James Zazzali, PhD, MPH¹; Michael S. Broder, MD, MSHS²; Eunice Chang, PhD² ¹Genentech Inc., South San Francisco, CA; ²Partnership for Health Analytic Research, Beverly Hills, CA

ABSTRACT

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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
- 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.
- 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 \geq 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 2. Cohort Selection for Omalizumab New Users



ID = identification

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, \pm 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).

All	766
All	700
Ace v (mean 13 1: SD 11	5)
10 17	.5)
12-17	00
18-34	111
35-44	183
45-54	234
55-64	141
65+	29
Sex	
Female	466
Male	300
Region	
Midwest	184
Northeast	86
South	387
West	109
Usual asthma care phys	icianª
Pulmonologist	214
Primary care	128
Alleraists	381
Allergists	00
Unier	22
Unknown	21
	<i>.</i> . –
No. of chronic condition	s (mean 4.7
1-2	155
3-4	227
5-6	216
7+	168
Charlson Comorbidity In	dex ⁷ (mean
1	530
2	86
3+	150
Evidence of allergy	
No	57
Yes	709
	R
COPD	
No	
	577
Yes	577 189
Yes Sinusitis	577 189
Yes Sinusitis	577 189 243
Yes Sinusitis No	577 189 243
Yes Sinusitis No Yes	577 189 243 523
Yes Sinusitis No Yes Rhinitis	577 189 243 523
Yes Sinusitis No Yes Rhinitis No	577 189 243 523 93
Yes Sinusitis No Yes Rhinitis No Yes	577 189 243 523 93 673
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Yes Sinusitis No Yes Rhinitis No Yes Tonsillitis No Yes Acute upper respiratory No Yes Conjunctivitis No Yes Chronic otitis media No Yes No Yes No Yes No No Yes No	577 189 243 523 93 673 731 35 infection 515 251 619 147 746 20 663 192
Yes Sinusitis No Yes Rhinitis No Yes Tonsillitis No Yes Acute upper respiratory No Yes Conjunctivitis No Yes Chronic otitis media No Yes No <tr td=""></tr>	577 189 243 523 93 673 731 35 infection 515 251 619 147 746 20 663 103
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Yes Sinusitis No Yes Rhinitis No Yes Tonsillitis No Yes Acute upper respiratory No Yes Conjunctivitis No Yes Chronic otitis media No Yes No Yes Chronic otitis media No Yes Cough No No <tr< td=""><td>577 189 243 523 93 673 731 35 infection 515 251 619 147 746 20 663 103 381</td></tr<>	577 189 243 523 93 673 731 35 infection 515 251 619 147 746 20 663 103 381

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

	10()	MPR	814
	(%)		P Value
	(100.0)	0.08 (0.30)	
	Demographics		0 157
	(8.9)	0.72 (0.28)	0.157
	(14.5)	0.62 (0.34)	
	(23.9)	0.66 (0.30)	
	(30.5)	0.68 (0.30)	
	(18.4)	0.71 (0.27)	
	(3.8)	0.65 (0.24)	
	(5.0)	0.03 (0.24)	0 174
	(60.8)	0.69 (0.30)	0.174
	(39.2)	0.66 (0.30)	
	(55.2)	0.00 (0.00)	0.056
	(24.0)	0.71 (0.28)	0.000
	(24.0)	0.62 (0.23)	
	(11.2)	0.62 (0.32)	
	(30.3)	0.00 (0.30)	
	(14.2)	0.70 (0.27)	
	Physician Specialty		0.000
	(07.0)	0.69 (0.00)	0.020
	(∠1.9) (16.7)		
	(10.7)	0.64 (0.31)	
	(49.7)	0.69 (0.29)	
	(2.9)	0.66 (0.36)	
	(2.7)	0.48 (0.39)	
(General Comorbidities	5	0.047
י נ	2.3)	0.62.(0.00)	0.047
	(20.2)	0.63 (0.33)	
	(29.6)	0.69 (0.29)	
	(28.2)	0.71 (0.27)	
	(21.9)	0.65 (0.29)	
3; 3	SD 1.7)		0.967
	(69.2)	0.68 (0.30)	
	(11.2)	0.68 (0.29)	
	(19.6)	0.67 (0.29)	
			<.001
	(7.4)	0.55 (0.34)	
	(92.6)	0.69 (0.29)	
ira	atory-Specific Comor	bidities	
			0.338
	(75.3)	0.67 (0.31)	
	(24.7)	0.69 (0.27)	
			0.551
	(31.7)	0.67 (0.31)	
	(68.3)	0.68 (0.29)	
			<0.001
	(12.1)	0.57 (0.33)	
	(87.9)	0.69 (0.29)	
			0.321
	(95.4)	0.67 (0.30)	
	(4.6)	0.72 (0.28)	
			0.471
	(67.2)	0.67 (0.30)	
	(32.8)	0.69 (0.28)	
			0.894
	(80.8)	0.68 (0.30)	
	(19.2)	0.67 (0.29)	
			0.002
	(97.4)	0.67 (0.30)	
	(2.6)	0.81 (0.17)	
			0.073
	(86.6)	0.68 (0.29)	
	(13.4)	0.63 (0.32)	
			0.427
	(49.7)	0.67 (0.31)	
	(50.3)	0.68 (0.28)	

	Ν	(%)	Mean (SD)	P Value
All	766	(100.0)	0.68 (0.30)	
	Asthma Co	ontrol in the Preindex	Period	
oor asthma control ^b				0.096
No	191	(24.9)	0.64 (0.32)	
Yes	575	(75.1)	0.69 (0.29)	
sthma-related inpat	ient hospitalization			0.340
No	657	(85.8)	0.68 (0.30)	
Yes	109	(14.2)	0.65 (0.30)	
Asthma-related ED vi	sit			0.412
No	705	(92.0)	0.67 (0.30)	
Yes	61	(8.0)	0.71 (0.29)	
Γwo or more oral cor	ticosteroid prescript	ions filled		0.031
No	265	(34.6)	0.64 (0.32)	
Yes	501	(65.4)	0.69 (0.28)	
Six or more short-act	ing beta-agonist pre	scriptions filled		0.310
No	434	(56.7)	0.67 (0.30)	
Yes	332	(43.3)	0.69 (0.29)	
	EPR-3 Guideline	s ⁸ Therapy Step in Pr	eindex Period	
Therapy step prior to	initiating omalizuma	b		0.006
No asthma meds	68	(8.9)	0.56 (0.33)	0.000
Sten 1	44	(5.7)	0.61 (0.32)	
Step 7	110	(3.7)	0.67 (0.32)	
Step 2	112	(14.0)	0.07 (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)	
Medicat	ion Ratio [°] and Other	Asthma Medication L	Jse in the Preindex P	eriod
Medication ratio (mea	in 0.64; SD 0.28 amon	g 718 patients with me	edication 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-age	onist 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)	0.011
Ves	245	(32.0)	0.00 (0.00)	
	240	(02.0)	0.70 (0.23)	0.110
No	152	(20.0)	0.64 (0.20)	0.119
No	100	(20.0)	0.04 (0.32)	
	613	(80.0)	0.68 (0.29)	0.057
				0.051
CS/LABA combinatio	on oto		0.01/0.01	
No	240	(31.3)	0.64 (0.31)	
CS/LABA combination	240 526	(31.3) (68.7)	0.64 (0.31) 0.69 (0.29)	
No Yes CS alone	240 526	(31.3) (68.7)	0.64 (0.31) 0.69 (0.29)	0.286
CS/LABA combination No Yes CS alone No	240 526 450	(31.3) (68.7) (58.7)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31)	0.286
CS/LABA combination No Yes CS alone No Yes	240 526 450 316	(31.3) (68.7) (58.7) (41.3)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31) 0.69 (0.28)	0.286
Yes CS/LABA combination No Yes No Yes LABA alone	240 526 450 316	(31.3) (68.7) (58.7) (41.3)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31) 0.69 (0.28)	0.286 0.790
No Yes CS alone No Yes ABA alone No	240 526 450 316 643	(31.3) (68.7) (58.7) (41.3) (83.9)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31) 0.69 (0.28) 0.67 (0.30)	0.286 0.790
Yes CS/LABA combination No Yes CS alone No Yes ABA alone No Yes	240 526 450 316 643 123	(31.3) (68.7) (58.7) (41.3) (83.9) (16.1)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31) 0.69 (0.28) 0.67 (0.30) 0.68 (0.30)	0.286 0.790
Yes CS/LABA combination No Yes CS alone No Yes MaBA alone No Yes Mast cell stabilizers	240 526 450 316 643 123	(31.3) (68.7) (58.7) (41.3) (83.9) (16.1)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31) 0.69 (0.28) 0.67 (0.30) 0.68 (0.30)	0.286 0.790 0.108
Yes CS/LABA combination No Yes CS alone No Yes ABA alone No Yes Mast cell stabilizers No	240 526 450 316 643 123 734	(31.3) (68.7) (58.7) (41.3) (83.9) (16.1) (95.8)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31) 0.69 (0.28) 0.67 (0.30) 0.68 (0.30) 0.67 (0.30)	0.286 0.790 0.108
Yes CS/LABA combination No Yes CS alone No Yes Mast cell stabilizers No Yes	240 526 450 316 643 123 734 32	(31.3) (68.7) (58.7) (41.3) (83.9) (16.1) (95.8) (4.2)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31) 0.69 (0.28) 0.67 (0.30) 0.68 (0.30) 0.67 (0.30) 0.67 (0.30)	0.286 0.790 0.108
Yes CS/LABA combination No Yes CS alone No Yes Mast cell stabilizers No Yes Ves Ves	240 526 450 316 643 123 734 32	(31.3) (68.7) (58.7) (41.3) (83.9) (16.1) (95.8) (4.2)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31) 0.69 (0.28) 0.67 (0.30) 0.68 (0.30) 0.67 (0.30) 0.67 (0.25)	0.286 0.790 0.108 0.810
Yes CS/LABA combination No Yes CS alone No Yes Mast cell stabilizers No Yes Methylxanthines No	240 526 450 316 643 123 734 32 670	(31.3) (68.7) (58.7) (41.3) (83.9) (16.1) (95.8) (4.2) (87.5)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31) 0.69 (0.28) 0.67 (0.30) 0.68 (0.30) 0.67 (0.30) 0.76 (0.25) 0.67 (0.30)	0.286 0.790 0.108 0.810
Yes CS/LABA combination No Yes CS alone No Yes Mast cell stabilizers No Yes Methylxanthines No Yes	240 526 450 316 643 123 734 32 670 96	(31.3) (68.7) (58.7) (41.3) (83.9) (16.1) (95.8) (4.2) (87.5) (12.5)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31) 0.69 (0.28) 0.67 (0.30) 0.68 (0.30) 0.67 (0.30) 0.76 (0.25) 0.67 (0.30) 0.68 (0.26)	0.286 0.790 0.108 0.810
Yes CS/LABA combination No Yes CS alone No Yes ABA alone No Yes Mast cell stabilizers No Yes Methylxanthines No Yes Labolariane No Yes No Yes Labolariane No Yes No	240 526 450 316 643 123 734 32 670 96 antagonists	(31.3) (68.7) (58.7) (41.3) (83.9) (16.1) (95.8) (4.2) (87.5) (12.5)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31) 0.69 (0.28) 0.67 (0.30) 0.68 (0.30) 0.67 (0.30) 0.76 (0.25) 0.67 (0.30) 0.68 (0.26)	0.286 0.790 0.108 0.810
Yes CS/LABA combination No Yes CS alone No Yes Mast cell stabilizers No Yes Methylxanthines No Yes Leukotriene receptor No	240 526 450 316 643 123 734 32 670 96 antagonists 221	(31.3) (68.7) (58.7) (41.3) (83.9) (16.1) (95.8) (4.2) (87.5) (12.5) (28.9)	0.64 (0.31) 0.69 (0.29) 0.67 (0.31) 0.69 (0.28) 0.67 (0.30) 0.68 (0.30) 0.67 (0.30) 0.76 (0.25) 0.67 (0.30) 0.68 (0.26)	0.286 0.790 0.108 0.810 0.078

management services and asthma diagnosis. ^bAsthma-related inpatient hospitalization, asthma-related ED visit, ≥2 oral corticosteroid prescriptions filled

or >6 short-acting beta-agonist prescriptions filled. 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 I (N=76)
MPR (Range 0-1)	Mean (SD)	0.68 (0.
	[Median]	[0.80
Discontinued omalizumab	n (%)	347 (45
Days to discontinuation/end of study	Mean (SD)	256.5 (1
	[Median]	[353
Number of omalizumab claims	Mean (SD)	10.1 (5
	[Median]	[11]
1	n (%)	64 (8.
2-5	n (%)	94 (12
6-11	n (%)	249 (32
12+	n (%)	359 (46

Figure 3. Days to Discontinuation of Omalizumab.



	95% Confidence Intervals			
P Value		HB	(95% CI)	P Value
< 0.001	Age. v		(,	
	12-17 vs 65+	0.82	(0.41 - 1.67)	0.576
0.567	18-34 vs 65+	1.15	(0.64 - 2.16)	0.655
0.520	35-44 vs 65+	0.86	(0.50 - 1.57)	0.600
0.845	45-54 vs 65+	0.81	(0.48 - 1.46)	0.457
0.483	55-64 vs 65+	0.76	(0.44 - 1.38)	0.344
0.298	Female vs male	0.83	(0.66 - 1.05)	0.121
0.268	Region		()	
	Midwest vs West	0.76	(0.52 - 1.12)	0.164
0.375	Northeast vs West	0.98	(0.63 - 1.51)	0.917
0.545	South vs West	1.16	(0.84 - 1.62)	0.380
0.290	Usual asthma care physician specialty		()	
	Allergist vs primary/other	0.85	(0.64 - 1.13)	0.264
0.178	Pulmonologist vs primary/other	0.84	(0.62 - 1.14)	0.273
0.193	No. of chronic conditions		(0.02)	
	1-2 vs 7+	0.89	(0.59 - 1.35)	0.596
0.522	3-4 vs 7+	0.81	(0.58 - 1.13)	0.212
0.334	5-6 vs 7+	0.69	(0.51 - 0.94)	0.020
0.028	Evidence of allergy	0.97	(0.53 - 1.71)	0.914
0.351	Therapy step		()	
	No asthma medication vs Step 6	1.25	(0.64 - 2.49)	0.518
0.818	Step 1 vs Step 6	1.21	(0.61 - 2.44)	0.580
0.933	Step 2 vs Step 6	1.18	(0.69 - 2.13)	0.560
0.817	Step 3 vs Step 6	0.79	(0.46 - 1.44)	0.430
0.138	Step 4 vs Step 6	0.92	(0.54 - 1.66)	0.769
0.506	Step 5 vs Step 6	0.90	(0.54 - 1.58)	0.689
0.443	Unclassified vs Step 6	0.73	(0.33 - 1.59)	0.437
0.182	Medication ratio		, ,	
	Low ratio (<0.5) vs high ratio (≥0.5)	1.18	(0.66 - 2.07)	0.563
0.602	Missing (no controller or reliever) vs high ratio (≥0.5)	1.36	(0.77 - 2.43)	0.289
0.011	COPD	0.93	(0.71 - 1.22)	0.613
0.211	Sinusitis	0.99	(0.77 - 1.27)	0.916
0.317	Rhinitis	0.65	(0.40 - 1.09)	0.082
0.927	Tonsillitis	0.58	(0.29 - 1.02)	0.083
0.112	Acute upper respiratory infection	1.12	(0.88 - 1.42)	0.341
0.178	Conjunctivitis	1.13	(0.85 - 1.49)	0.384
0.950	Chronic otitis media	0.61	(0.26 - 1.24)	0.218
0.477	Nasal polyposis	1.46	(1.05 - 2.00)	0.019
0.050	Cough	0.95	(0.75 - 1.19)	0.627
0.005	Diseases of the circulatory system	1.32	(1.00 - 1.76)	0.052
0.684				
0.008	GI = confidence interval; HK = 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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This study was supported by Genentech, Inc., South San Francisco, CA, and Novartis Pharmaceuticals Corporation, East Hanover, NJ, and third-party writing assistance for this poster was provided by Genentech, Inc., South San Francisco CA, and Novartis Pharmaceuticals, East Hanover, NJ.

Table 4. Risk of Discontinuing Omalizumab: Adjusted Hazard Ratios and

New Users 131.6)

Characteristics Associated With Medication Adherence Among New Omalizumab Users 46

James Zazzali, PhD, MPH'; Michael S. Broder, MD, MSHS²; Eunice Chang, PhD² ¹Genentech Inc., South San Francisco, CA; ²Partnership for Health Analytic Research, Beverly Hills, CA

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 \geq 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 \div 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 \geq 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).







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).

Figure 1. Study Timeline

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

MPR						
	N	(%)	Mean (SD)	P Value		
All	766	(100.0)	0.68 (0.30)			
		Demographics				
Age. v (mean 43.4; S	0.157					
12-17	68	(8.9)	0.72 (0.28)			
10.04	111	(1.4.5)	0.62 (0.24)			
10-34	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)			
Pagion	000	(0012)	0.00 (0.00)	0.056		
Region	101	(0.1.0)	0.71 (0.00)	0.050		
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	physiciana			0.020		
Pulmonologist	214	(27.9)	0.68 (0.28)			
Primany core	109	(16.7)	0.64 (0.21)			
Allersiet	120	(10.7)	0.04 (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	6			
No. of chronic cond	ditions (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)			
3-0	210	(20.2)	0.71 (0.27)			
1+						
Charlson Comorbio	lity Index' (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)			
100	Poopir	atory Specific Comor	hidition			
CORD	nespii	atory-opecific comor	bluitles	0.228		
COFD		(75.0)	0.07 (0.01)	0.336		
NO	5//	(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)			
Tonsillitie	0.0	(0.10)		0 321		
TOTISIIILIS	704	(05.4)	0.07 (0.00)	0.321		
NO	/31	(95.4)	0.07 (0.30)			
Yes	35	(4.6)	0.72 (0.28)			
Acute upper respira	atory 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 modi	a	()	(0.20)	0.002		
No.	7/6	(07.4)	0.67 (0.20)	0.002		
NO	/40	(97.4)	0.07 (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)	
AII	Asthma C	ontrol in the Preinder	Period	
Poor asthma control	Astinu			0.006
No	101	(24.0)	0.64 (0.22)	0.096
NO	191	(24.9)	0.64 (0.32)	
Yes	5/5	(75.1)	0.69 (0.29)	
Asthma-related inpat	ient hospitalization			0.340
No	657	(85.8)	0.68 (0.30)	
Yes	109	(14.2)	0.65 (0.30)	
Asthma-related ED v	isit			0.412
No	705	(92.0)	0.67 (0.30)	
Yes	61	(8.0)	0.71 (0.29)	
Two or more oral cor	ticosteroid prescript	ions filled		0.031
No	265	(34.6)	0.64 (0.32)	
Yes	501	(65.4)	0.69 (0.28)	
Six or more short-act	ting beta-agonist pre	scriptions filled		0.310
No	434	(56.7)	0.67 (0.30)	
Yes	332	(43.3)	0.69 (0.29)	
	EPR-3 Guideline	s [®] Therapy Step in Pr	eindex Period	
Therapy step prior to	initiating omalizuma	ıb		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)	
Stop 5	214	(17.0)	0.69 (0.20)	
Step 5	214	(21:3)	0.63 (0.23)	
Step o	37	(4.6)	0.03 (0.33)	
Unclassified	34	(4.4)	0.72 (0.28)	
Medicat	ion Ratio [®] and Other	Asthma Medication	Use in the Preindex P	eriod
Medication ratio (mea	an 0.64; SD 0.28 amor	ig /18 patients with m	edication 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	48	(6.3)	0.55 (0.35)	
or reliever)	40	(0.0)	0.00 (0.00)	
Short-acting beta-ag	onist 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/I ABA combinatio	on0	(0010)	0.00 (0.20)	0.051
No	240	(31.3)	0.64 (0.31)	0.001
Voc	526	(69.7)	0.69 (0.31)	
	520	(00.7)	0.09 (0.29)	0.296
No.	450	(59.7)	0.67 (0.21)	0.260
NO	450	(36.7)	0.67 (0.31)	
res	316	(41.3)	0.69 (0.28)	0.700
LABA alone	0.40	(22.0)	0.07 (0.00)	0.790
No	643	(83.9)	0.67 (0.30)	
Yes	123	(16.1)	0.68 (0.30)	0.455
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)	

^aThe usual asthma care physician was determined by the largest plurality of office visits with evaluation and management services and asthma diagnosis. ^bAsthma-related inpatient hospitalization, asthma-related ED visit, ≥2 oral corticosteroid prescriptions filled, or ≥6 short-acting beta-agonist prescriptions filled. ^cMedication 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
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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
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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
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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.

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This study was supported by Genentech, Inc., South San Francisco, CA, and Novartis Pharmaceuticals Corporation, East Hanover, NJ, and third-party writing assistance for this poster was provided by Genentech, Inc., South San Francisco CA, and Novartis Pharmaceuticals, East Hanover, NJ.