective date were censored at the policy effective date.

RESULTS

Patient liability

- In the states that implemented a CAAP ban, the mean patient liability for a 12-month period reduced from \$9389 to \$6510 while increasing from \$2630 to \$2953 in states which did not implement a ban, representing an adjusted annual saving of \$3228 (Figure 2).
- For states with a CAAP ban, patient liability was similar to those of states without a CAAP ban in January and February, but were lower from March through December, with reductions ranging from 41% to 63% (Table 1)

Treatment adherence

• Patients in states with a CAAP ban had a 14% greater odds of being adherent after policy implementation than patients in states without a CAAP ban (Table 2).

Treatment persistence

- Before CAAP bans, there was no significant difference in the risk of discontinuing treatment between states that had a CAAP ban or not (**Figure 3A**).
- After CAAP bans, states that had banned CAAPs had a 13% reduction in risk of patients discontinuing treatment compared with states without a CAAP ban (Figure 3B).

Median persistence was 4 months longer for states with a CAAP ban than those without.

Figure 1. Study design for patient out-of-pocket costs (A) and treatment adherence and persistence (B) Effective date of bar Follow-up Patient 1st drug use Follow-up Baseline Patient 1st drug use Baseline Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Before CAAP ban Effective date of ba Patient 1^a 1st drug use (index) Patient 2^b lst drua us Follow-up

Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov De After CAAP ban **Before CAAP** bar

Patient 1 was categorized as being treated before a CAAP ban and was included only in the persistence analysis because 3 months or more, but not 1 year, of follow-up was observed. herence and persistence analyses because more than 1 year of continuous enrollment was observed. The patient was categorized as being treated before a CAAP ban for both adherence and persistence; in addition, for persistence analysis the patient was censored because follow-up occurred at the effective date Patient 3 was included in both adherence and persistence analyses because more than 1 year of continuous enrollment was observed. The patient was categorized as being treated before a CAAP ban for both adherence and persistence analyses CAAP, copay accumulator adjustment program.



Table 1. Relative out-of-pocket costs before and after CAAP ban, by CAAP status

Month	Ratio of costs before and after ban		Adjusted	Effect of CAAP ban on
	CAAP allowed	CAAP banned	ratio	out-of-pocket costs
Jan	0.95 (0.86, 1.05)	1.07 (0.80, 1.43)	0.89 (0.6, 1.21)	-11%
Feb	0.89 (0.81, 0.98)	1.18 (0.88, 1.58)	0.75 (0.55, 1.02)	-25%
Mar	0.87 (0.78, 0.95)	1.60 (1.20, 2.14)	0.54 (0.40, 0.73)	-46%
Apr	0.86 (0.78, 0.95)	2.06 (1.53, 2.78)	0.42 (0.30, 0.57)	-58%
Мау	0.91 (0.82, 1.01)	2.43 (1.79, 3.30)	0.37 (0.27, 0.52)	-63%
Jun	0.85 (0.77, 0.94)	2.12 (1.56, 2.89)	0.40 (0.29, 0.56)	-60%
Jul	0.84 (0.76, 0.93)	2.28 (1.70, 3.04)	0.37 (0.27, 0.50)	-63%
Aug	0.83 (0.74, 0.92)	1.98 (1.48, 2.65)	0.42 (0.31, 0.57)	-58%
Sep	0.82 (0.73, 0.91)	2.00 (1.47, 2.71)	0.41 (0.30, 0.56)	-59%
Oct	0.92 (0.82, 1.03)	1.76 (1.29, 2.39)	0.52 (0.38, 0.72)	-48%
Nov	0.82 (0.73, 0.91)	1.77 (1.30, 2.41)	0.46 (0.33, 0.64)	-54%
Dec	0.83 (0.74, 0.93)	1.42 (1.04, 1.95)	0.59 (0.42, 0.82)	-41%

Table 2. Treatment adherence before and after CAAP ban, by CAAP status

	N	Mean PDC (SD)	<i>p</i> value	IPTW-weighted OR (95% CI) for adherence (PDC ≥ 0.8)	<i>p</i> value
Before CAAP ban			'		
CAAP allowed	25 643	0.66 (0.31)	0.7	Ref	0.9
CAAP banned	2865	0.66 (0.31)	0.7	0.99 (0.91–1.08)	
After CAAP ban					
CAAP allowed	14 613	0.66 (0.31)	< 0.01	Ref	0.01
CAAP banned	1848	0.69 (0.31)	< 0.01	1.14 (1.03–1.27)	

Weighting was performed for propensity of a patient in a state with a CAAP ban versus a patient in a state without a CAAP ban according to: age, sex, drug type, patient region, psoriasis status at baseline period, rheumatoid arthritis status at baseline period, multiple sclerosis status at baseline period, total baseline costs, number of prescription fills at baseline period, and quarter of drug start. CAAP, copay accumulator adjustment program; CI, confidence interval; IPTW, inverse probability of treatment weighting; OR, odds ratio; PDC, proportion of days covered; SD, standard deviation.

LIMITATIONS

- States implementing a CAAP ban were observed to have higher patient liability before the ban than states without a CAAP ban; therefore, the absolute effect could be weaker for new bans implemented in states with lower out-of-pocket costs.
- Because this study was unable to detect copay card use, it includes the entire population of fully insured patients, rather than only those receiving copay assistance.
- Lastly, it was not possible to distinguish between copay card value and patient out-of-pocket costs in the database.

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Itiple sclerosis status at baseline period, total baseline costs, number of prescription fills at baseline period, and quarter of drug start. CAAP, copay accumulator adjustment program: CI, confidence interval; HR, hazard ratio,

CONCLUSIONS

The implementation of state legislation to restrict the use of CAAPs in state-regulated plans was associated with reductions in patient liability and improvements in treatment adherence and persistence for the five states that were early implementers of a CAAP ban.

Implications to policy, delivery, or clinical practice

- The reductions in patient liability and improvements in adherence and persistence for states that have implemented a CAAP ban suggest that the policies have worked as intended.
- These results may offer insights for states that have recently implemented a CAAP ban as well as those considering enacting similar legislation.

DISCLOSURES

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