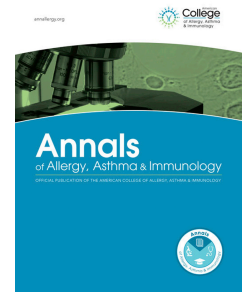


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Retrospective Review of Insurance Coverage for Patch Testing

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1 Introduction

Insurance coverage and prior authorization (PA) requirements imposed by insurance companies have resulted in widespread barriers to care for both dermatology and allergy patients.¹⁻³ In a recent survey conducted by the American Academy of Dermatology (AAD), greater than two-thirds of 177 respondents from US-based AAD committee/task force members under the Council on Government Affairs, Health Policy, and Practice and Association of Dermatology Administrators/Managers members reported that PA requirements negatively affect at least 1 patient daily.³ According to dermatologists surveyed, acne medications and biologic drugs required PAs greater than 95% of the time, while even calcineurin inhibitors required PAs over 80% of the time.³ Out-of-pocket (OOP) expenses for topical steroids by Medicare patients rose 145.9% from 2011 through 2015, with only a 37% increase in the annual number of prescriptions during this time.² Furthermore, previous work has demonstrated substantial costs associated with processing PAs for non-formulary drugs prescribed by allergists on both the physician office and insurance sides of the process.⁴

According to the AAD Skin Disease Briefs, over 13 million Americans sought medical treatment for contact dermatitis in 2013, resulting in about 1.5 billion dollars in medical treatment and almost 700 million dollars of lost productivity.⁵ In a 2013 study evaluating German patients with occupational hand dermatitis, Diepgen et al found that annual societal costs amounted to €8,799 per patient, a figure similar to patients with atopic dermatitis or psoriasis.⁶ Furthermore, although patients in this sample suffered from varying levels of disease severity, direct and indirect costs were not significantly different between the group with worse disease in comparison to the group with mild disease.⁶ This finding suggests that patients with even mild disease encounter a substantial cost burden.⁶ Contact dermatitis involves not only

substantial economic costs to society and patients, but also confers a high burden of disease and diminished quality of life (QoL) in patients affected.⁷⁻⁹

Allergic contact dermatitis (ACD) is characterized by an inflammatory cutaneous response resulting from direct skin contact with inciting agents which trigger a delayed-type hypersensitivity reaction. Evidence suggests that the prevalence of contact allergy is upwards of 20%, and the most common allergens implicated include nickel, fragrance mix, methylisothiazolinone, and neomycin.¹⁰⁻¹² Patch testing is currently the most reliable method for accurately diagnosing ACD, allowing dermatologists and allergists to identify the causative agent in a timely manner while providing patients the necessary information to facilitate allergen avoidance.¹³⁻¹⁵ Beyond its diagnostic validity, patch testing is considered to be cost effective and beneficial to improving patient QoL.¹⁶⁻¹⁸ In addition to improving QoL, the dual diagnostic and therapeutic benefits of patch testing alleviates the appreciable socioeconomic costs of ACD for patients at all levels of severity of the disease.^{7,14-16,18} Little is known about OOP expenses for patients undergoing patch testing, however.

Considering the substantial costs to society for diagnosis and management of ACD, a more robust understanding of how patch testing contributes to the individual patient's financial burden of illness is needed.¹⁹ The present study aims to describe insurance coverage of patch testing in a sample of patients in the United States, while characterizing both allergen limitations imposed by insurers and patient OOP cost burden. Additionally, discrepancies across demographic variables including gender, race, and age, were investigated.

Methods

A retrospective review of patients with a diagnosis of contact dermatitis (International Classification of Disease [ICD], Ninth Edition, code ICD 692) who received patch testing at the George Washington Medical Faculty Associates Dermatology Clinic between January 1, 2015 and June 30, 2017 was conducted. OOP costs were calculated to determine the cost of allergens and office visits for testing for individual patients after insurance. No facility fees were charged and expenditures from health savings accounts were considered as OOP cost. The 95044 Current Procedural Terminology (CPT) billing code included was based on the outpatient schedule. Patients insured by Medicaid coverage, lost to follow up, with indeterminable OOP expenses, with incomplete testing, or receiving testing as part of pre-surgical evaluation, were excluded. A sample size of 29 patients per insurance group was calculated to be sufficient to detect an effect size of 0.75 at $\alpha=0.05$. Inclusion and exclusion criteria are shown in *Table 1*.

Separate analysis was performed for each of these nine outcome variables, including: number of total allergens tested, OOP costs, percent of patients getting the North American (NA)-80 Standard Extended tray only, number of total allergens limited by insurance policy, percent of patients getting multiple rounds of testing, percent of patients with partial coverage, percent of patients paying copay only (defined as the policy-specific minimal OOP payment for service), percent of patients with insurance limits resulting multiple rounds of testing, and percent of patient with insurance limits in general. Comparisons were made between private insurance versus government-sponsored insurance and individual major private insurance providers (including Insurers A, B, C, and D). Basic characteristics of included insurers are presented in *Table 2*. Differences between patients with Health Maintenance Organization (HMO) versus Preferred Provider Organization (PPO) within major insurance providers and across all insurance providers were also computed. Specifically, the t-test and Wilcoxon rank

sum test or one-way ANOVA and Kruskal Wallis tests were applied to continuous outcome variables depending on the distribution of data. The Kolmogorov-Smirnov test was utilized to assess the normality of continuous outcome variables. The Chi-Square and Fisher exact tests were employed to analyze categorical variables.

Investigation into influence of demographic characteristics such as age, gender, race and occupational status on OOP costs was also conducted. The t-test and Wilcoxon rank sum test or one-way ANOVA and Kruskal Wallis tests were performed to assess the differences of OOP cost for categorical predictors such as gender, race, and occupational status. The association of OOP costs with the continuous variable of age was evaluated by Kendal correlation coefficient.

Means of continuous variables are reported $\pm$ standard error of the mean (SEM) unless otherwise noted. A p-value of 0.05 was used as the threshold for statistical significance. SAS version 9.4 (SAS Institute, Cary, NC) was used for all analyses.

Results

A total of 371 records met inclusion and exclusion criteria, including 53 patients with government-sponsored insurance coverage and 318 patients with private insurance coverage. The sample of patients studied was predominantly female (72.8%) with a mean age of 49 years. Data from those covered by private insurance companies was further stratified by major private insurers, defined as those with at least 30 policyholders. Insurer A (N=52), Insurer B (N=40), Insurer C (N=162), and Insurer D (N=38) were the major private insurers included.

Patients with government-sponsored insurance coverage more frequently encountered insurance limitations on the number of allergens tested in comparison to patients with private insurance (86.8% and 14.2%, respectively, $p<0.0001$) (*Table 2*). Patients insured by Insurer A

were the privately-insured patients most likely to encounter insurance limits (65.38%), while Insurer B (20.0%), Insurer C (1.2%) and Insurer D (0%) patients encountered limits less often ($p<0.0001$) (*Table 2*). Overall, no significant difference in the presence of insurance limits between those with HMO plans versus those with PPO plans was found (*Table 2*). Among patients who encountered insurance limitations, 41.3% of patients with government-sponsored coverage received multiple rounds of patch testing, which was similar to 35.6% proportion of privately-insured patients ($p=0.6679$) (*Table 2*).

The mean number of total allergens tested per year was significantly greater for patients with private insurance coverage (139.16 ± 1.89) in comparison to patients with government-sponsored insurance coverage (103.00 ± 5.08 , $p<0.0001$) (*Table 3*). This mean was the greatest for patients insured by Insurer D (152.26 ± 3.82), followed by those insured by Insurer C (146.06 ± 2.24), Insurer B (130.23 ± 6.03), and Insurer A (108.35 ± 5.01) (*Table 3*). Differences in mean number of total allergens tested per year between individual major private insurers were significant ($p<0.0001$) (*Table 3*). Overall, HMO and PPO plans did not yield significant differences in the mean total number of allergens tested per year ($p=0.3452$) (*Table 3*). However, patients with HMO plans within Insurer B ($N=4$) received significantly fewer 103.0 ± 11.87 allergens on average in comparison to Insurer B patients with PPO plans ($N=5$, 142.33 ± 3.05 , $p=0.0145$) (data not shown).

Patients with government-sponsored insurance received significantly more frequent testing to the NA-80 Standard Extended tray alone (30.2%) in comparison to those with private insurance (10.4%, $p<0.0001$) (*Table 3*). Patients insured by Insurer A were most likely to receive testing to the NA-80 Standard Extended tray alone (42.3%), followed by Provider B (17.5%), Insurer C (2.5%) and Insurer D (0%) patients. Differences between major insurance providers

were statistically significant ($p < 0.0001$) (*Table 3*). However, no significant differences in the frequency of NA-80 Standard Extended tray-only testing were found upon comparing those with HMO plans to those with PPO plans overall (*Table 3*) or within each individual major private insurance provider.

Mean OOP expense was significantly greater for privately-insured patients (\$402.60±35.81) in comparison to patients with government-sponsored coverage (\$179.30±57.89, $p < 0.0001$) (*Figure 1*), while only a trend toward significance was noted for mean OOP expenses compared between individual major private insurance providers ($p = 0.0652$) (*Table 4*). No significant differences in mean OOP expense were found upon comparing those with HMO plans to those with PPO plans overall ($p = 0.0955$) (*Table 4*), or within each major private insurance provider (data not shown). Gender, race, and age had no significant influence on mean OOP expense (data not shown), while employment status proved to have a significant impact ($p = 0.0045$) (*Table 4*). Expenses for patients with unknown employment status (\$476.28±120.36) were the greatest, while student patients (\$224.65±166.07) encountered the least OOP expense (*Table 4*). Patients with private health insurance were significantly more likely to only have to pay the copay in comparison to patients with government-sponsored insurance (43.7% and 0%, respectively, $p < 0.0001$) (*Table 5*). Significant differences in the proportions of patients paying only a copay were also found upon comparing between major private insurance providers ($p = 0.0451$), with Insurer B patients most likely to pay only a copay (65.0%), followed by Insurer C (43.2%), Insurer D (39.5%) and Insurer A patients (38.5%) (*Table 5*). Overall, patients with HMO plans were significantly more likely to pay only a copay in comparison to patients with PPO plans (75.0% and 42.3%, respectively, $p = 0.0032$) (*Table 5*). Furthermore, patients insured by Insurer C HMO plans were significantly more likely to pay

only a copay in comparison to patients with PPO plans under the same insurer ($p=0.0248$) (data not shown). Within each other major private insurance provider, no significant difference between proportions of patients only having to pay a copay was found upon comparing those with HMO plans versus those with PPO plans.

No significant difference in the proportion of patients with $<100\%$ coverage was found upon comparing those with government-sponsored insurance to those with private insurance ($p=0.6155$) (*Table 5*). Similarly, no significant differences in the proportion of patients with $<100\%$ coverage was found upon comparing between those insured by individual major private insurance providers (*Table 5*). Patients with PPO plans were significantly more likely to have $<100\%$ coverage in comparison to patients with HMO plans (44.6% and 0%, respectively, $p<0.0001$) (*Table 5*). Among insurance company C patients, the difference in proportions patients with $<100\%$ coverage between PPO and HMO plans was significant (0% versus 45.7%, $p=0.0002$) (*Table 5*) while no significant differences were found within other individual major private insurance plans (data not shown).

Overall, Insurer A patients paid the highest OOP expense per allergen ($\$3.16\pm4.13$), while both government-sponsored insurance and Insurer C patients paid the least ($\$1.60\pm3.56$ and $\$2.40\pm5.13$, respectively) (*Table 6*). Significant differences were found in mean paid per allergen tested between patients with government-sponsored insurance compared to those with private insurance ($p<0.0001$) and between individual major private insurers ($p=0.0409$) (*Table 6*).

Discussion

Findings from this study characterize the cost burden of patch testing in a University outpatient setting in Washington, DC. Patient government-sponsored and private insurance paid a mean of \$179.30 and \$402.60 for testing to a mean of 103 and 139 allergens, respectively (*Figure 1*). Differences in the total number of allergens tested yearly was associated with the frequency of encountering allergen limitations in testing; a barrier which government-sponsored insurance patients encountered significantly more often than privately insured patients (*Table 2*).

Insurer C and D patients were least likely to encounter limitations on the number of allergens to be tested (1.2% and 0%, respectively), while 42.3% of Insurer A patients encountered allergen limitations (*Table 2*). These discrepancies corresponded to the mean total number of allergens tested per year, which were the highest for Insurer C and D patients (146 and 152, respectively) in contrast to Insurer A patients, who received the least mean number of allergens tested in comparison to the other major private insurers (108 allergens) (*Table 3*). Interestingly, no significance was found in the difference in OOP expenses amongst all major insurance providers ($p=0.0652$) (*Table 4*). This lack of difference in OOP expenses coupled with strong association of allergen limitations and mean total number of allergens tested per year suggests a direct influence of limitations imposed by insurance companies on the total number of allergens tested by year. Because increased total number of allergens tested has been shown to lead to increased positive reactions and increased relevant reactions, this evidence supports that patients with more generous coverage likely have a higher quality diagnostic workup, and in turn, treatment, as patients have better guidance about which allergens to avoid.²⁰

The NA-80 Standard Extended tray is an assortment of 80 allergens commonly implicated in ACD and is implemented as an alternative to more extended testing with additional trays.²¹ Insurer A and government-sponsored insurance patients received the most frequent

testing to this tray alone. In fact, Insurer A patients received testing to the NA-80 Standard Extended tray alone more than double the frequency of patients from other major providers (*Table 3*). This was likely related to the high frequency of allergen limits imposed on patients insured by Insurer A and government-sponsored insurance.

Although 0% of Insurer D patients encountered allergen limitations, average OOP expense per allergen tested was still higher than both Insurer B and government-sponsored insurance patients, who encountered allergen limitations 20.00% and 86.79% of the time, respectively (*Tables 2 and 3*). This finding is contrary to the hypothesis that increased allergen limitations would be expected to be met with increased mean OOP expense per allergen tested. This observed discrepancy is likely due to limitations in our dataset, as there was no control for ages of individuals, which may influence spending patterns and willingness to spend. Computation of OOP expense per allergen showed a wide variation based on the insurance coverage of the patient (*Table 6*). Lower expense for patients with government-sponsored insurance is likely due to differences in spending preferences and the confounding factor of age in this Medicare population.

Other limitations of our study include the lack of notation of what time of year testing occurred, and the skewed population of government-sponsored insurance patients which limits external validity. Time of the year in which testing was obtained could have a large influence on OOP expense given that more patients are likely to have deductibles filled toward the end of the year. Furthermore, in terms of the Medicare-only population remaining in our sample of government-sponsored insurance patients, our patient population is likely skewed toward those of a demographic with wealthier socio-economic backgrounds given the geographic location of our clinic. In turn, the 42.3% of government-sponsored patients determined in the present study

to pay any OOP expense is likely an overestimate of the general population, which includes Medicaid and Tricare patients (excluded from the present study due to low sample), along with patients from possibly more diverse socio-economic backgrounds. In the senior author's experience, however, Medicare coverage limitations of 75 allergens per visit does sway some patients to prefer testing to be more limited than what is clinically recommended. Furthermore, patients may opt for multiple rounds of testing in order to ensure full coverage of all recommended allergens. Indeed, the present study found that 41.3% of patients with government-sponsored insurance patients received multiple rounds of patch testing. Lastly, we do not correlate OOP cost or insurance limitations to clinical outcomes such as symptom improvement or corticosteroid use in this study.

This study is the first to characterize the OOP expense burden for patients undergoing patch testing, while conveying important differences in insurance coverages. Results of the present suggest that these coverages demonstrate wide variability and strongly influence the quality of the diagnostic workups. Improved diagnostic workups can lead to better managed disease, including enhanced QoL and money saved on chronic use of topical corticosteroids. Given the high level of impact ACD bears on QoL and the tremendous cost burden of disease, these findings convey the importance of reducing inequities in dermatology and allergy practices while drawing attention to concerns about insurance coverage of patch testing.

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Figure Legend

Figure 1. Mean total out-of-pocket (OOP) expenses by type of insurance. Mean OOP expense was significantly higher for those privately insured ($\$402.60 \pm 35.81$) in comparison to patients with government-sponsored insurance ($\$179.30 \pm 57.89$). $*p < 0.0001$. Error bars show standard error of the mean.

Tables

INCLUSION	
1.	Patients at the GW MFA receiving patch testing from January 1, 2015 through June 30, 2017
EXCLUSION	
1.	Uninsured or Medicaid patients
2.	Lost to follow up (did not complete a single week of testing)
3.	Patients who received previous patch testing at GW MFA prior to January 1, 2015
4.	Patients with indeterminable OOP expenses
5.	Patients who did not return for round 2 of testing when advised
6.	Patients receiving testing as part of pre-surgical evaluation
Total number of records analyzed: 371	

Table 1. Inclusion and exclusion criteria.

Insurance	Basic Characteristics	Proportion of patients encountering allergen limits	P-value	Proportion of patients with limits who received multiple rounds of testing
Government-sponsored	Medicare	86.8% (46/53)	<0.0001	41.3% (19/46)*
All private	Mixed	14.2% (45/318)		35.6% (16/45)*
Insurer A	For-profit, nationwide, employer + individual plans	65.4% (34/52)	<0.0001	29.4% (10/34)
Insurer B	For-profit, nationwide, lower premiums, employer + individual plans	20.0% (8/40)		37.5% (3/8)
Insurer C	Non-profit, largest regional insurer, employer + individual plans	1.2% (2/162)		100% (2/2)
Insurer D	For-profit, nationwide, largely PPO-focused, employer + individual plans	0.0% (0/38)		0% (0/0)
Plan: HMO	Mixed	8.3% (2/24)	1.0	50% (1/2)
Plan: PPO	Mixed	9.2% (12/130)		41.7% (5/12)
*p=0.6679				

Table 2. Basic characteristics of insurance providers and allergen limits imposed by government-sponsored and private insurances with resulting multiple rounds of testing.

Insurance	Mean number of total allergens tested	P-value	Proportion of patients tested to STD EXT alone	P-value
Government-sponsored	103.00±5.08 (N=53)	<0.0001	30.2% (16/53)	<0.0001
All private	139.16±1.89 (N=318)		10.4% (33/318)	
Insurer A	108.35±5.01 (N=52)	<0.0001	42.3% (22/52)	<0.0001
Insurer B	130.23±6.03 (N=40)		17.5% (7/40)	
Insurer C	146.06±2.24 (N=162)		2.5% (4/162)	
Insurer D	152.26±3.82 (N=38)		0.0% (0/38)	
Plan: HMO	136.25±6.69 (N=24)	0.3452	8.3% (2/24)	0.6816
Plan: PPO	142.33±2.71 (N=130)		6.9% (9/130)	

Table 3. Mean number of allergens tested and proportion of patients tested to the North American-80 Standard Extended tray (STD EXT) alone by insurance provider and plan. N; sample size.

Insurance	Mean OOP expense	P-value
Government-sponsored	\$179.30±57.89 (N=53)	<0.0001
All private	\$402.60±35.81 (N=318)	
Insurer A	355.86±73.96 (N=52)	0.0652
Insurer B	234.43±73.19 (N=40)	
Insurer C	396.58±44.72 (N=162)	
Insurer D	379.64±104.42 (N=38)	
Plan: HMO	395.63±194.01 (N=24)	0.0955
Plan: PPO	377.35±45.54 (N=130)	
Employment Status	Mean OOP expense	P-value
Employed	387.30±38.77 (N=266)	0.0045
Retired	238.40±65.55 (N=44)	
Student	224.65±166.07 (N=12)	
None	292.96±101.21 (N=11)	
Unknown	476.28±120.36 (N=38)	

Table 4. Mean total out-of-pocket (OOP) expenses by insurance type and employment status.

Insurance	Proportion of patients paying only a copay	P-value	Proportion of patients with <100% coverage	P-value
Government-sponsored	0.0% (0/53)	<0.0001	42.3% (11/53)	0.6155
All private	43.7% (139/318)		37.3% (118/318)	
Insurer A	38.5% (20/52)	0.0451	41.2% (21/52)	0.2662
Insurer B	65.0% (26/40)		22.5% (9/40)	
Insurer C	43.2% (70/162)		37.7% (61/162)	
Insurer D	39.5% (15/38)		36.8% (14/38)	
Plan: All HMO	75.0% (18/24)	0.0032	0.0% (0/24)	<0.0001
Plan: All PPO	42.3% (55/130)		44.62% (58/130)	

Table 5. Proportions of patients paying copay alone and with less than 100% coverage by insurance type.

Insurance	Mean OOP Expense per Allergen Tested	P-value
Government-sponsored	Medicare (N=53) \$1.60±3.56	<0.0001
Private	All (N=318) \$2.97±4.52	
	Insurer A (N=52) \$3.16±4.13	0.0409
	Insurer C (N=162) \$2.40±5.13	
	Insurer D (N=38) \$2.81±3.75	
	Insurer B (N=40) \$2.46±4.15	
Plan: All HMO	\$2.38±5.38	0.1968
Plan: All PPO	\$2.71±3.68	

Table 6. Out-of-pocket (OOP) expense per allergen by insurance.

Mean Total OOP Expenses

