Rationale: We conducted this analysis to examine concomitant asthma medication use in omalizumab patients.

Methods: We conducted a descriptive study using a HIPAA-compliant claims database that included pharmacy and medical claims from 7/1/2003-6/30/2008 for a large, national insurer. The study used variable timeframes (5 years or 5 individual 1-year cohorts), criteria for continuous enrollment (none or 1 year), and number of omalizumab claims required (≥1 or ≥2) to create multiple groups. We classified asthma medications into 8 therapeutic categories and reported concomitant medication use for each cohort; combination products counted as 2 categories.

Results: Study groups ranged in size from 302-1,382 for 1-year cohorts to 4,318 for all 5 years combined. Across all groups, mean age was 42-44 years, 60-63% were female, and 13-18% had a pulmonologist and 34-45% an allergist as their usual care physician. Across all study groups, over 99% of patients had an asthma diagnosis. For 7–10% of patients, omalizumab was the only asthma medication identified. For 8-10%, one additional class of asthma medications was found. Sixty-six to 74% used medications from 3 or more therapeutic categories (excluding omalizumab). The proportion using ≥3 categories was not consistently higher or lower in new or continuing omalizumab users.

Conclusions: Regardless of the cohort inclusion criteria, nearly all omalizumab patients had an asthma diagnosis and were using additional asthma medications. A large majority used multiple categories of asthma medications. Omalizumab appears to be used by an appropriate group of patients with appropriate concomitant medications in most instances.

#375 Concomitant Asthma Medication Use in Patients Treated with Omalizumab

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Introduction

- Omalizumab is the only biologic therapy approved for use in asthma.
- Approved in 2003 for patients 12 years and older with moderate-to-severe persistent allergic asthma when symptoms inadequately controlled with inhaled corticosteroids (ICS).[1]
- EPR3 expert guidelines recommend considering omalizumab in conjunction with high-dose ICS and long-acting beta-agonists (LABA).[2]

Objective

- To estimate the extent to which, in the first 5 years of availability, omalizumab was used appropriately

Methods

- Series of retrospective cohort analyses, each representing 1 year from 2003 through 2007
- HIPAA-compliant administrative claims database with data for 10 million US individuals
- Reported patient demographics (race/ethnicity not available in database)
- Reported asthma medication use by these classes (combination products counted as two drug classes):

short-acting beta agonists (SABA)	mast cell stabilizers (MCS)
long-acting beta agonists (LABA)	methylxanthines (MX)
inhaled corticosteroids (ICS)	oral corticosteroids (OCS)
leukotriene receptor antagonists (LTRA)	long-acting anticholinergics (LAMA)

Results

Patient Selection

	Y2003	Y2004	Y2005	Y2006	Y2007
Omalizumab users	597	1,550	2,045	2,239	2,163
≥ 2 omalizumab claims	448	1,347	1,828	1,984	1,976
Continuously enrolled, no.	302	970	1,301	1,361	1,382

Patient Characteristics

	Cohort				
	Y2003	Y2004	Y2005	Y2006	Y2007
	N=302	N=970	N=1,301	N=1,361	N=1,382
Age, y mean (SD)	43.9 (13.5)	42.8 (14.4)	42.9 (14.6)	43.5 (14.7)	44.1 (14.9)
	No. (%)				
0-11	1 (0.3)	7 (0.7)	13 (1.0)	16 (1.2)	17 (1.2)
12-17	21 (7.0)	84 (8.7)	114 (8.8)	109 (8.0)	95 (6.9)
18+	280 (92.7)	879 (90.6)	1,174 (90.2)	1,236 (90.8)	1,270 (91.9)
Female	182 (60.3)	592 (61.0)	805 (61.9)	849 (62.4)	866 (62.7)
New users	302 (100.0)	601 (62.0)	525 (40.4)	411 (30.2)	386 (27.9)

- 99% of patients had at least one asthma diagnosis, and 98.5% had 3 or more
- Physician specialty associated with first omalizumab prescription was allergy/immunology in 39%, primary care in 19%, pulmonology in 18%, and other/unknown in the remainder

Additional Asthma Medications in Conjunction with Omalizumab

	Cohort				
	Y2003	Y2004	Y2005	Y2006	Y2007
	N=302	N=970	N=1,301	N=1,361	N=1,382
Additional Classes of Asthma Medication, no. (%)					
0	12 (4.0)	73 (7.5)	92 (7.1)	95 (7.0)	114 (8.2)
1	19 (6.3)	74 (7.6)	95 (7.3)	110 (8.1)	123 (8.9)
2	21 (7.0)	103 (10.6)	147 (11.3)	154 (11.3)	177 (12.8)
3	33 (10.9)	150 (15.5)	212 (16.3)	205 (15.1)	229 (16.6)
4	71 (23.5)	217 (22.4)	259 (19.9)	311 (22.9)	281 (20.3)
5	80 (26.5)	213 (22.0)	309 (23.8)	298 (21.9)	290 (21.0)
≥6	66 (21.9)	140 (14.4)	187 (14.4)	188 (13.8)	168 (12.2)

- Overall, 72% of patients used omalizumab in combination with ICS in some form (either alone or with LABA), and 63% used it with both ICS and LABA.
- 8 of the 10 most common treatment regimens included ICS and LABA
- 73% of patients used at least 3 classes of asthma medications in addition to omalizumab

Conclusions

- Expert guidelines recommend omalizumab as adjunctive therapy for patients in whom medium-dose ICS and LABA fail to control symptoms.[2]
- The guidelines also recommend expert consultation for these same patients.[2]
- In this study of a large sample of commercial health insurance claims covering the first 5 years after approval, we found strong evidence that recommended practices were followed:
  - Nearly all omalizumab users had multiple asthma diagnoses.
  - A large majority of omalizumab prescriptions were filled by patients who also filled prescriptions for ICS and LABA.
  - Omalizumab prescriptions came from specialist physicians in most cases.

Limitations

- EPR3 recommends treatment based on clinical assessment, but clinical detail is limited in administrative claims.
- Omalizumab is indicated in patients with allergic asthma,[1] but an allergic component cannot be specifically identified in claims.
- As in all claims studies, we measured prescription fills, not medication use.
- Findings may not be applicable to non-commercially insured populations.
- Some of the care we included occurred before EPR3 was released, so clinicians could not have been trying to comply with these guidelines, likely biasing our results to find less appropriate use.

1. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; 2010.
2. Expert Panel Report 3: Guidelines for the diagnosis and management of asthma. Bethesda, MD: NHLBI; 2007.

Poster presented March 20, 2011, at the American Academy of Allergy Asthma & Immunology, 2011 Annual Meeting, San Francisco, CA

Research funded by Genentech, a member of the Roche Group