

Impact of a Co-pay Accumulator Adjustment Program on Specialty Drug Adherence

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Employers are concerned about the rapid growth of specialty pharmaceutical (SpRx) expenditures. In a 2018 survey of large employers, 80% identified SpRx costs as a top 3 driver of healthcare costs, and 26% said it was their greatest healthcare cost driver, up substantially from 6% in 2014.¹

Employers have acted to constrain SpRx expenditures. Those offering high-deductible health plans (HDHPs) have combined medical and pharmacy plan deductibles into one, thereby shifting initial payment for prescriptions to enrollees until they reach the deductible limit.² Some employers have added pharmacy benefit management features, including utilization management, use of a SpRx vendor, and the addition of a SpRx tier in formularies.¹ Others have excluded many SpRx products from medical plan coverage, thereby shifting greater oversight of SpRx use to pharmacy benefits.³

For enrollees, the financial implications of these cost-sharing tactics may be significant, particularly for lower-wage earners.⁴ Combined with premiums, out-of-pocket (OOP) costs for healthcare may represent one-fifth or more of an employee's wages,⁴ forcing enrollees to make challenging resource allocation decisions between medical care and other basic needs.

Pharmaceutical manufacturers have sought to improve patients' access to treatment by reducing their OOP costs via co-pay assistance cards, which have become widespread among branded therapies. Nearly 70% of the 132 highest-spend branded drugs in 2014 offered co-pay assistance cards.⁵ Employers are concerned that by lowering OOP costs with co-pay assistance cards, enrollees may increase medication use and associated expenditures,^{6,7} despite formulary design and step edits.

Until recently, co-pay assistance funds counted toward the overall patient payment for medications because no accounting process existed to distinguish patient OOP payments from manufacturer subsidies. With co-pay assistance cards, HDHP enrollees could reach their deductible limit after only nominal OOP expenditure, resulting in more patients reaching their deductible thresholds sooner and exacerbating employers' concerns around increasing medical spending.

To mitigate this issue, pharmacy benefit managers (PBMs) have started co-pay accumulator adjustment programs (CAAPs), which

ABSTRACT

OBJECTIVES: To assess the impact of a co-pay accumulator adjustment program (CAAP) on usage patterns of autoimmune specialty drugs, comparing health savings account (HSA) or preferred provider organization (PPO) plan enrollees before and after implementation of the CAAP.

STUDY DESIGN: Retrospective cohort analysis.

METHODS: Data on HSA and PPO patients with autoimmune specialty drug use were drawn from the Conduent pharmacy benefit manager for January 2016 to October 2017 from 15 self-insured employers initiating a CAAP in January 2017. Outcomes included monthly mean fills per person, therapy discontinuation, and proportion of days covered (PDC). Linear regressions, Kaplan-Meier survival curves, and Cox proportional hazards models assessed differences while adjusting for patient characteristics.

RESULTS: There were 365 HSA and 238 PPO patients. After the CAAP implementation, for HSA versus PPO patients, adjusted trends in monthly fills per person decreased more rapidly, the risk of treatment discontinuation was significantly higher, and PDC was significantly lower. Prior to the CAAP, these metrics were not statistically different between groups except in 1 case. To help place the post-CAAP adjusted differences in trends in context, by the end of October 2017, 10 months after the CAAP start, HSA patients had 233 fewer autoimmune drug fills per 1000 patients, 20 percentage points higher treatment discontinuation, and 12 percentage points lower PDC.

CONCLUSIONS: After the CAAP, HSA patients on autoimmune drugs had significantly lower monthly fill rates, higher risk of discontinuation, and lower PDC than did PPO patients, suggesting that CAAPs have the potential to negatively affect specialty drug use.

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TAKEAWAY POINTS

Pharmacy benefit managers are offering co-pay accumulator adjustment programs (CAAPs) to counter pharmaceutical company co-pay assistance subsidies for enrollees receiving specialty medications, although the impact of these programs on medication adherence is unknown.

- ▶ In this analysis, implementation of a CAAP was associated with significant reductions in autoimmune specialty drug adherence.
- ▶ Risk of treatment discontinuation was significantly higher following CAAP implementation.
- ▶ Use of specialty drugs included on the preventive drug list, which eliminates co-payments, was not affected by the CAAP.
- ▶ Further analysis is needed to evaluate the implications for subsequent healthcare utilization and costs.

claim detail and sent to the health plan, which then updated the combined pharmacy and medical deductible accumulator total to reflect only the patient-paid amount. To assess the CAAP's impact, this study compared patterns of autoimmune SpRx use between HSA and PPO enrollees before and after CAAP implementation. We hypothesized that autoimmune drug use decreased more rapidly for HSA enrollees than PPO enrollees under the CAAP but that their drug use trends were parallel before CAAP implementation.

ensure that any pharmaceutical manufacturer subsidy toward patients' OOP medication cost is not credited toward their deductible. Under a CAAP, HDHP enrollees may experience an abrupt spike in OOP medication costs during treatment when manufacturer subsidy limits are reached but before patients have reached their deductible. This potentially unanticipated OOP expense may lower medication adherence and persistence. To date, however, no studies have examined this issue empirically.

Even without outcomes data, CAAPs have become popular among employers. In a recent survey of large employers, nearly 30% implemented a CAAP for 2019 and 21% were contemplating one for 2020 or 2021.¹ In another recent employer survey, 54% of respondents did not credit third-party co-pay assistance toward patient deductibles.⁸

We sought to assess the impact of a CAAP on autoimmune SpRx use in a commercially insured population. Autoimmune drugs provide a salient setting for CAAPs, as there are multiple branded drugs with high patient co-pays. Roughly 2% of the US adult population have either gastrointestinal or arthritis-related autoimmune disorders possibly treated with SpRx.^{9,10} The large number of affected individuals and the chronicity of autoimmune illness generate a sizable study population. In contrast, SpRx treatments for other conditions have therapeutic or benefit design attributes limiting the relevance of adherence. For example, adherence rates for HIV medications among employed individuals are typically high.¹¹ SpRx for multiple sclerosis (MS) may be included on PBMs' preventive drug lists and thus not subject to the deductible. Other SpRx (eg, for hepatitis C virus or cancer) have brief or unpredictable courses.

METHODS

Overview

The CAAP studied here was started on January 1, 2017, by self-insured employers in a private health insurance exchange. This analysis used enrollment and SpRx claims data for patients enrolled in high-deductible health savings account (HSA) plans or zero pharmacy deductible preferred provider organization (PPO) plans. The CAAP was operationalized by the PBM, separately tracking the dollar amounts from the co-pay assistance card and a patient's actual OOP expenditure. These amounts were added to the pharmacy

Data and Sample

This study examined SpRx use among a convenience sample of more than 150,000 enrollees in employer-sponsored healthcare coverage during 2016 and 2017 through a private health insurance exchange (RightOpt, Conduent HR Services). The RightOpt exchange is administratively managed as a portfolio of integrated health plan offerings. Benefit design options include a no-deductible PPO and HDHPs with HSA or health reimbursement arrangement benefit design options. (This analysis used data only from PPO and HSA enrollees who were subject to the CAAP. All HSAs had combined medical/pharmacy annual deductibles of at least \$1400.) To preserve confidentiality, no additional details were available.

Deidentified SpRx claims and enrollment data during January 1, 2016, through October 31, 2017, were collected on 3543 individuals with SpRx claims from 15 employers, each with a nationally distributed workforce, from the PBM (CVS Caremark; Woonsocket, Rhode Island). Besides standard pharmacy claims content, the data from January 1, 2017, onward included information on co-pay assistance card use and the patient net OOP payment to ensure that only the actual patient payment amount was credited toward the deductible.

The analytic sample consisted of patients who had at least 1 claim for any of 23 SpRx medications used to treat any of 8 autoimmune conditions (**eAppendix** [available at ajmc.com]) listed in the CVS specialty pharmacy drug list¹² and had continuous enrollment in 1 HSA or PPO plan (ie, no coverage interruptions or plan switching) during the study period.

Statistical Analyses

There were 3 primary outcomes (monthly fills per person, risk of treatment discontinuation, and proportion of days covered [PDC]) and 1 secondary outcome (risk of absolute treatment discontinuation), as described below. Trends in unadjusted outcomes were plotted graphically. Adjusted analyses controlled for patient age as of January 1, 2017; sex; and zip code-level estimated adjusted gross income (AGI) in 2015.¹³ Statistical comparisons were made between HSA and PPO enrollees for 2016 (prior to the CAAP start) and 2017 (when enrollees were subject to the CAAP) using regression models. Model standard errors were made robust to heteroskedasticity and clustering where relevant. HSA- and PPO-specific expected outcomes,

their differences, and their 95% CIs were calculated at the end of each period's follow-up (December 31, 2016, and October 31, 2017, respectively) from the model results.

Mean fills per person was calculated by calendar month and plan type for January 2016 through October 2017 as the number of autoimmune SpRx claims divided by the number of individuals with plan coverage in that month. Using data at the person-month level, an adjusted linear regression was estimated on the outcome of number of fills as a function of plan-specific linear time-trend splines with knots at December 2016. Slope coefficients represented monthly changes in mean fills per person and were compared for HSA versus PPO enrollees by calendar year using Wald tests.

Treatment discontinuation was defined as the presence of a gap between the end of a patient's drug supply and the next refill claim that exceeded 60 days. We identified separate subsamples of patients with autoimmune prescriptions that were not yet discontinued as of index dates of February 1, 2016 (pre-CAAP), and January 1, 2017 (post-CAAP). The time to discontinuation following each index date was characterized with unadjusted Kaplan-Meier survival curves and compared between plan types with adjusted Cox proportional hazards models that produced hazard ratios (HRs). Patients who ended insurance coverage prematurely or reached the end of follow-up (December 31, 2016, or October 31, 2017, respectively) without discontinuation were censored. Besides age, sex, and AGI, the Cox models controlled for the number of fills observed prior to the index date and were stratified by the patient's drug at the index date (ie, adalimumab, etanercept, or other). Analyses were repeated for the secondary end point of absolute discontinuation, which was defined as treatment discontinuation with no evidence of treatment restart or switching.

Construction of the PDC outcome paralleled treatment discontinuation. Separate subsamples were constructed for patients with positive drug supply from previously filled autoimmune prescriptions as of index dates February 1, 2016, and January 1, 2017. From the index date until the end of follow-up (December 31, 2016, and October 31, 2017, respectively), PDC was calculated daily for each enrollee as days with positive drug supply divided by total days since the index date. Patients' stockpiling drug supply was calculated from January 1, 2016, forward. Separately for the 2016 and 2017 subsamples, linear trendlines were fit on patient-day-level PDC data for HSA and PPO enrollees starting 30 days after index date through the end of follow-up. The trendlines were estimated using linear regression models that adjusted for patient age, sex, AGI, observed fills before index date, and drug. Slope coefficients were scaled to represent changes in mean PDC per 30 days and were compared between plan types pre- and post CAAP using Wald tests.

Three sensitivity analyses were conducted. First, as a robustness check, the treatment discontinuation and PDC analyses were repeated for the post-CAAP period with an alternate index date of February 1, 2017. Second, all analyses were repeated with stricter sample selection criteria. Enrollees were required to have continuous coverage from January 1, 2016, through October 31, 2017, and to have used a co-pay

card during the first quarter of 2017. Third, the main analyses were conducted for HSA and PPO enrollees with MS SpRx, which were on the preventive drug list, not subject to the HSA deductible, and thus not expected to be affected by the CAAP.

Statistical significance was based on 2-sided tests with $\alpha = .05$. Analyses were conducted using Stata MP 15.1 (StataCorp; College Station, Texas).

RESULTS

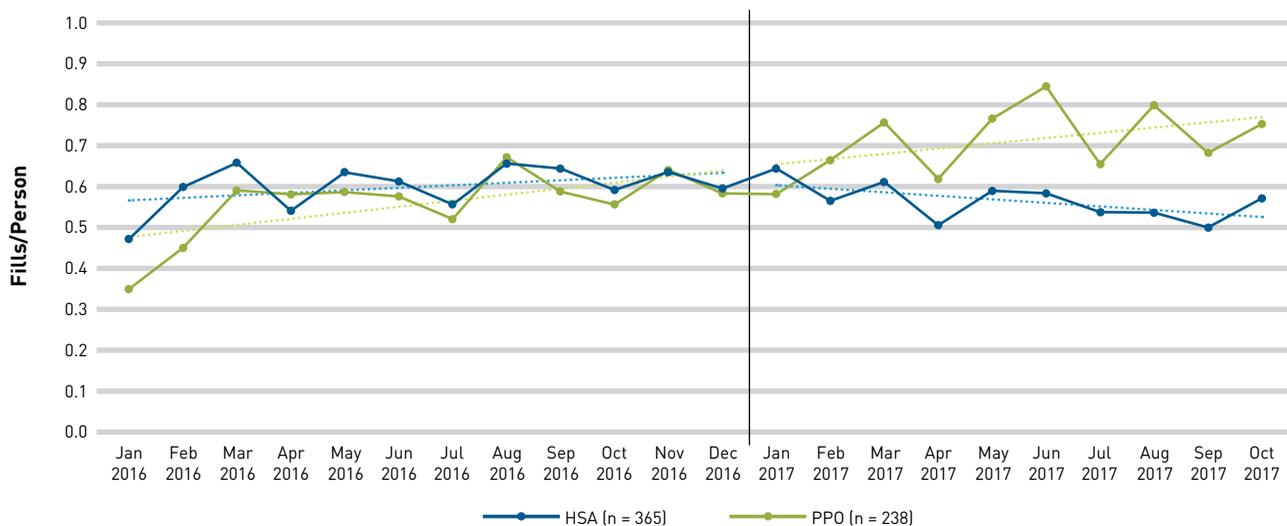
After exclusions for no autoimmune SpRx claims ($n = 2752$) and health plan coverage changes ($n = 25$), 603 patients were in the main study sample, including 365 HSA enrollees and 238 PPO enrollees. Mean (SD) age was 48 (13) years, 60% were women, and mean (SD) AGI was \$68,273 (\$25,294). These characteristics were not statistically significantly different between HSA and PPO enrollees. Of note, during 2017, 92% of enrollees in the HSA and PPO groups used at least 1 co-pay assistance coupon (**Appendix Table 1**). Coupon use during 2016 was not tracked by the PBM.

Unadjusted trends in monthly mean fills per person by plan type are shown in **Figure 1**. Across the 22-month study period, there were, on average, 284 HSA patients (range, 252-307) and 184 PPO patients (range, 166-196) with insurance coverage in each month. During 2016, although adjusted monthly fills per person increased nominally for both plan types, the adjusted HSA slope was 0.010 (95% CI, 0.001-0.019) fills per person-month lower, translating to 118 (95% CI, 12-224) fewer fills per 1000 patients by December 2016. After the CAAP started, fills decreased for HSA enrollees and increased for PPO enrollees nominally, and the adjusted difference in slopes was 0.023 (95% CI, 0.012-0.035) fills per person-month lower for HSA patients, which translated to 233 (95% CI, 117-349) fewer fills per 1000 patients by October 2017.

For the treatment discontinuation analyses, 199 patients had active autoimmune prescriptions on February 1, 2016; 278 had them on January 1, 2017. Kaplan-Meier curves of unadjusted discontinuation risk are shown in **Figure 2** (A [2016] and B [2017]). Adjusted discontinuation risk was comparable between HSA and PPO enrollees in 2016 (HR, 0.97; 95% CI, 0.57-1.65) and statistically significantly higher for HSA enrollees in 2017 (HR, 2.17; 95% CI, 1.39-3.40). Based on predicted values from the adjusted Cox model, on October 31, 2017, discontinuation was 20.0 (95% CI, 3.9-36.1) percentage points higher for HSA (42.2%) versus PPO (22.3%) enrollees. In comparison, at the end of the pre-CAAP follow-up (December 31, 2016), discontinuation was not statistically different (HSA, 14.8% vs PPO, 15.2%; difference, -0.5 percentage points; 95% CI, -40.3 to 39.4).

Findings for the adjusted risk of absolute treatment discontinuation were similar. The risk was comparable for HSA versus PPO enrollees before the CAAP (HR, 0.99; 95% CI, 0.42-2.35) and significantly larger for HSA enrollees after (HR, 4.98; 95% CI, 2.35-10.59). Likewise, predicted absolute discontinuation was not statistically different (HSA, 87.2% vs PPO, 87.2%; difference, -0.05 percentage points; 95% CI, -36.9 to 37.0) at the end of pre-CAAP

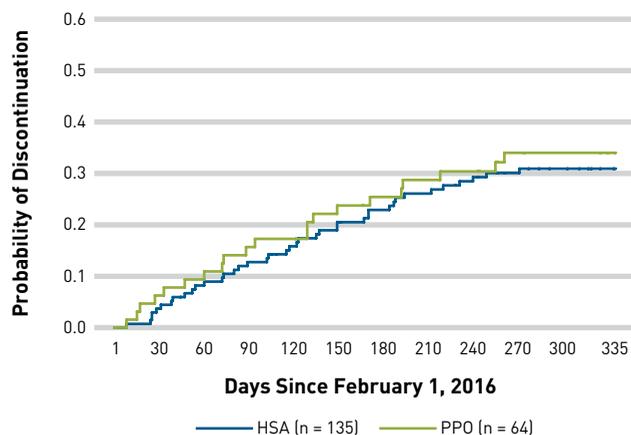
FIGURE 1. Unadjusted Trends in Monthly Mean Fills per Person



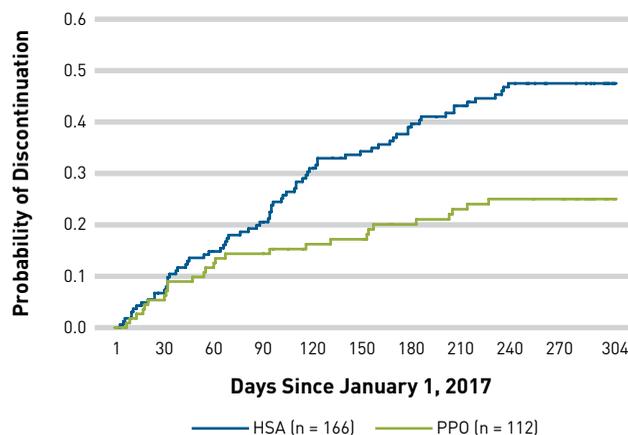
HSA indicates health savings account; PPO, preferred provider organization.

FIGURE 2. Unadjusted Risk of Treatment Discontinuation

A. Before CAAP: February 1, 2016-December 31, 2016



B. After CAAP: January 1, 2017-October 31, 2017



CAAP indicates co-pay accumulator adjustment program; HSA, health savings account; PPO, preferred provider organization.

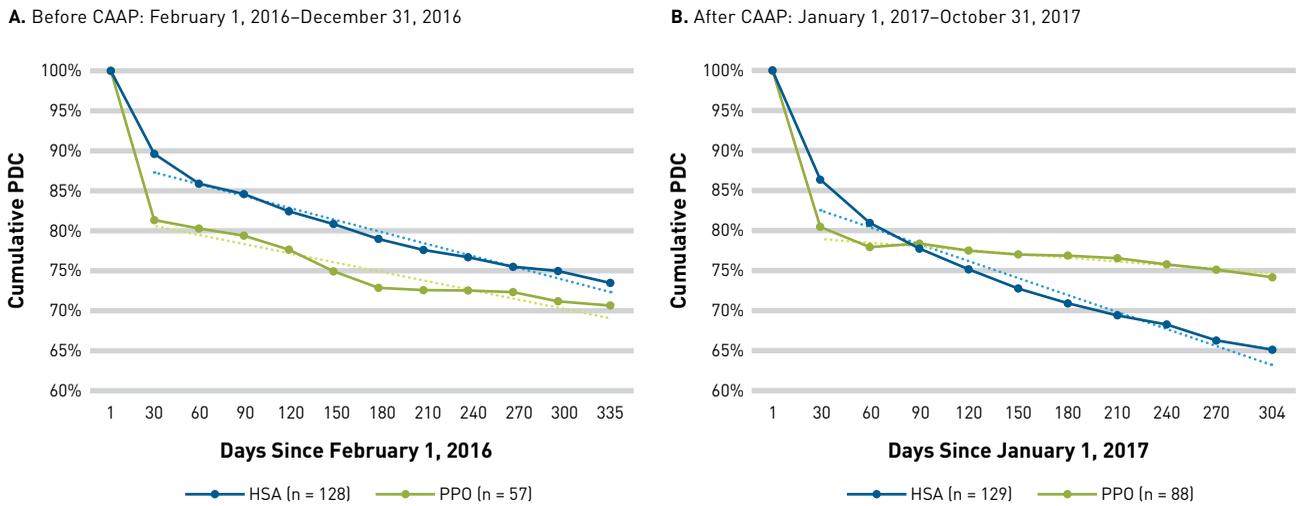
follow-up, but it was higher by 25.6 (95% CI, 10.5-40.6) percentage points for HSA (33.3%) versus PPO (7.7%) enrollees at the end of post-CAAP follow-up.

In the PDC analyses, 185 patients as of February 1, 2016, and 217 as of January 1, 2017, had an active prescription. Unadjusted trends in PDC are shown in Figure 3 (A [2016] and B [2017]). From 30 days after February 1, 2016, through December 31, 2016, adjusted PDC declined nominally faster for HSA enrollees by 0.3 (95% CI, -0.6 to 1.2) percentage points per 30 days. In contrast, from 30 days after January 1, 2017, through October 31, 2017, adjusted PDC declined

faster for HSA enrollees by 1.7 (95% CI, 0.8-2.5) percentage points per 30 days. Based on the intercepts and slopes of the fitted trendlines, adjusted mean PDC was 11.7 (95% CI, 2.7-20.6) percentage points lower for HSA patients on October 31, 2017 (HSA, 63.0%; PPO, 74.7%), compared with 0.2 (95% CI, -9.6 to 10.0) percentage points lower on December 31, 2016 (HSA, 70.9%; PPO, 71.1%).

Results of the first 2 sensitivity analyses were consistent with the main findings. Resetting the post-CAAP index date from January 1, 2017, to February 1, 2017, yielded a minor change in the post-CAAP risk of SpRx treatment discontinuation (adjusted HR, 2.32; 95% CI,

FIGURE 3. Unadjusted Trends in PDC



CAAP indicates co-pay accumulator adjustment program; HSA, health savings account; PDC, proportion of days covered; PPO, preferred provider organization.

1.46-3.70) (eAppendix Figure 1). The same change led to a small increase in the HSA–PPO difference in PDC slopes (adjusted slope, 1.9 percentage points; 95% CI, 1.0-2.8) (eAppendix Figure 2).

Post-CAAP differences between HSA and PPO enrollees were similar in the subset of 225 patients who had continuous enrollment throughout the study period and used a co-pay assistance card in the first quarter of 2017. The adjusted slope difference in fills per person-month grew to 0.028 (95% CI, 0.018-0.038), the adjusted HSA versus PPO HR for the risk of treatment discontinuation grew to 2.41 (95% CI, 1.43-4.09), and adjusted PDC remained steeper for HSA enrollees (slope difference, 1.6 percentage points; 95% CI, 0.6-2.5).

The third sensitivity analysis compared HSA and PPO patients' use of MS drugs, finding no statistically significant adjusted difference in trends in monthly fills (slope difference, 0.010 fills per person-month higher for HSA enrollees; 95% CI, -0.010 to 0.030), risk of discontinuation (HR, 0.69; 95% CI, 0.30-1.58), risk of absolute discontinuation (HR, 0.74; 95% CI, 0.25-2.24), or PDC (slope difference, -0.06 percentage points; 95% CI, -1.1 to 1.0) after CAAP implementation. As of October 31, 2017, predicted discontinuation risk and adjusted mean PDC were statistically no different between plan types (eAppendix Table 2).

DISCUSSION

Employers have been challenged with balancing expenditures and affordability in their benefits design strategic planning, particularly given current SpRx costs and the SpRx development pipeline. HDHP benefit designs were envisioned to promote consumerism and more informed healthcare use.

Affordability concerns may limit individual access to SpRx, however. Following CAAP implementation, our study indicates that,

in association with higher OOP costs, a sizable share of individuals either reduced or discontinued their use of autoimmune SpRx.

In the face of growing healthcare affordability challenges, we question whether CAAPs are appropriate. Evidence suggests that although SpRx expenditures may fall because of reduced drug use, overall healthcare expenditures may increase.¹⁴ Similarly, as an alternative cost containment approach, nonmedical switching of medications based on formulary considerations may negatively affect health outcomes and costs.¹⁴⁻¹⁶ Furthermore, suboptimal condition management may result in higher medical expenditures, illness-related absence, and productivity impairment, so the net impact on employers may be contrary to their cost-containment objectives.¹⁷ Unfortunately, this is consistent with surveys suggesting that employer benefits personnel generally prioritize near-term, transactional data related to benefits cost containment ahead of longer-term health, productivity, and business cost implications.¹

If our initial findings of affordability-related treatment adherence concerns are confirmed, several potential solutions warrant consideration. Wage-based employer benefits subsidies, whether through premium support, HSA contributions, or deductible amounts, may be helpful. Income-based co-pay support from SpRx manufacturers is another approach. Alternatively, our findings regarding adherence and persistence with medications for treatment of MS suggest that including selected medications on the HSA preventive drug list may be effective.

Limitations

Our study has several limitations. First, generalizability is constrained by a small patient sample, 2 therapeutic classes of drugs, a single CAAP, and 10 months of follow-up. Second, endogenous selection from employers' starting CAAPs and from enrollees' switching plans

may bias our results, although just 25 individuals with SpRx use in 2016 switched between HSAs and PPOs in 2017. Third, our data were limited in scope. Only pharmacy claims data were available, precluding analysis of spending, health outcomes, or clinical appropriateness of prescribed medications. All SpRx were provided by the same PBM, however, with a consistent SpRx management process. Lastly, without plan design details, we were unable to account for deductible thresholds, employer contributions to the HSA, or timing of employer HSA seeding. However, none of the employers provided accelerated or on-demand HSA contributions, and none of the plan designs changed during the study period.

CONCLUSIONS

Our analysis of commercially insured patients with autoimmune diseases found that CAAP implementation was associated with near-term reductions in SpRx adherence and persistence. Effects on overall health status, healthcare use, and health outcomes are unknown, as are longer-term responses to CAAPs. Further research is needed to understand better the “all-in” health, pharmacy, and medical cost and productivity implications of both patient co-pay assistance support and CAAPs. ■

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Authorship Information: Concept and design (BWS, AJE, BM, MM); acquisition of data (BWS); analysis and interpretation of data (BWS, AJE, BM, MM); drafting

of the manuscript (BWS, AJE, BM, MM); critical revision of the manuscript for important intellectual content (BWS, AJE, BM, MM); statistical analysis (AJE); provision of patients or study materials (BWS); administrative, technical, or logistic support (BWS, BM, MM); and supervision (BM, MM).

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eAppendix

There were eight autoimmune conditions included in analysis: rheumatoid arthritis, psoriatic arthritis, psoriasis, Crohn's disease, ulcerative colitis, systemic lupus erythematosus, primary biliary cirrhosis, immune thrombocytopenic purpura.

There were 23 medications used to treat autoimmune conditions: abatacept, adalimumab, apremilast, belimumab, brodalumab, certolizumab, eculizumab, eltrombopag, etanercept, golimumab, infliximab, infliximab-dyyb, ixekizumab, methotrexate, obeticholic acid, rituximab, romiplostim, sarilumab, secukinumab, tocilizumab, tofacinitib, ustekinumab, and vedolizumab.

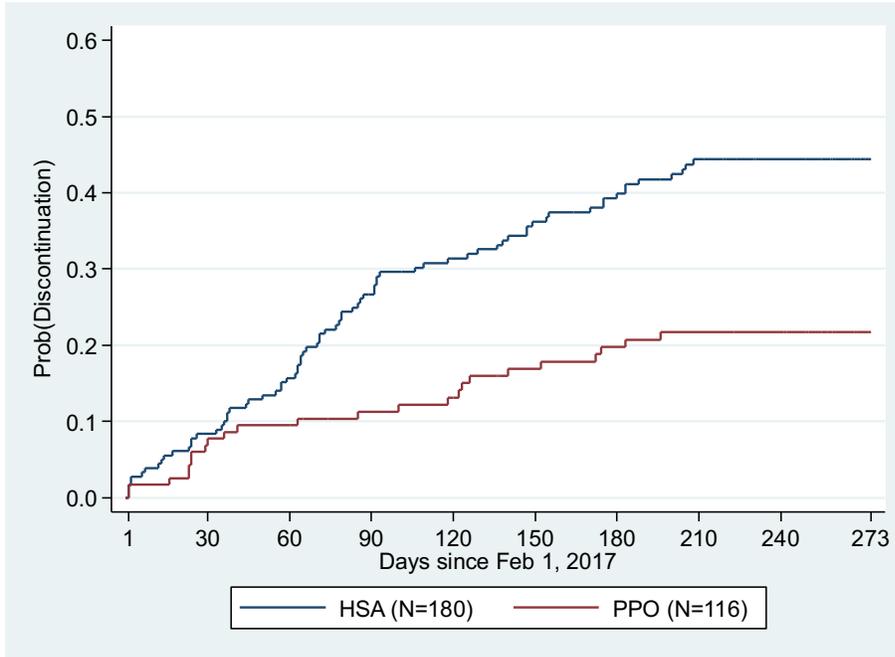
eAppendix Table 1. Copay assistance coupon use from 2017, following Copay Accumulator Adjustment Program (CAAP) implementation. Corresponding data for 2016 are not available.

Variable Name	Overall	HSA	PPO	P-Value
Share of patients using ≥ 1 copay coupon (patient count)	92% (404)	92% (241)	92% (163)	0.77
Total copay coupon amount \$				
Mean (SD)	3,775 (4,395)	5,992 (4,494)	524 (502)	<0.001
Median (IQR)	955 (6,735)	6,028 (8,063)	483 (535)	<0.001
Share of OOP cost covered by copay coupon				
Mean (SD)	0.86 (0.27)	0.86 (0.29)	0.86 (0.25)	0.97
Median (IQR)	0.95 (0.10)	0.99 (0.10)	0.95 (0.06)	<0.001
Sample Size	439	261	178	

eAppendix Table 2. Expected outcomes as of October 31, 2017

Expected outcome			HSA – PPO Difference (percentage points)
	HSA (%)	PPO (%)	
Predicted risk of discontinuation (CI)	21.98	30.25	–8.27 (–33.76, 17.22)
Predicted risk of absolute discontinuation (CI)	17.88	23.31	–5.44 (–30.38, 19.50)
Adjusted mean PDC (CI)			–1.84 (–12.54, 8.86)

eAppendix Figure 1. Unadjusted risk of treatment discontinuation after CAAP: February 1, 2017–October 31, 2017



eAppendix Figure 2. Unadjusted trends in PDC after CAAP: February 1, 2017–October 31, 2017

