46 Characteristics Associated With Medication Adherence Among New Omalizumab Users

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ABSTRACT

OBJECTIVE: Adherence to omalizumab (OMA) therapy has not been well studied. We sought to identify characteristics associated with adherence among new OMA users.

METHODS: This was a retrospective cohort analysis using a HIPAA-compliant claims database. The study identified asthma patients who were ≥12 years old, newly treated with OMA between 7/1/2004 and 6/30/2007, and enrolled for 1 year before and 1 year after the first OMA claim. Adherence was measured by medication possession ratio (MPR) (total days of medication supplied ÷ 365) with each OMA claim considered a 28-day supply. Therapy step, as defined by the EPR3 guidelines, was assigned using a published algorithm. A base linear regression model was conducted with MPR as the dependent variable and demographics, physician specialty, respiratory comorbidities, asthma control, therapy step, and medication ratio forced into the model as independent variables. Other comorbidities were considered with forward selection and retained if significant at p<.05.

RESULTS: We identified 766 new OMA users; mean age was 43 (SD 14) years, and 61% (n=466) were female. Forty-two percent of patients had allergists as their usual source of care, 20% pulmonologists, 28.3% primary care physicians, and the remainder other/unspecified. The mean number of chronic conditions was 5 (SD 2). Before starting OMA, most of patients were on EPR3 Step 5 therapy (28%), followed by Step 4 (18%), Step 3 (16%), Step 2 (15%), Step 1 (6%), and Step 6 (5%). Mean MPR in the year after treatment initiation was 0.68 (SD 0.30), and 55% persisted with therapy for at least 1 year. The final model included the base variables and diseases of circulatory system (the only additional significant predictor). Significant predictors of higher MPR were: care provided by allergists or pulmonologists, chronic otitis media, 5 or 6 vs ≥7 chronic conditions, and no disease of the circulatory system.

CONCLUSIONS: We found MPR for omalizumab to be higher on average than what has been reported for combination corticosteroid/long-acting beta-agonist therapy. Care by an allergist or pulmonologist was associated with greater adherence. Confounding by disease severity is possible, but the relationship was significant after controlling for therapy step. If this finding is confirmed in other studies, it supports the value of specialist care for patients with difficult to treat asthma.

BACKGROUND

- Lack of adherence to prescribed treatments for asthma is a well-known problem. Rates of nonadherence range from 30% to 70%.[1-3]
- Poor asthma medication adherence is associated with decreases in asthma control and increases in emergency department visits, hospitalizations, and the need for oral corticosteroids.[3,4]
- Omalizumab, a humanized monoclonal antibody targeting immunoglobulin E, is approved in the United States for the treatment of adults and adolescents (≥12 years) with moderate to severe persistent allergic asthma that is inadequately controlled with inhaled corticosteroids.[5]
- Adherence to omalizumab therapy has not been well studied. One prior analysis of asthma patients newly treated with omalizumab estimated adherence rates to be 64.6% with 54% persisting up to one year.[6]

OBJECTIVE

- To identify characteristics associated with adherence and persistence among new omalizumab users

METHODS

Study Design

- A retrospective cohort analysis using a HIPAA-compliant administrative claims database of 10 million covered lives representing all major regions of the United States.
- Eligible patients were ≥12 years old, diagnosed with asthma, newly treated with omalizumab between 7/1/2004 and 6/30/2007, and followed for a year (**Figures 1** and **2**).

Figure 1. Study Timeline

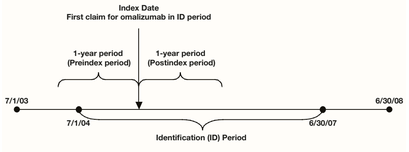
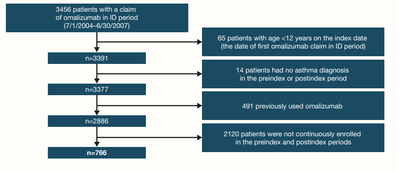


Figure 2. Cohort Selection for Omalizumab New Users.



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Study Outcomes

- Adherence to omalizumab therapy during the postindex period, as measured by the medication possession ratio (MPR)
  - Calculated as the total days of medication supplied over the year, divided by 365
  - Each omalizumab claim was considered a 28-day supply
- Medication persistence during the postindex period, as measured by time to discontinuation
  - Calculated as the number of days on omalizumab with no gaps of more than 45 days

Statistical Analysis

- To evaluate the association of baseline measures (patient demographic and clinical characteristics) with omalizumab adherence and persistence, we conducted a linear regression model with adherence (MPR) as the continuous dependent variable and all baseline measures as independent variables and a similar logistic regression model to predict persistence at one year.
  - Based on bivariate analysis results and clinical relevance, demographics (age, sex, and region), asthma physician specialty, number of chronic conditions, evidence of allergy, respiratory-specific comorbidities, therapy step, and medication ratio were first included in the linear regression model; we then used forward selection to identify significant results for other baseline measures.

RESULTS

- We identified 766 new omalizumab users; average age was 43.4 years and 61% were female. Fifty percent of patients received asthma care from an allergist, 28% a pulmonologist, and 17% a primary care physician.
- Overall, the MPR was 0.68 (SD, ± 0.30). MPR stratified by baseline measures are presented in **Table 1** and results of the multivariate analysis in **Table 2**.
- During follow-up, 45.3% of patients discontinued treatment. Mean (SD) time to discontinuation/end of study was 256.5 (131.6) days; median was 353 days (**Table 3**, **Figure 3**).
- The risk of discontinuing omalizumab was examined across a number of variables (**Table 4**).

Table 1. MPR of Omalizumab Stratified by Patient Demographics and Clinical Characteristics

	N	(%)	MPR Mean (SD)	*P* Value
All	766	(100.0)	0.68 (0.30)	
Demographics				
Age, y (mean 43.4; SD 14.5)				0.157
12-17	68	(8.9)	0.72 (0.28)	
18-34	111	(14.5)	0.62 (0.34)	
35-44	183	(23.9)	0.66 (0.30)	
45-54	234	(30.5)	0.68 (0.30)	
55-64	141	(18.4)	0.71 (0.27)	
65+	29	(3.8)	0.65 (0.24)	
Sex				0.174
Female	466	(60.8)	0.69 (0.30)	
Male	300	(39.2)	0.66 (0.30)	
Region				0.056
Midwest	184	(24.0)	0.71 (0.28)	
Northeast	86	(11.2)	0.62 (0.32)	
South	387	(50.5)	0.66 (0.30)	
West	109	(14.2)	0.70 (0.27)	
Physician Specialty				
Usual asthma care physician[a]				0.020
Pulmonologist	214	(27.9)	0.68 (0.28)	
Primary care	128	(16.7)	0.64 (0.31)	
Allergists	381	(49.7)	0.69 (0.29)	
Other	22	(2.9)	0.66 (0.36)	
Unknown	21	(2.7)	0.48 (0.39)	
General Comorbidities				
No. of chronic conditions (mean 4.7; SD 2.3)				0.047
1-2	155	(20.2)	0.63 (0.33)	
3-4	227	(29.6)	0.69 (0.29)	
5-6	216	(28.2)	0.71 (0.27)	
7+	168	(21.9)	0.65 (0.29)	
Charlson Comorbidity Index[7] (mean 1.8; SD 1.7)				0.967
1	530	(69.2)	0.68 (0.30)	
2	86	(11.2)	0.68 (0.29)	
3+	150	(19.6)	0.67 (0.29)	
Evidence of allergy				<.001
No	57	(7.4)	0.55 (0.34)	
Yes	709	(92.6)	0.69 (0.29)	
Respiratory-Specific Comorbidities				
COPD				0.338
No	577	(75.3)	0.67 (0.31)	
Yes	189	(24.7)	0.69 (0.27)	
Sinusitis				0.551
No	243	(31.7)	0.67 (0.31)	
Yes	523	(68.3)	0.68 (0.29)	
Rhinitis				<0.001
No	93	(12.1)	0.57 (0.33)	
Yes	673	(87.9)	0.69 (0.29)	
Tonsillitis				0.321
No	731	(95.4)	0.67 (0.30)	
Yes	35	(4.6)	0.72 (0.28)	
Acute upper respiratory infection				0.471
No	515	(67.2)	0.67 (0.30)	
Yes	251	(32.8)	0.69 (0.28)	
Conjunctivitis				0.894
No	619	(80.8)	0.68 (0.30)	
Yes	147	(19.2)	0.67 (0.29)	
Chronic otitis media				0.002
No	746	(97.4)	0.67 (0.30)	
Yes	20	(2.6)	0.81 (0.17)	
Nasal polyposis				0.073
No	663	(86.6)	0.68 (0.29)	
Yes	103	(13.4)	0.63 (0.32)	
Cough				0.427
No	381	(49.7)	0.67 (0.31)	
Yes	385	(50.3)	0.68 (0.28)	
Asthma Control in the Preindex Period				
Poor asthma control[b]				0.096
No	191	(24.9)	0.64 (0.32)	
Yes	575	(75.1)	0.69 (0.29)	
Asthma-related inpatient hospitalization				0.340
No	657	(85.8)	0.68 (0.30)	
Yes	109	(14.2)	0.65 (0.30)	
Asthma-related ED visit				0.412
No	705	(92.0)	0.67 (0.30)	
Yes	61	(8.0)	0.71 (0.29)	
Two or more oral corticosteroid prescriptions filled				0.031
No	265	(34.6)	0.64 (0.32)	
Yes	501	(65.4)	0.69 (0.28)	
Six or more short-acting beta-agonist prescriptions filled				0.310
No	434	(56.7)	0.67 (0.30)	
Yes	332	(43.3)	0.69 (0.29)	
EPR-3 Guidelines[8] Therapy Step in Preindex Period				
Therapy step prior to initiating omalizumab				0.006
No asthma meds	68	(8.9)	0.56 (0.33)	
Step 1	44	(5.7)	0.61 (0.32)	
Step 2	112	(14.6)	0.67 (0.30)	
Step 3	121	(15.8)	0.73 (0.27)	
Step 4	136	(17.8)	0.69 (0.28)	
Step 5	214	(27.9)	0.69 (0.29)	
Step 6	37	(4.8)	0.63 (0.33)	
Unclassified	34	(4.4)	0.72 (0.28)	
Medication Ratio[c] and Other Asthma Medication Use in the Preindex Period				
Medication ratio (mean 0.64; SD 0.28 among 718 patients with medication ratios)				0.003
Low ratio (<0.5)	197	(25.7)	0.64 (0.31)	
High ratio (≥0.5)	521	(68.0)	0.70 (0.28)	
Missing (no controller or reliever)	48	(6.3)	0.55 (0.35)	
Short-acting beta-agonist inhalers				0.044
No	115	(15.0)	0.62 (0.32)	
Yes	651	(85.0)	0.68 (0.29)	
Anticholinergics				0.077
No	521	(68.0)	0.66 (0.30)	
Yes	245	(32.0)	0.70 (0.29)	
Oral corticosteroids				0.119
No	153	(20.0)	0.64 (0.32)	
Yes	613	(80.0)	0.68 (0.29)	
ICS/LABA combination				0.051
No	240	(31.3)	0.64 (0.31)	
Yes	526	(68.7)	0.69 (0.29)	
ICS alone				0.286
No	450	(58.7)	0.67 (0.31)	
Yes	316	(41.3)	0.69 (0.28)	
LABA alone				0.790
No	643	(83.9)	0.67 (0.30)	
Yes	123	(16.1)	0.68 (0.30)	
Mast cell stabilizers				0.108
No	734	(95.8)	0.67 (0.30)	
Yes	32	(4.2)	0.76 (0.25)	
Methylxanthines				0.810
No	670	(87.5)	0.67 (0.30)	
Yes	96	(12.5)	0.68 (0.26)	
Leukotriene receptor antagonists				0.078
No	221	(28.9)	0.65 (0.31)	
Yes	545	(71.1)	0.69 (0.29)	

[a]The usual asthma care physician was determined by the largest plurality of office visits with evaluation and management services and asthma diagnosis.
[b]Asthma-related inpatient hospitalization, asthma-related ED visit, ≥2 oral corticosteroid prescriptions filled, or ≥6 short-acting beta-agonist prescriptions filled.
[c]Medication ratio is units of asthma controllers to units of controllers + units of relievers.
COPD = chronic obstructive pulmonary disease; ED = emergency department; EPR-3 = National Asthma Education and Prevention Program Expert Panel Report 3; ICS = inhaled corticosteroid; LABA = long-acting beta-agonist; MPR = medication possession ratio.

Table 2. Multivariate Analysis: Characteristics Associated With Omalizumab MPR

	Coefficient	SE	*P* Value
Intercept	0.49	0.10	<0.001
Age, y			
12-17 vs 65+	0.04	0.07	0.567
18-34 vs 65+	-0.04	0.06	0.520
35-44 vs 65+	0.01	0.06	0.845
45-54 vs 65+	0.04	0.06	0.483
55-64 vs 65+	0.06	0.06	0.298
Female vs male	0.03	0.02	0.268
Region			
Midwest vs West	0.03	0.04	0.375
Northeast vs West	-0.03	0.04	0.545
South vs West	-0.03	0.03	0.290
Usual asthma care physician specialty			
Allergist vs primary/other	0.04	0.03	0.178
Pulmonologist vs primary/other	0.04	0.03	0.193
No. of chronic conditions			
1-2 vs 7+	-0.03	0.04	0.522
3-4 vs 7+	0.03	0.03	0.334
5-6 vs 7+	0.07	0.03	0.028
Evidence of allergy	0.06	0.06	0.351
Therapy step			
No asthma medication vs Step 6	-0.02	0.07	0.818
Step 1 vs Step 6	-0.01	0.07	0.933
Step 2 vs Step 6	0.01	0.06	0.817
Step 3 vs Step 6	0.08	0.06	0.138
Step 4 vs Step 6	0.04	0.05	0.506
Step 5 vs Step 6	0.04	0.05	0.443
Unclassified vs Step 6	0.10	0.07	0.182
Medication ratio			
Low ratio (<0.5) vs high ratio (≥0.5)	-0.03	0.06	0.602
Missing (no controller or reliever) vs high ratio (≥0.5)	-0.08	0.06	0.211
COPD	0.03	0.03	0.317
Sinusitis	0.00	0.02	0.927
Rhinitis	0.08	0.05	0.112
Tonsillitis	0.07	0.05	0.178
Acute upper respiratory infection	0.00	0.02	0.950
Conjunctivitis	-0.02	0.03	0.477
Chronic otitis media	0.13	0.07	0.050
Nasal polyposis	-0.09	0.03	0.005
Cough	0.01	0.02	0.684
Diseases of the circulatory system	0.07	0.03	0.008

COPD = chronic obstructive pulmonary disease; MPR = medication possession ratio.

Table 3. Omalizumab Use in the Postindex Period

		Omalizumab New Users (N=766)
MPR (Range 0-1)	Mean (SD)	0.68 (0.30)
	[Median]	[0.80]
Discontinued omalizumab	n (%)	347 (45.3)
Days to discontinuation/end of study	Mean (SD)	256.5 (131.6)
	[Median]	[353]
Number of omalizumab claims	Mean (SD)	10.1 (5.4)
	[Median]	[11]
1	n (%)	64 (8.4)
2-5	n (%)	94 (12.3)
6-11	n (%)	249 (32.5)
12+	n (%)	359 (46.9)

Figure 3. Days to Discontinuation of Omalizumab.

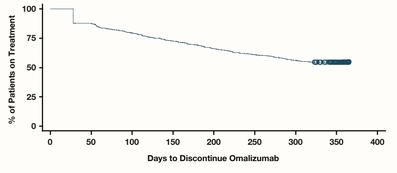

Table 4. Risk of Discontinuing Omalizumab: Adjusted Hazard Ratios and 95% Confidence Intervals

	HR	(95% CI)	*P* Value
Age, y			
12-17 vs 65+	0.82	(0.41 - 1.67)	0.576
18-34 vs 65+	1.15	(0.64 - 2.16)	0.655
35-44 vs 65+	0.86	(0.50 - 1.57)	0.600
45-54 vs 65+	0.81	(0.48 - 1.46)	0.457
55-64 vs 65+	0.76	(0.44 - 1.38)	0.344
Female vs male	0.83	(0.66 - 1.05)	0.121
Region			
Midwest vs West	0.76	(0.52 - 1.12)	0.164
Northeast vs West	0.98	(0.63 - 1.51)	0.917
South vs West	1.16	(0.84 - 1.62)	0.380
Usual asthma care physician specialty			
Allergist vs primary/other	0.85	(0.64 - 1.13)	0.264
Pulmonologist vs primary/other	0.84	(0.62 - 1.14)	0.273
No. of chronic conditions			
1-2 vs 7+	0.89	(0.59 - 1.35)	0.596
3-4 vs 7+	0.81	(0.58 - 1.13)	0.212
5-6 vs 7+	0.69	(0.51 - 0.94)	0.020
Evidence of allergy	0.97	(0.53 - 1.71)	0.914
Therapy step			
No asthma medication vs Step 6	1.25	(0.64 - 2.49)	0.518
Step 1 vs Step 6	1.21	(0.61 - 2.44)	0.580
Step 2 vs Step 6	1.18	(0.69 - 2.13)	0.560
Step 3 vs Step 6	0.79	(0.46 - 1.44)	0.430
Step 4 vs Step 6	0.92	(0.54 - 1.66)	0.769
Step 5 vs Step 6	0.90	(0.54 - 1.58)	0.689
Unclassified vs Step 6	0.73	(0.33 - 1.59)	0.437
Medication ratio			
Low ratio (<0.5) vs high ratio (≥0.5)	1.18	(0.66 - 2.07)	0.563
Missing (no controller or reliever) vs high ratio (≥0.5)	1.36	(0.77 - 2.43)	0.289
COPD	0.93	(0.71 - 1.22)	0.613
Sinusitis	0.99	(0.77 - 1.27)	0.916
Rhinitis	0.65	(0.40 - 1.09)	0.082
Tonsillitis	0.58	(0.29 - 1.02)	0.083
Acute upper respiratory infection	1.12	(0.88 - 1.42)	0.341
Conjunctivitis	1.13	(0.85 - 1.49)	0.384
Chronic otitis media	0.61	(0.26 - 1.24)	0.218
Nasal polyposis	1.46	(1.05 - 2.00)	0.019
Cough	0.95	(0.75 - 1.19)	0.627
Diseases of the circulatory system	1.32	(1.00 - 1.76)	0.052

CI = confidence interval; HR = hazard ratio.

LIMITATIONS

- Administrative claims data do not indicate the dosing schedule for omalizumab; in this analysis, each dose of omalizumab was assumed to be a 28 day supply.
- Inclusion of concomitant asthma medications as covariates is indicative only of those medications filled and not reflective of patient adherence to therapy.

CONCLUSIONS

- Among new omalizumab users, we estimated the MPR to be 0.68 with 54.7% persisting on omalizumab at one year after initiating therapy.
- Omalizumab adherence and persistence are consistent with previously published reports, although this analysis indicates slightly higher estimates.
- The number of chronic conditions and select respiratory comorbidities were significant predictors of adherence and persistence in our multivariate models.

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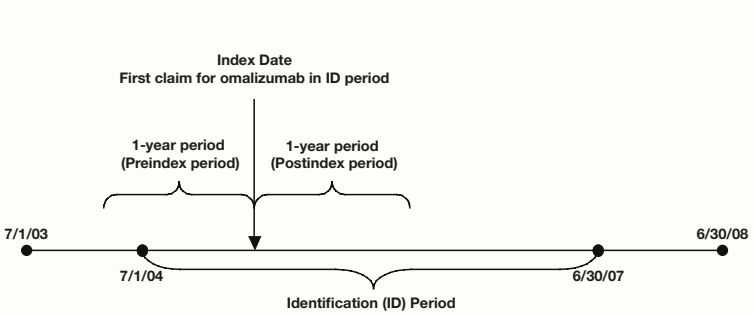

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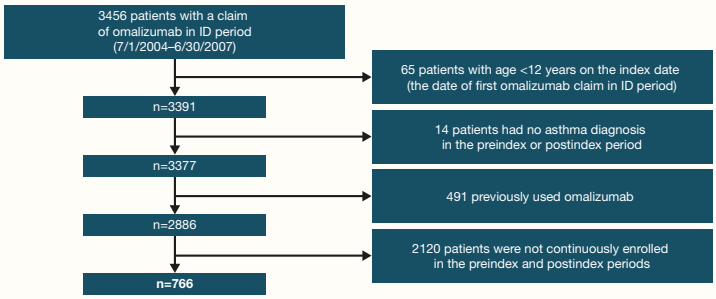

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  - Based on bivariate analysis results and clinical relevance, demographics (age, sex, and region), asthma physician specialty, number of chronic conditions, evidence of allergy, respiratory-specific comorbidities, therapy step, and medication ratio were first included in the linear regression model; we then used forward selection to identify significant results for other baseline measures.

RESULTS

- We identified 766 new omalizumab users; average age was 43.4 years and 61% were female. Fifty percent of patients received asthma care from an allergist, 28% a pulmonologist, and 17% a primary care physician.
- Overall, the MPR was 0.68 (SD, ± 0.30). MPR stratified by baseline measures are presented in **Table 1** and results of the multivariate analysis in **Table 2**.
- During follow-up, 45.3% of patients discontinued treatment. Mean (SD) time to discontinuation/end of study was 256.5 (131.6) days; median was 353 days (**Table 3**, **Figure 3**).
- The risk of discontinuing omalizumab was examined across a number of variables (**Table 4**).

Table 1. MPR of Omalizumab Stratified by Patient Demographics and Clinical Characteristics

	N	(%)	MPR Mean (SD)	*P* Value
All	766	(100.0)	0.68 (0.30)	
Demographics				
Age, y (mean 43.4; SD 14.5)				0.157
12-17	68	(8.9)	0.72 (0.28)	
18-34	111	(14.5)	0.62 (0.34)	
35-44	183	(23.9)	0.66 (0.30)	
45-54	234	(30.5)	0.68 (0.30)	
55-64	141	(18.4)	0.71 (0.27)	
65+	29	(3.8)	0.65 (0.24)	
Sex				0.174
Female	466	(60.8)	0.69 (0.30)	
Male	300	(39.2)	0.66 (0.30)	
Region				0.056
Midwest	184	(24.0)	0.71 (0.28)	
Northeast	86	(11.2)	0.62 (0.32)	
South	387	(50.5)	0.66 (0.30)	
West	109	(14.2)	0.70 (0.27)	
Physician Specialty				
Usual asthma care physician[a]				0.020
Pulmonologist	214	(27.9)	0.68 (0.28)	
Primary care	128	(16.7)	0.64 (0.31)	
Allergists	381	(49.7)	0.69 (0.29)	
Other	22	(2.9)	0.66 (0.36)	
Unknown	21	(2.7)	0.48 (0.39)	
General Comorbidities				
No. of chronic conditions (mean 4.7; SD 2.3)				0.047
1-2	155	(20.2)	0.63 (0.33)	
3-4	227	(29.6)	0.69 (0.29)	
5-6	216	(28.2)	0.71 (0.27)	
7+	168	(21.9)	0.65 (0.29)	
Charlson Comorbidity Index[7] (mean 1.8; SD 1.7)				0.967
1	530	(69.2)	0.68 (0.30)	
2	86	(11.2)	0.68 (0.29)	
3+	150	(19.6)	0.67 (0.29)	
Evidence of allergy				<.001
No	57	(7.4)	0.55 (0.34)	
Yes	709	(92.6)	0.69 (0.29)	
Respiratory-Specific Comorbidities				
COPD				0.338
No	577	(75.3)	0.67 (0.31)	
Yes	189	(24.7)	0.69 (0.27)	
Sinusitis				0.551
No	243	(31.7)	0.67 (0.31)	
Yes	523	(68.3)	0.68 (0.29)	
Rhinitis				<0.001
No	93	(12.1)	0.57 (0.33)	
Yes	673	(87.9)	0.69 (0.29)	
Tonsillitis				0.321
No	731	(95.4)	0.67 (0.30)	
Yes	35	(4.6)	0.72 (0.28)	
Acute upper respiratory infection				0.471
No	515	(67.2)	0.67 (0.30)	
Yes	251	(32.8)	0.69 (0.28)	
Conjunctivitis				0.894
No	619	(80.8)	0.68 (0.30)	
Yes	147	(19.2)	0.67 (0.29)	
Chronic otitis media				0.002
No	746	(97.4)	0.67 (0.30)	
Yes	20	(2.6)	0.81 (0.17)	
Nasal polyposis				0.073
No	663	(86.6)	0.68 (0.29)	
Yes	103	(13.4)	0.63 (0.32)	
Cough				0.427
No	381	(49.7)	0.67 (0.31)	
Yes	385	(50.3)	0.68 (0.28)	

	N	(%)	MPR Mean (SD)	*P* Value
All	766	(100.0)	0.68 (0.30)	
Asthma Control in the Preindex Period				
Poor asthma control[b]				0.096
No	191	(24.9)	0.64 (0.32)	
Yes	575	(75.1)	0.69 (0.29)	
Asthma-related inpatient hospitalization				0.340
No	657	(85.8)	0.68 (0.30)	
Yes	109	(14.2)	0.65 (0.30)	
Asthma-related ED visit				0.412
No	705	(92.0)	0.67 (0.30)	
Yes	61	(8.0)	0.71 (0.29)	
Two or more oral corticosteroid prescriptions filled				0.031
No	265	(34.6)	0.64 (0.32)	
Yes	501	(65.4)	0.69 (0.28)	
Six or more short-acting beta-agonist prescriptions filled				0.310
No	434	(56.7)	0.67 (0.30)	
Yes	332	(43.3)	0.69 (0.29)	
EPR-3 Guidelines[8] **Therapy Step in Preindex Period**				
Therapy step prior to initiating omalizumab				0.006
No asthma meds	68	(8.9)	0.56 (0.33)	
Step 1	44	(5.7)	0.61 (0.32)	
Step 2	112	(14.6)	0.67 (0.30)	
Step 3	121	(15.8)	0.73 (0.27)	
Step 4	136	(17.8)	0.69 (0.28)	
Step 5	214	(27.9)	0.69 (0.29)	
Step 6	37	(4.8)	0.63 (0.33)	
Unclassified	34	(4.4)	0.72 (0.28)	
Medication Ratio[c] **and Other Asthma Medication Use in the Preindex Period**				
Medication ratio (mean 0.64; SD 0.28 among 718 patients with medication ratios)				0.003
Low ratio (<0.5)	197	(25.7)	0.64 (0.31)	
High ratio (≥0.5)	521	(68.0)	0.70 (0.28)	
Missing (no controller or reliever)	48	(6.3)	0.55 (0.35)	
Short-acting beta-agonist inhalers				0.044
No	115	(15.0)	0.62 (0.32)	
Yes	651	(85.0)	0.68 (0.29)	
Anticholinergics				0.077
No	521	(68.0)	0.66 (0.30)	
Yes	245	(32.0)	0.70 (0.29)	
Oral corticosteroids				0.119
No	153	(20.0)	0.64 (0.32)	
Yes	613	(80.0)	0.68 (0.29)	
ICS/LABA combination				0.051
No	240	(31.3)	0.64 (0.31)	
Yes	526	(68.7)	0.69 (0.29)	
ICS alone				0.286
No	450	(58.7)	0.67 (0.31)	
Yes	316	(41.3)	0.69 (0.28)	
LABA alone				0.790
No	643	(83.9)	0.67 (0.30)	
Yes	123	(16.1)	0.68 (0.30)	
Mast cell stabilizers				0.108
No	734	(95.8)	0.67 (0.30)	
Yes	32	(4.2)	0.76 (0.25)	
Methylxanthines				0.810
No	670	(87.5)	0.67 (0.30)	
Yes	96	(12.5)	0.68 (0.26)	
Leukotriene receptor antagonists				0.078
No	221	(28.9)	0.65 (0.31)	
Yes	545	(71.1)	0.69 (0.29)	

[a]The usual asthma care physician was determined by the largest plurality of office visits with evaluation and management services and asthma diagnosis.
[b]Asthma-related inpatient hospitalization, asthma-related ED visit, ≥2 oral corticosteroid prescriptions filled, or ≥6 short-acting beta-agonist prescriptions filled.
[c]Medication ratio is units of asthma controllers to units of controllers + units of relievers.
COPD = chronic obstructive pulmonary disease; ED = emergency department; EPR-3 = National Asthma Education and Prevention Program Expert Panel Report 3; ICS = inhaled corticosteroid; LABA = long-acting beta-agonist; MPR = medication possession ratio.

Table 2. Multivariate Analysis: Characteristics Associated With Omalizumab MPR

	Coefficient	SE	*P* Value
Intercept	0.49	0.10	<0.001
Age, y			
12-17 vs 65+	0.04	0.07	0.567
18-34 vs 65+	-0.04	0.06	0.520
35-44 vs 65+	0.01	0.06	0.845
45-54 vs 65+	0.04	0.06	0.483
55-64 vs 65+	0.06	0.06	0.298
Female vs male	0.03	0.02	0.268
Region			
Midwest vs West	0.03	0.04	0.375
Northeast vs West	-0.03	0.04	0.545
South vs West	-0.03	0.03	0.290
Usual asthma care physician specialty			
Allergist vs primary/other	0.04	0.03	0.178
Pulmonologist vs primary/other	0.04	0.03	0.193
No. of chronic conditions			
1-2 vs 7+	-0.03	0.04	0.522
3-4 vs 7+	0.03	0.03	0.334
5-6 vs 7+	0.07	0.03	0.028
Evidence of allergy	0.06	0.06	0.351
Therapy step			
No asthma medication vs Step 6	-0.02	0.07	0.818
Step 1 vs Step 6	-0.01	0.07	0.933
Step 2 vs Step 6	0.01	0.06	0.817
Step 3 vs Step 6	0.08	0.06	0.138
Step 4 vs Step 6	0.04	0.05	0.506
Step 5 vs Step 6	0.04	0.05	0.443
Unclassified vs Step 6	0.10	0.07	0.182
Medication ratio			
Low ratio (<0.5) vs high ratio (≥0.5)	-0.03	0.06	0.602
Missing (no controller or reliever) vs high ratio (≥0.5)	-0.08	0.06	0.211
COPD	0.03	0.03	0.317
Sinusitis	0.00	0.02	0.927
Rhinitis	0.08	0.05	0.112
Tonsillitis	0.07	0.05	0.178
Acute upper respiratory infection	0.00	0.02	0.950
Conjunctivitis	-0.02	0.03	0.477
Chronic otitis media	0.13	0.07	0.050
Nasal polyposis	-0.09	0.03	0.005
Cough	0.01	0.02	0.684
Diseases of the circulatory system	-0.07	0.03	0.008

COPD = chronic obstructive pulmonary disease; MPR = medication possession ratio.

Table 3. Omalizumab Use in the Postindex Period

		Omalizumab New Users (N=766)
MPR (Range 0-1)	Mean (SD)	0.68 (0.30)
	[Median]	[0.80]
Discontinued omalizumab	n (%)	347 (45.3)
Days to discontinuation/end of study	Mean (SD)	256.5 (131.6)
	[Median]	[353]
Number of omalizumab claims	Mean (SD)	10.1 (5.4)
	[Median]	[11]
1	n (%)	64 (8.4)
2-5	n (%)	94 (12.3)
6-11	n (%)	249 (32.5)
12+	n (%)	359 (46.9)

Figure 3. Days to Discontinuation of Omalizumab.

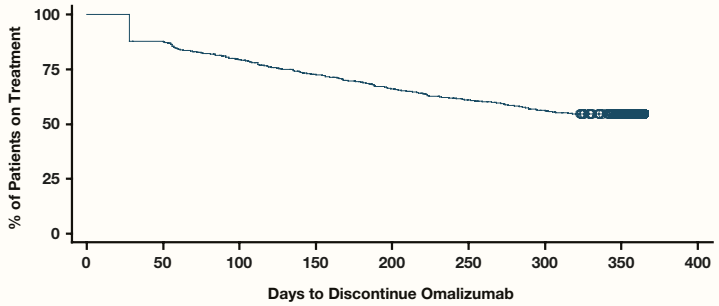

Table 4. Risk of Discontinuing Omalizumab: Adjusted Hazard Ratios and 95% Confidence Intervals

	HR	(95% CI)	*P* Value
Age, y			
12-17 vs 65+	0.82	(0.41 - 1.67)	0.576
18-34 vs 65+	1.15	(0.64 - 2.16)	0.655
35-44 vs 65+	0.86	(0.50 - 1.57)	0.600
45-54 vs 65+	0.81	(0.48 - 1.46)	0.457
55-64 vs 65+	0.76	(0.44 - 1.38)	0.344
Female vs male	0.83	(0.66 - 1.05)	0.121
Region			
Midwest vs West	0.76	(0.52 - 1.12)	0.164
Northeast vs West	0.98	(0.63 - 1.51)	0.917
South vs West	1.16	(0.84 - 1.62)	0.380
Usual asthma care physician specialty			
Allergist vs primary/other	0.85	(0.64 - 1.13)	0.264
Pulmonologist vs primary/other	0.84	(0.62 - 1.14)	0.273
No. of chronic conditions			
1-2 vs 7+	0.89	(0.59 - 1.35)	0.596
3-4 vs 7+	0.81	(0.58 - 1.13)	0.212
5-6 vs 7+	0.69	(0.51 - 0.94)	0.020
Evidence of allergy	0.97	(0.53 - 1.71)	0.914
Therapy step			
No asthma medication vs Step 6	1.25	(0.64 - 2.49)	0.518
Step 1 vs Step 6	1.21	(0.61 - 2.44)	0.580
Step 2 vs Step 6	1.18	(0.69 - 2.13)	0.560
Step 3 vs Step 6	0.79	(0.46 - 1.44)	0.430
Step 4 vs Step 6	0.92	(0.54 - 1.66)	0.769
Step 5 vs Step 6	0.90	(0.54 - 1.58)	0.689
Unclassified vs Step 6	0.73	(0.33 - 1.59)	0.437
Medication ratio			
Low ratio (<0.5) vs high ratio (≥0.5)	1.18	(0.66 - 2.07)	0.563
Missing (no controller or reliever) vs high ratio (≥0.5)	1.36	(0.77 - 2.43)	0.289
COPD	0.93	(0.71 - 1.22)	0.613
Sinusitis	0.99	(0.77 - 1.27)	0.916
Rhinitis	0.65	(0.40 - 1.09)	0.082
Tonsillitis	0.58	(0.29 - 1.02)	0.083
Acute upper respiratory infection	1.12	(0.88 - 1.42)	0.341
Conjunctivitis	1.13	(0.85 - 1.49)	0.384
Chronic otitis media	0.61	(0.26 - 1.24)	0.218
Nasal polyposis	1.46	(1.05 - 2.00)	0.019
Cough	0.95	(0.75 - 1.19)	0.627
Diseases of the circulatory system	1.32	(1.00 - 1.76)	0.052

CI = confidence interval; HR = hazard ratio.

LIMITATIONS

- Administrative claims data do not indicate the dosing schedule for omalizumab; in this analysis, each dose of omalizumab was assumed to be a 28 day supply.
- Inclusion of concomitant asthma medications as covariates is indicative only of those medications filled and not reflective of patient adherence to therapy.

CONCLUSIONS

- Among new omalizumab users, we estimated the MPR to be 0.68 with 54.7% persisting on omalizumab at one year after initiating therapy.
- Omalizumab adherence and persistence are consistent with previously published reports, although this analysis indicates slightly higher estimates.
- The number of chronic conditions and select respiratory comorbidities were significant predictors of adherence and persistence in our multivariate models.

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