

Increasing Pharmaceutical Copayments: Impact on Asthma Medication Utilization and Outcomes

Jonathan D. Campbell, PhD; Felicia Allen-Ramey, PhD; Shiva G. Sajjan, PhD;
Eric M. Maiese, PhD; and Sean D. Sullivan, PhD

As the costs of healthcare rise, healthcare payers struggle to balance access and affordability for patients and plan sponsors. To mitigate overconsumption of pharmaceuticals, many US pharmacy benefits have built-in, out-of-pocket (OOP) payments for pharmaceuticals. Historically, the patient's contribution to pharmaceutical purchases (copayments) has been quite low, on the order of 10% to 15% of the average market price. In recent years, however, payers have increased patient copayment substantially and have created tiered pharmacy benefits and step-edits to countermand increasing demand for expensive drugs.¹ For example, a 3-tier pharmacy benefit may require a monthly patient (OOP) cost of \$10 for less costly generic drugs, a \$25 copayment for preferred branded drugs, and a \$50 copayment for nonpreferred branded drugs. This type of system is intended to incentivize the patient to move toward less costly substitutes. Substitutes are not, however, always available at the lower copayment level.

An unintended and possibly harmful consequence of changes in pharmacy benefit design is the impact that higher copayments have on clinically beneficial or optimal medication consumption.^{2,3} Several studies have shown that increasing OOP costs for prescription drugs reduces the rate of utilization of medications for patients with chronic diseases.⁴⁻⁶ However, the literature is limited on the impact that changes in health benefit design have on asthma controller medication utilization. Canadian researchers have found that increases in patient contributions to controller medications, such as inhaled corticosteroids (ICS), have reduced ICS utilization.^{7,8} In the United States, findings on the impact of changes in health benefit design have been mixed. Fung et al showed a reduction in ICS use with increased demand barriers on the Medicare population,⁹ whereas Crown et al suggested a limited change in patient-level treatment patterns due to higher patient contributions.¹⁰ The latter did, however, suggest that physician and practice prescribing preferences influenced patient treatment.¹⁰

An important unanswered question is to what extent changes in consumption resulting from alterations in pharmacy benefit design impact health outcomes. Our study objective fills a gap in the literature that relates changes in long-term asthma controller (LTC) medication patient copayment with LTC utilization and with asthma health outcomes. We

Objectives: Unintended consequences may result from changes in pharmacy benefit design. The objective was to determine the impact of increasing patient prescription copayments for guideline-recommended, long-term asthma controller (LTC) medications on asthma-related medication use and healthcare services.

Study Design: We used 2005 MarketScan healthcare and pharmacy claims data to identify asthma (*International Classification of Diseases, 9th Revision, Clinical Modification [ICD-9-CM]* diagnosis code 493.xx) patients aged 12 to 64 years who were continuously enrolled through 2006 with ≥ 1 claim for an asthma medication in 2005. LTCs included: inhaled corticosteroid (ICS) (n = 10,251), ICS plus long-acting beta agonist (COMBO) (n = 27,407), and leukotriene receptor antagonist (LTRA) (n = 20,664).

Methods: Using multivariable models, we estimated the associations between changes in LTC copayments and LTC consumption and asthma-related outpatient and emergency department (ED) visits.

Results: Patients were dichotomized into $\geq \$5$ average increase in patient copayments per month of medication supplied (yes/no). The mean annual change (2005-2006) in copayments per month was \$13.23 versus $-\$3.88$ (ICS), \$11.76 versus $-\$3.06$ (COMBO), and \$9.78 versus $-\$2.06$ (LTRA). The $\geq \$5$ group experienced a significant decline in average annual days of medication supplied of -47.1 days of ICS (95% CI -43.5 to -50.8), -35.3 days of COMBO (-32.4 to -38.2), and -47.5 days of LTRA (-43.2 to -51.7). Among COMBO and LTRA medication users, the $\geq \$5$ copayment increase was associated with more asthma-related outpatient visits and ED visits compared with the $< \$5$ group.

Conclusions: The findings suggest that even small changes in average copayment for asthma medications can result in significant reductions in medication use and unintended increases in healthcare services.

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Take-Away Points

- Patients were dichotomized into $\geq \$5$ average increase in patient copayments per month of medication supplied (yes/no).
- A $\geq \$5$ increase in copayment was associated with more than 1 month's supply less utilization of long-term controller medications over the course of 1 year.
- For certain classes of long-term controller medications, a $\geq \$5$ increase in copayment was associated with more subsequent oral corticosteroid bursts, increases in asthma outpatient visits, and increases in asthma emergency department visits.
- The study findings should be considered when designing drug benefit decisions that change formulary patient copayment structures.

tested whether or not an increase in patient-level average LTC prescription copayment per month would result in lower LTC utilization and higher rates of asthma-related health services, which are typically thought of as components of asthma exacerbations. Asthma is a convenient disease state to test these hypotheses using years 2005 and 2006 claims data because: (1) LTCs are guideline-recommended therapies; (2) LTCs prevent inflammation and reduce the risk of asthma exacerbations but many LTC users do not necessarily observe noticeable and immediate benefits from LTCs; (3) some consequences of LTC medication failure can be observed in health insurance claims data; and (4) during the study period, no known large changes occurred to the LTC market in terms of new LTCs or new generics.

METHODS

Data Source

We performed a retrospective cohort analysis using the Thompson Healthcare MarketScan commercial database (29 million covered lives in all geographic regions of the United States). MarketScan captures medical (inpatient, outpatient, and emergency care) and pharmacy claims information including the claim-level patient copayment amount, as well as eligibility status, from employees of large corporations. MarketScan is known for its high standard of claims-based information that is representative of the privately insured US population.¹¹

Study Design

We used the 2005 and 2006 years of the MarketScan claims database to identify the study cohort and test our hypotheses. Inclusion criteria for the study (Figure) were: (1) a 2005 diagnosis of asthma defined by 1 of the following criteria: at least 2 outpatient claims with primary or secondary diagnoses of asthma (*International Classification of Diseases, 9th Revision, Clinical Modification [ICD-9-CM]* diagnosis code 493.xx) OR at least 1 emergency department (ED) or hospitalization claim with primary diagnosis of asthma (493.xx);

(2) continuous enrollment during 2005 and 2006; (3) age ≥ 12 and < 64 years on January 1, 2005; and (4) at least 1 drug claim for an LTC medication (ICS, ICS combined with long-acting beta-2 agonist [LABA], leukotriene receptor antagonist [LTRA], mast cell stabilizers, or omalizumab) with ≥ 30 days supply during 2005. Patients were excluded (Figure) if they had: (1) a diagnosis of chronic obstructive pulmonary disease

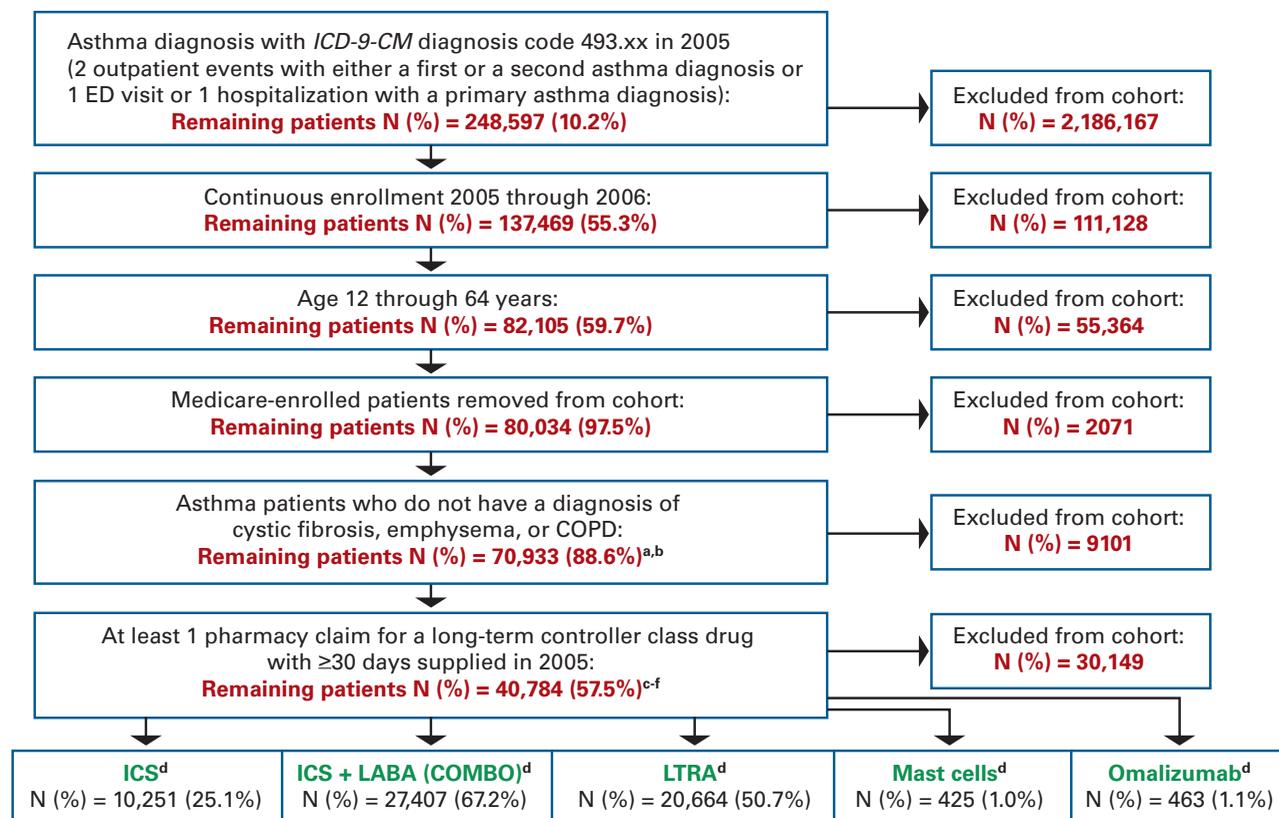
(ICD-9-CM 491.2, 493.2, 496, 506.4), or at least 1 claim for an anticholinergic medication; (2) a diagnosis of emphysema (ICD-9-CM 492.x, 506.4, 518.1, or 518.2); (3) a diagnosis of cystic fibrosis (ICD-9-CM 277.0x); or (4) were enrolled in Medicare.

We linked national drug codes in the Medstat data with classes as defined in the Healthcare Effectiveness Data and Information Set 2009 Final NDC table.¹² Upon reviewing the LTC utilization patterns of the study cohort during the year 2005 (Figure), we included the following most common LTC classes for analysis: ICS, ICS plus long-acting beta agonist (COMBO), and LTRA. The primary exposure variable of interest was the average change in patients' monthly prescription copayment from 2005 to 2006 for each LTC class.

The average copayment per patient month for a given LTC class within a claim year was estimated by averaging all of the LTC claims filled for a patient and the patient OOP payment (copayment) divided by the number of months supplied (assuming 100% medication adherence). The months supplied were estimated using the days supplied field in the claims data. Patients who filled an LTC class in 2005 but not in 2006 were assigned the plan-level average monthly copayment for 2006. In this way, we assumed such patients would have faced this copayment had they filled the same LTC class in 2006. The change in copayment was calculated for each LTC class and patient by taking the average copayment per month supplied in 2006 and subtracting the average copayment per month supplied in 2005.

The outcome measures captured from 2006 pharmacy and medical claims included the following for 2005 LTC users: LTC utilization (yes/no), LTC days supplied, LTC substitution and switching patterns, oral corticosteroid bursts, asthma-related outpatient visits (primary or secondary diagnosis of asthma with ICD-9-CM 493.xx), asthma-related ED visits (primary asthma diagnosis with ICD-9-CM 493.xx) and asthma-related hospitalizations (primary asthma diagnosis with ICD-9-CM 493.xx). LTC utilization was characterized in terms of average days supplied and also adherence for those who had at least 30 days supplied. Adherence was defined as

■ **Figure.** Study Cohort Flow Chart



COMBO indicates ICS plus long-acting beta agonist; COPD, chronic obstructive pulmonary disease; ED, emergency department; ICS, inhaled corticosteroid; LABA, long-acting β_2 agonist; LTC, long-term asthma controller; LTRA, leukotriene receptor antagonist.

^aEmphysema ICD-9-CM: 492.x, 506.4, 518.1, 518.2.

^bCOPD ICD-9-CM: 491.2, 493.2, 496, 506.4 or ≥ 1 claim for an anticholinergic medication.

^cLong-term controller class = ICS, ICS combined with LABA, LTRA, mast cell stabilizers, or omalizumab.

^dPatients could be included in >1 controller class.

^eOne pharmacy claim of omalizumab was required instead of ≥ 30 days supplied.

^fRemoved 44 patients that had an average copayment per month supplied of >\$300 in either year for any LTC (\$300 was approximately the monthly cost of high-dose COMBO medication and therefore was thought to be the upper end of a patient's out-of-pocket cost).

the medication possession ratio where the total days supplied in a year was divided by the number of days in 1 year.¹³

Statistical Methods

The distribution of patient copayment change (primary exposure measure) was split into those experiencing $\geq \$5$ average increase in monthly copayment versus $< \$5$, based on an empiric analysis. We also had interest in evaluating an economically significant change of at least a \$5 increase because previous evaluations suggested that this exposure variable is likely to not be linearly related to outcome measures.¹⁰ We used descriptive statistics to display the 2005 demographics and clinical characteristics and the 2005 versus 2006 LTC utilization by copayment change category for each LTC. Differences in continuous characteristics were tested using *t* tests and differences in the categorical characteristics and utilization proportions were tested using χ^2 test. For

each LTC, we used linear regression to test for differences in the continuous outcome of 2006 days supplied and Poisson (negative binomial distribution for asthma-related hospitalizations) regression to test for differences in 2006 count outcomes, including oral corticosteroid bursts, asthma-related outpatient visits, asthma-related ED visits, and asthma-related hospitalizations.

We adjusted all regression analyses for 2005 baseline and clinical characteristics including: age, gender, insurance plan type, comorbidities, LTC use in terms of 2005 annual days supplied, asthma-related outpatient visits, oral corticosteroid bursts, asthma-related ED visits, asthma-related hospitalizations, and total OOP patient expenditures. We applied a modified Charlson Index (Quan et al index) to generate scores on the level and burden of comorbidity for the study cohorts to adjust for the potential confounding of health status.¹⁴ The Quan et al index draws on diagnostic information from ICD-

■ **Table 1.** Average Change in Patient Copayment (US\$) per Month Supplied (2006 Minus 2005) by Copayment Threshold and Drug Class

	<\$5 Increase in copayment		≥\$5 Increase in copayment	
	N	Mean (SD)	N	Mean (SD)
ICS	7630	-3.88 (10.78)	2621	13.23 (12.24)
ICS + LABA (COMBO)	22,594	-3.06 (8.99)	4813	11.76 (10.10)
LTRA	17,860	-2.06 (6.28)	2804	9.78 (6.98)

ICS indicates inhaled corticosteroid; LABA, long-acting beta-2 agonist; LTRA, leukotriene receptor antagonist; SD, standard deviation.

9-CM codes and procedure codes, resulting in conditions that are weighted based on the adjusted risk of 1-year mortality. The index score is the sum of the weights for all of a patient's conditions, with higher numbers indicating increased levels of comorbidity.

We conducted 2 sensitivity analyses on key exposure and outcome variables. First, we examined the ≥\$5 average increase in monthly copayment only in those who filled the same LTC in both 2005 and 2006 (a subgroup of the base case cohort). Second, we examined the effect of a ≥\$10 average increase in monthly copayment cutoff on the base case cohort.

RESULTS

Descriptive Analyses

Of a possible 2,434,764 patients with claims in the 2005 MarketScan claims data set, our study cohort was a sample size of 40,784 (Figure). Of the overall study cohort, 10,251 (25.1%) patients filled at least 30 days supplied of ICS; 27,407 (67.2%) filled at least 30 days of COMBO; and 20,664 (50.7%) filled at least 30 days of LTRA. Note that the LTC categories are not mutually exclusive. A patient could be counted in more than 1 LTC category if he or she filled at least 30 days supplied in each category.

The 2005 mean copayment per month supplied was \$18.51 with standard deviation (SD) of \$15.10 for the ICS cohort, \$19.16 for the COMBO cohort (SD = \$13.10), and \$16.46 for the LTRA cohort (SD = \$10.60). The mean copayment per month supplied from 2005 to 2006 for all 3 LTC class cohorts changed less than \$1.00 in absolute value. Patients in all 3 cohorts with <\$5 change in copayment per month supplied had, on average, a reduction in monthly copayment from 2005 to 2006 (Table 1). Conversely, patients in all 3 cohorts with ≥\$5 increase in copayment per month supplied had, on average, an increase in monthly copayment from 2005 to 2006 (Table 1).

Among the LTRA cohort, patients with a ≥\$5 increase in patient copayment per month supplied, compared with patients with a <\$5 increase, were younger ($P < .0001$), had a different distribution of insurance plan type ($P < .0001$), had

lower baseline LTRA copayment ($P < .0001$), lower ICS adherence ($P = .0006$), lower COMBO adherence ($P < .0001$), lower LTRA adherence ($P < .0001$), fewer LABA users ($P = .008$), and lower annual patient OOP expenses ($P < .0001$) (Table 2). The 2005 demographic and clinical characteristics for the ICS and COMBO cohorts were not displayed. However, statistical differences between copayment groups followed the same trend as in the LTRA cohort.

Table 3 displays the proportion of patients who filled the same LTC in 2006, comparing those with <\$5 increase in average monthly copayment with patients with ≥\$5 increase in average monthly copayment. Among the ICS cohort, 66.7% (<\$5 increase) versus 37.3% (≥\$5 increase) ($P < .0001$) filled an ICS prescription in 2006. Among the COMBO cohort, 70.8% (<\$5 increase) versus 58.3% (≥\$5 increase) ($P < .0001$) filled a COMBO prescription in 2006. Among the LTRA cohort, 77.3% (<\$5 increase) versus 59.8% (≥\$5 increase) ($P < .0001$) filled an LTRA prescription in 2006. Further, patients in the ICS cohort with a ≥\$5 increase in copayment per month supplied were more likely to fill a prescription for a COMBO in 2006 (28.7%) compared with patients with a <\$5 increase (21.7%). The proportions of patients with a 2006 LTRA prescription fill were similar between the copayment groups in the ICS cohort (36.3% and 37.9% for ≥\$5 increase and <\$5 increase, respectively). COMBO patients with a ≥\$5 increase in copayment per month supplied were slightly more likely to fill a prescription for an ICS in 2006 (13.5%) compared with patients with a <\$5 increase (11.0%), but not as likely to fill a prescription for an LTRA (39.7% and 41.5% for ≥\$5 increase and <\$5 increase, respectively). Patients in the LTRA cohort with a ≥\$5 increase in copayment per month supplied were less likely to fill a prescription for an ICS or a COMBO in 2006 compared with patients with a <\$5 increase in copayment (ICS 18.3% and 20.6%; COMBO 59.8% and 77.3%, respectively).

Adjusted Analyses

The ≥\$5 average increase in 2006 copayment resulted in declines in adjusted average annual days supplied for: ICS of -47.1 days (95% confidence interval [CI], -43.5 to -50.8),

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Table 2. 2005 Demographics and Characteristics for the LTRA Group by Copayment Threshold (\geq \$5 Average Increase in Copayment per Month Supplied From 2005 to 2006)

	<\$5 Increase in copayment N = 17,860	\geq\$5 Increase in copayment N = 2804	P
Demographics			
Age in years, mean (SD)	41.3 (15.6)	39.4 (15.6)	<.0001
Gender, female, %	68.0	67.9	.92
Insurance plan type			<.0001
Comprehensive, %	11.1	11.8	—
EPO, %	0.2	0.3	—
HMO, %	18.3	20.4	—
POS (non-capitated), %	13.4	12.6	—
PPO, %	54.9	53.7	—
POS (capitated), %	1.9	0.5	—
CDHP, %	0.2	0.7	—
Comorbidities			
Quan et al comorbidity index,¹⁴ mean (SD)	0.29 (0.79)	0.29 (0.79)	.96
Allergic rhinitis, %	36.4	37.5	.24
Anxiety, %	5.8	6.2	.35
Depression, %	7.5	7.3	.77
Gastroesophageal reflux disease, %	9.2	9.0	.69
Obesity, %	2.7	2.4	.33
Health Care Utilization and Patient Costs			
Copayment per month supplied, mean (SD)	\$17.05 (\$10.66)	\$12.63 (\$9.63)	<.0001
ICS users, %	23.3	21.6%	.05
ICS adherence, mean (SD)	0.29 (0.26)	0.25 (0.23)	.0006
COMBO users, %	61.6	62.8%	.23
COMBO adherence, mean (SD)	0.44 (0.34)	0.41 (0.32)	<.0001
LTRA adherence, mean (SD)	0.54 (0.35)	0.46 (0.33)	<.0001
LABA users, %	8.3	6.9%	.008
LABA only adherence, mean (SD)	0.43 (0.34)	0.39 (0.33)	.14
SABA users, %	72.2	72.0%	.89
SABA days supplied, mean (SD)	64.5 (90.8)	62.9 (93.8)	.37
Oral corticosteroid users, %	37.2	37.0%	.78
Oral corticosteroid days supplied, mean (SD)	8.5 (27.5)	8.3 (29.4)	.82
Oral corticosteroid bursts, mean (SD)	0.62 (1.12)	0.61 (1.12)	.78
Outpatient visits (asthma diagnosis), mean (SD)	4.0 (4.7)	4.1 (4.5)	.25
ED visits (asthma diagnosis), mean (SD)	0.13 (0.64)	0.15 (0.59)	.06
Hospital stays (asthma diagnosis), mean (SD)	0.036 (0.20)	0.031 (0.20)	.23
Annual patient OOP total, mean (SD)	\$999 (\$834)	\$921 (\$821)	<.0001
<small>CDHP indicates consumer-driven health plan; COMBO, ICS plus LABA; ED, emergency department; EPO, exclusive provider organization; HMO, health maintenance organization; ICS, inhaled corticosteroid; LABA, long-acting beta-2 agonist; LTRA, leukotriene receptor antagonist; OOP, out-of-pocket; POS, point of service; PPO, preferred provider organization; SABA, short-acting beta agonist; SD, standard deviation.</small>			

■ **Table 3.** 2006 Long-term Controller Use by Study Cohort and Copayment Threshold (\geq \$5 Increase in Copayment per Month Supplied From 2005 to 2006)

	ICS cohort			COMBO cohort			LTRA cohort		
	<\$5 Increase in copayment N = 7630	\geq \$5 Increase in copayment N = 2621	P	<\$5 Increase in copayment N = 22,594	\geq \$5 Increase in copayment N = 4813	P	<\$5 Increase in copayment N = 17,860	\geq \$5 Increase in copayment N = 2804	P
ICS fills, %	66.7	37.3	<.0001	11.0	13.5	<.0001	20.6	18.3	.005
COMBO fills, %	21.7	28.7	<.0001	70.8	58.3	<.0001	49.5	45.7	<.0001
LTRA fills, %	37.9	36.3	.15	41.5	39.7	.026	77.3	59.8	<.0001

COMBO indicates ICS plus long-acting beta-2 agonist; ICS, inhaled corticosteroid; LTRA, leukotriene receptor antagonist.

ICOMBO of -35.3 days (-32.4 to -38.2), and LTRA of -47.5 days (-43.2 to -51.7). **Table 4** displays the adjusted rate ratios of asthma-related health services for those with a \geq \$5 increase in copayment per month supplied compared with those without a \$5 increase. Among all 3 LTC classes, the \geq \$5 copayment increase was associated with more asthma-related outpatient visits. Among LTRA and COMBO, the \geq \$5 copayment increase was associated with more asthma-related ED visits. Among the COMBO cohort, the \geq \$5 copayment increase was associated with more oral corticosteroid bursts.

Sensitivity Analysis Requiring Same LTC Use for Both 2005 and 2006. The \geq \$5 average increase in 2006 copayment resulted in declines in adjusted average annual days supplied for: ICS of -35.3 days (95% CI -29.5 to -41.1), COMBO of -26.7 days (-23.0 to -30.3), and LTRA of -27.7 days (-22.9 to -32.5). We found similar results as compared with our base case analysis when estimating the adjusted rate ratios of asthma health services. The only statistical change from base case results was that the ICS oral corticosteroids comparison became statistically significant for oral corticosteroids (adjusted rate ratio: 1.12 [95% CI 1.02-1.23]).

Sensitivity Analysis of the \geq \$10 Cut-off for Average Increase in 2006 Copayment. The \geq \$10 average increase in 2006 copayment resulted in declines in adjusted average annual days supplied for: ICS of -53.2 days (95% CI -48.5 to -57.8), COMBO of -41.1 days (-36.8 to -45.4), and LTRA

of -72.2 days (-65.5 to -78.9). We found similar results as compared with our base case analysis when estimating the adjusted rate ratios of asthma health services. The only statistical change as compared with the base case was that the LTRA outpatient visit rate ratio (RR) became not statistically significant (adjusted RR: 0.99 [95% CI 0.95-1.03]).

DISCUSSION

Among controller medication users (\geq 30-day supply), we found that LTC average adherence was low regardless of copayment (medication possession ratio across the 3 LTC classes ranged from 0.54 for LTRA to 0.26 for ICS). Asthma LTC medications such as ICS, ICS+LABA, and LTRA are prescribed to achieve control of asthma symptoms, maintain pulmonary function, and prevent exacerbations. Even without additional financial barriers such as patient copayment, previous research suggests that optimal asthma LTC consumption falls short for many patients.¹⁵ Bahadori et al reported in their burden of illness study that large variation of asthma control can partly be explained by variation in guideline adherence to medication use and deficits of patients' management.¹⁶ Suboptimal LTC adherence is linked with suboptimal asthma control.¹⁷ No matter the definition of asthma control, those with poorer control have vastly greater burden in terms of the propensity to reach asthma

■ **Table 4.** Adjusted Rate Ratios (95% CI) of Asthma-Related Health Services for \geq \$5 Increase in 2006 Average Copayment per Month

2006 Outcome	ICS	COMBO	LTRA
Oral corticosteroid bursts	0.95 (0.89-1.02)	1.07 (1.02-1.13)	0.96 (0.90-1.02)
Asthma outpatient visits	1.03 (1.00-1.06)	1.06 (1.03-1.08)	1.05 (1.02-1.08)
Asthma ED visits	1.02 (0.83-1.25)	1.48 (1.30-1.69)	1.19 (1.01-1.40)
Asthma hospitalizations	1.00 (0.93-1.08)	1.01 (0.96-1.07)	1.02 (0.95-1.08)

CI indicates confidence interval; COMBO, ICS plus long-acting beta agonist; ED, emergency department; ICS, inhaled corticosteroid; LTC, long-term asthma controller; LTRA, leukotriene receptor antagonist; OOP, out-of-pocket.

Note: We adjusted all regression analyses for 2005 baseline and clinical characteristics including: age, gender, insurance plan type, comorbidities, LTC use in terms of 2005 annual days supplied, asthma-related outpatient visits, oral corticosteroid bursts, asthma-related ED visits, asthma-related hospitalizations, and total OOP patient expenditures.

control in the future, direct and indirect costs, and health-related quality of life.^{18,19}

Acknowledging that the baseline LTC consumption is not optimal in the real world (more patients likely underconsume than overconsume), our study sought to test the impact of potential financial barriers to LTC consumption in terms of an increased patient LTC copayment on LTC utilization and asthma-related healthcare utilization. A \geq \$5 increase in copayment was associated with greater than 1 month's supply less utilization of LTCs over the course of 1 year for ICS, COMBO, and LTRA. Our primary objective for the study was to determine if a \geq \$5 increase in copayment was not only associated with lower LTC utilization but also impacted meaningful asthma-related health services. The multivariable models suggest that when adjusting for 2005 demographics, insurance plan type, comorbidities, LTC use, healthcare resource use, and total patient OOP expenses, a \geq \$5 increase in copayment was associated with more subsequent oral corticosteroid bursts (7% increase for COMBO), a 3% to 6% increase in asthma outpatient visits (ICS, COMBO, and LTRA), and a 48% and a 19% increase in asthma ED visits for COMBO and LTRA, respectively. The adjusted asthma-related health services findings from our sensitivity analyses were similar to those of the base case analysis.

Our study findings may be of use to value-based insurance design. Value-based insurance design is growing in the United States. It attempts to address the underuse of essential therapies by linking cost-sharing and value.²⁰ Evidence suggests that suboptimal adherence to LTCs is linked with suboptimal asthma control which, in turn, is linked with suboptimal value. However, value may have different definitions based on the stakeholders and perspective.

Bae et al modeled the health outcomes and cost shifts associated with an increase in monthly Medicaid copayment from \$0.50 to \$2.00 for ICS medication in adults.²¹ They projected that this small increase (but large relative increase) in patient copayment for a financially vulnerable population in Massachusetts would increase the annual number of acute asthma events by 646 due to lower adherence of ICS. In the Bae et al paper, the Medicaid plan was better off by \$2.10 million by increasing the copayment because of savings due to decreased medication utilization and lower pharmacy reimbursement rates as compared with the additional costs of the acute events. The Bae et al model brings into question the perspective of the analysis. In this case, the average Medicaid asthma patient was worse off because they paid more OOP and experienced more acute events. Decreased adherence may also have affected other patient outcomes such as asthma symptoms and health-related quality of life. The payer, on the other hand, was financially better off, as was the pharmacy benefit manager. In certain instances, shifting costs to the patient may be fiscally beneficial

to the pharmacy benefit manager and/or payer in the short run, but such actions may have clinical- (eg, asthma exacerbations) and humanistic- (eg, patient health-related quality of life) relevant consequences as well as potential long-term economic consequences that were not modeled in the Bae et al study.

This study has several limitations. Sociodemographic characteristics such as income, education, race, and local geography that are important to financial decision making are lacking in claims data. Elasticity of demand likely varies by income and we were unable to directly stratify or adjust for income in this analysis. Further, Ungar and colleagues recently showed that an increase in the proportion of family income spent on OOP asthma medications was associated with an increase in asthma exacerbations in children.²² We do not, however, have reason to believe that increases in copayment were more likely to occur for those with lower income. Additionally, we adjusted for baseline total OOP patient expenses as a proxy for healthcare burden on the patient's budget. Shifting and substitution patterns among various LTCs for those facing increased copayment were not observed to a great extent, thus lessening the potential for confounding by medication switching. We did not focus on a plan-level analysis or include other barriers to access such as step edits²³ due to the inability to follow these benefits longitudinally with the data set. Our study focused only on 2 consecutive years of data and found that, on average, patient copayment did not significantly change from 2005 to 2006 for ICS, COMBO, and LTRA medication classes; however, we did not test the trend of copayment change over long periods of time. We suspect that the general trend for patient LTC and other copayment is monotone, increasing over the past decade. Finally, we estimated the short-term impact of changes in patient copayment, but the long-term impact may be different from the shock of short-term copayment changes.

The study findings should be considered when designing drug benefit decisions that change formulary patient copayment structures. Although payer costs for LTCs may be lowered by shifting more burden to patients for LTC copayment, other economic, clinical, and humanistic outcomes pertinent to the medical payer, patient, and society, including increased outpatient and ED visits, should be weighed in drug benefit design decisions.

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Author Affiliations: From University of Colorado Anschutz Medical Campus (JDC), Aurora, CO; Merck & Co, Inc (FA-R, SGS, EMM), Whitehouse Station, NJ; University of Washington (SDS), Seattle, WA.

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Address correspondence to: Jonathan D. Campbell, PhD, University of Colorado School of Pharmacy, Mail Stop C238, Pharmacy and Pharmaceutical Sciences Bldg, 12850 E Montview Blvd, Aurora, CO 80045. E-mail: Jon.Campbell@ucdenver.edu.

REFERENCES

- Dor A, Encinosa W.** How does cost-sharing affect drug purchases? insurance regimes in the private market for prescription drugs. *J Econ Manage Strategy*. 2010;19:545-574.
- Gibson TB, Ozminkowski RJ, Goetzel RZ.** The effects of prescription drug cost sharing: a review of the evidence. *Am J Manag Care*. 2005;11(11):730-740.
- Remler DK, Greene J.** Cost-sharing: a blunt instrument. *Annu Rev Public Health*. 2009;30:293-311.
- Goldman DP, Joyce GF, Escarce JJ, et al.** Pharmacy benefits and the use of drugs by the chronically ill. *JAMA*. 2004;291(19):2344-2350.
- Huskamp HA, Deverka PA, Epstein AM, Epstein RS, McGuigan KA, Frank RG.** The effect of incentive-based formularies on prescription-drug utilization and spending. *N Engl J Med*. 2003;349(23):2224-2232.
- Joyce GF, Escarce JJ, Solomon MD, Goldman DP.** Employer drug benefit plans and spending on prescription drugs. *JAMA*. 2002;288(14):1733-1739.
- Dormuth CR, Glynn RJ, Neumann P, Maclure M, Brookhart AM, Schneeweiss S.** Impact of two sequential drug cost-sharing policies on the use of inhaled medications in older patients with chronic obstructive pulmonary disease or asthma. *Clin Ther*. 2006;28(6):964-978; discussion 962-963.
- Kozyrskyj AL, Mustard CA, Cheang MS, Simons FE.** Income-based drug benefit policy: impact on receipt of inhaled corticosteroid prescriptions by Manitoba children with asthma. *CMAJ*. 2001;165(7):897-902.
- Fung V, Tager IB, Brand R, Newhouse JP, Hsu J.** The impact of generic-only drug benefits on patients' use of inhaled corticosteroids in a Medicare population with asthma. *BMC Health Serv Res*. 2008;8:151.
- Crown WH, Berndt ER, Baser O, et al.** Benefit plan design and prescription drug utilization among asthmatics: do patient copayments matter? *Front Health Policy Res*. 2004;7:95-127.
- Thomson Reuters.** MarketScan Database Description. http://thomsonreuters.com/products_services/healthcare/healthcare_products/Pharmaceuticals/mktscan_res_db. Accessed September 1, 2010.
- HEDIS.** NDC 2009. <http://www.ncqa.org/tabid/892/Default.aspx>. Accessed June 1, 2010.
- Karve S, Cleves MA, Helm M, Hudson TJ, West DS, Martin BC.** Prospective validation of eight different adherence measures for use with administrative claims data among patients with schizophrenia. *Value Health*. 2009;12(6):989-995.
- Quan H, Sundararajan V, Halfon P, et al.** Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. *Med Care*. 2005;43(11):1130-1139.
- Gilberg K, Laouri M, Wade S, Isonaka S.** Analysis of medication use patterns: apparent overuse of antibiotics and underuse of prescription drugs for asthma, depression, and CHF. *J Manag Care Pharm*. 2003;9(3):232-237.
- Bahadori K, Doyle-Waters MM, Marra C, et al.** Economic burden of asthma: a systematic review. *BMC Pulm Med*. 2009;9:24.
- Navaratnam P, Friedman H, Urdaneta E.** The impact of adherence and disease control on resource use and charges in patients with mild asthma managed on inhaled corticosteroid agents. *Patient Prefer Adherence*. 2010;4:197-205.
- Campbell JD, Blough DK, Sullivan SD.** Comparison of guideline-based control definitions and associations with outcomes in severe or difficult-to-treat asthma. *Ann Allergy Asthma Immunol*. 2008;101(5):474-481.
- Sullivan SD, Rasouliyan L, Russo PA, Kamath T, Chipps BE.** Extent, patterns, and burden of uncontrolled disease in severe or difficult-to-treat asthma. *Allergy*. 2007;62(2):126-133.
- Choudhry NK, Rosenthal MB, Milstein A.** Assessing the evidence for value-based insurance design. *Health Aff (Millwood)*. 2010;29(11):1988-1994.
- Bae SJ, Paltiel AD, Fuhlbrigge AL, Weiss ST, Kuntz KM.** Modeling the potential impact of a prescription drug copayment increase on the adult asthmatic Medicaid population. *Value Health*. 2008;11(1):110-118.
- Ungar WJ, Paterson JM, Gomes T, et al.** Relationship of asthma management, socioeconomic status, and medication insurance characteristics to exacerbation frequency in children with asthma. *Ann Allergy Asthma Immunol*. 2011;106(1):17-23.
- Carlton RI, Bramley TJ, Nightengale B, Conner TM, Zacker C.** Review of outcomes associated with formulary restrictions: focus on step therapy. *Am J Pharm Benefits*. 2010;2(1):50-58. ■