

HEALTH ECONOMICS

Concomitant Asthma Medication Use in Patients Receiving Omalizumab: Results from Three Large Insurance Claims Databases

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Background. Omalizumab (Xolair®) is a monoclonal antibody indicated for moderate to severe persistent allergic asthma patients with symptoms that are inadequately controlled with inhaled corticosteroids (ICS). **Objective.** This study describes concomitant asthma medication use in patients treated with omalizumab. **Methods.** An analysis of health insurance claims from MarketScan (2002–2009), Medicaid (2002–2009), and the HealthCore Integrated Research Database (HIRD™) (2002–2010) was conducted. Medical charts were also extracted for a subset of HIRD patients. Patients aged ≥12 years and newly initiated on omalizumab with 12 months of continuous insurance coverage prior to the first omalizumab dispensing (baseline period) and ≥2 asthma claims were included. Concomitant asthma medication use was summarized in eight medication classes. **Results.** A total of 6038 patients were identified (Medicaid: 731; MarketScan: 3521; HIRD: 1786). A high proportion of new omalizumab users had an asthma-related emergency room visit (Medicaid: 34%; MarketScan: 17%; HIRD: 16%) or hospitalization (Medicaid: 36%; MarketScan: 14%; HIRD: 21%) within 12 months prior to initiating omalizumab. Most patients (Medicaid: 96%; MarketScan: 89%; HIRD: 86%) received three concomitant asthma medication classes or more during the baseline period. Concomitant ICS use was observed in 95%, 89%, and 86% of Medicaid, MarketScan, and HIRD patients, respectively. In HIRD patients without evidence of receiving other asthma medication prior to omalizumab, 17 out of 20 patients had a documented baseline history of asthma-related medication use in their medical charts. **Conclusions.** This large observational study using health insurance claims from three databases and confirming results from medical charts provides evidence that nearly all omalizumab users had received other asthma medications prior to initiating omalizumab.

Keywords allergic asthma, control, corticosteroids, medical charts

INTRODUCTION

Asthma is a chronic respiratory disease characterized by inflammation of the airways and lungs, and can have a severe impact on daily life and may even prove to be fatal when uncontrolled. Asthma poses a significant public health burden in the United States, affecting about 16 million adults and approximately 7 million children (1, 2). For the 3-year period (2001–2003), asthma accounted for more than 12 million physician office visits, more than 500,000 hospitalizations, and 1.8 million emergency department visits (3). There are several factors that trigger asthma symptoms including certain allergens (pollens, cockroaches, dust mites, animal dander, mold), smoke, frequent infections, cockroaches, dust mites, or strong chemicals (4). Asthma symptoms include wheezing, shortness of breath, chest tightness, and coughing (4, 5).

Pharmacologic therapy for asthma consists of quick-relief medications to relieve acute episodes of asthma exacerbation, and long-term control medications used to achieve and maintain control of persistent asthma. Quick-relief medications consist of short-acting beta₂-agonists

(SABA), anticholinergics, and systemic corticosteroids. Long-term control medications may include inhaled corticosteroids (ICS), long-acting beta₂-agonists (LABA), oral corticosteroids, methylxanthines, leukotriene receptor antagonists, cromolyn sodium and nedocromil, and immunomodulators. The 2007 National Asthma Education and Prevention Program recommends a stepwise approach for managing asthma. In moderate to severe cases, omalizumab therapy is considered along with high-dose ICS + LABA (Step 5) or high-dose ICS + LABA + oral corticosteroids (Step 6) (5).

Omalizumab, a monoclonal antibody administered subcutaneously that prevents binding of immunoglobulin E to the high-affinity receptors limiting the degree of release of mediators of the allergic response, is used as an adjunctive therapy in patients aged ≥12 years with severe persistent asthma (6). Patients that are sensitized to perennial aeroallergens requiring higher doses of ICS and those with severe exacerbations are likely to benefit from omalizumab therapy (7).

Although omalizumab is indicated as an add-on therapy in patients with inadequately controlled severe persistent asthma, the Office of Surveillance and Epidemiology of the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA) reported that 29% of patients who received omalizumab

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during 2008 did not receive other asthma medications during the same year (8). In the FDA report, outpatient omalizumab utilization patterns were evaluated using the Wolters Kluwer's Health Source[®] Lx database, a longitudinal provider-based data source that is limited in the ability to link patient claims across different providers because different patient IDs might be assigned by each provider or pharmacist. To further evaluate the FDA findings and to ensure that omalizumab is being used appropriately, the current study was conducted using three large health insurance claims databases with complete medical history of patients, linking medical and pharmacy claims to patients regardless of the provider, and evaluate concomitant asthma medication use among omalizumab users. The obtained results were further corroborated by medical chart data that were linked to one of the claims databases.

METHODS

Data Sources

Health insurance claims from MarketScan, Medicaid, and HealthCore Integrated Research Database (HIRD), covering both government- and privately insured populations, and medical chart data from HIRD were used to conduct this study. A Health Insurance Portability and Accountability Act waiver of authorization was obtained from a central institutional review board allowing the use of protected health information to obtain medical charts. All study materials were handled in compliance with the Health Insurance Portability and Accountability Act.

MarketScan. The MarketScan database is a large, integrated, de-identified, individual-level database containing health services information for over 107 million unique patients from 1996 to the first quarter of 2009, with 37 million unique patients represented in the 2008 calendar year. Enrollees in the database include employees, dependents, and retirees in the United States with primary or Medicare supplemental coverage through privately insured fee-for-service, point-of-service, or capitated health plans, from all US census regions.

Medicaid. Medicaid insurance claims from five different states (Florida: 2002–2008, Kansas: 2002–2009, New Jersey: 2002–2008, Missouri: 2002–2008, Iowa: 2002–2006) were used for the current study. The multi-state database includes complete medical claims and pharmacy dispensings from Medicaid records for all the Medicaid-eligible subscribers during the covered years, and includes Medicare/Medicaid crossovers.

HealthCore Integrated Research Database. The HIRD is a broad, fully integrated database containing health services information from 14 health plans for approximately 44 million patients from the Northeast, Midwest, South, and West regions of the United States. This study used integrated medical and pharmacy claims and health plan eligibility information from the HIRD for services between 1 January 2002 and 31 January 2010.

All databases include patients' complete enrollment history, demographics, claims for medical services (inpatient and outpatient services), and prescription drugs. The medical claims also contain diagnosis and procedure information, and the prescription drug claims contain information on the name, dosage, formulation, and days of supply of the medication.

Study Design

Administrative Claims Data. A retrospective cohort design was used for this study. To be included in the study population, patients were required to have at least one pharmacy dispensing (National Drug Codes: 50242006062; 50242004201) or medical claim (Healthcare Common Procedure Coding System: J2357; S0107; C9217) for omalizumab. In addition, patients were required to be at least 12 years old at the date of first omalizumab dispensing (index date), have at least 12 months of continuous insurance coverage prior to the index date (baseline period), and have at least two claims for asthma (International Classification of Diseases, 9th edition: 493.xx) within 12 months of the index date. Figure 1 summarizes the study design scheme.

Asthma Medication Classes

Concomitant asthma medication use with omalizumab was summarized in eight mutually exclusive medication

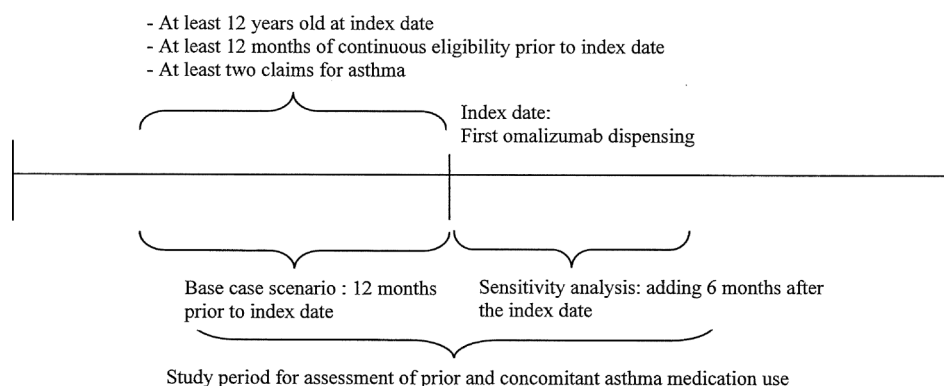


FIGURE 1.—Study design scheme.

TABLE 1.—Asthma medication classes.

Classes	Medications
ICS	Beclomethasone dipropionate, budesonide, ciclesonide, dexamethasone, flunisolide, fluticasone, mometasone, and triamcinolone
LABA	Arformoterol, formoterol, and salmeterol
Leukotriene modifiers	Montelukast, zafirlukast, and zileuton
Mast cell stabilizers	Cromolyn and nedocromil
Anticholinergics	Ipratropium and tiotropium
SABA	Albuterol, bitolterol, isoetharine, isoproterenol, levalbuterol, metaproterenol, pirbuterol, and terbutaline
Methylxanthines	Aminophylline, dyphylline, oxtriphylline, and theophylline
Oral corticosteroids	Cortisone acetate, dexamethasone, hydrocortisone, prednisolone, prednisolone, prednisone, and triamcinolone

Notes: ICS, inhaled corticosteroids; HIRD, HealthCore Integrated Research Database; LABA, long-acting beta₂ agonist; SABA, short-acting beta₂ agonist.

classes, according to the 2007 National Asthma Education and Prevention Program guidelines for managing asthma (see Table 1). Both pharmacy dispensings and medical claims were used to identify the medications listed in Table 1. Medications prescribed through combination therapies were counted in each of their respective medication classes when summarizing the most frequent asthma medication combinations used with omalizumab.

Statistical Analysis

The baseline demographic and clinical characteristics of patients, including age, region, and year of index date were reported. To evaluate asthma severity, the number of asthma claims during the 12-month baseline period prior to the index date was calculated. History of asthma-related healthcare resource utilization (emergency room visits, hospitalizations, outpatient and other healthcare visits) was also evaluated during the baseline period. Finally, the number of non-overlapping days with prescribed asthma medication and the total number of days of supply (including overlapping days) of prescribed medication during the 12 months prior to initiating omalizumab were reported separately for ICS and for asthma controllers. Asthma controller medications include the following classes of drugs: ICS, leukotriene modifiers, LABA, oral corticosteroids, methylxanthines, and mast cell stabilizers.

Concomitant asthma medication use among omalizumab users was summarized as the proportion of patients using omalizumab alone or along with 1, 2, or 3 or more classes. Additionally, the proportion of patients treated with omalizumab in addition to ICS or in addition to any asthma controller was reported. The period for assessment of prior and concomitant asthma medication use was defined as 12 months prior to the index date, including the index date. A sensitivity analysis additionally including 6 months after the index date was also conducted. Finally, to present a complete portrait of the full medication profile of patients using omalizumab,

the most frequent asthma medication combinations were presented.

Medical Chart Data Extraction. Medical chart data were extracted for patients identified through the HIRD database as having received no other asthma-related medications in the 12 months prior to initiating omalizumab. The purpose of the medical chart data extraction was to further corroborate the use of omalizumab and other asthma-related medications in these patients. Medical chart data were extracted for a period of 12 months prior to the index date identified in the claims data and history of asthma-related medication use was reported.

RESULTS

Baseline Demographics and Clinical Characteristics

Baseline demographics from the three databases are shown in Table 2. A total of 6038 patients were identified (Medicaid: 731; MarketScan: 3521; HIRD: 1786). Mean age (SD) was 38.8 (12.6) in Medicaid, 44.6 (14.0) in MarketScan, and 47.3 (15.6) in the HIRD. About 87% of patients in Medicaid and 93% in MarketScan and the HIRD were above 18 years of age. Approximately, one-third of the patients were male (proportion of men, Medicaid: 31%; MarketScan: 36%; HIRD: 39%).

In Medicaid, patients were mostly from Florida (37%), followed by Missouri (33%) and New Jersey (22%), with patients from Iowa and Kansas constituting less than 8% of the Medicaid sample. In MarketScan, almost half the patients were from the South (46%) while the rest were distributed between the Midwest (23%), West (19%), and Northeast (11%) regions of the United States. Patients in the HIRD were more or less equally distributed throughout the US regions.

Table 3 displays the clinical characteristics of the study population. Of note, the majority of patients had five or more asthma claims (Medicaid: 76%; MarketScan: 65%; HIRD: 75%) during the year prior to the first omalizumab dispensing. In Medicaid, about one-third of the study population experienced asthma-related ER (34%) and hospitalization visits requiring at least one night spent in the hospital (36%). The mean (SD) number of non-overlapping days with an ICS dispensing during the 12 months prior to the index date was 201 (112) for Medicaid, 180 (122) for MarketScan, and 165 (99) for HIRD patients whereas the mean (SD) total number of days of supply was 350 (279) for Medicaid, 289 (258) for MarketScan, and 212 (157) for HIRD patients. When all the asthma controllers were considered, the mean (SD) number of non-overlapping days with at least one asthma controller dispensing was 236 (108) for Medicaid, 220 (118) for MarketScan, and 221 (108) for HIRD patients, whereas the mean (SD) total number of days of supply increased to 495 (345) for Medicaid, 408 (304) for MarketScan, and 346 (233) for HIRD patients.

TABLE 2.—Baseline characteristics of the study population.

	Medicaid (N = 731)	MarketScan (N = 3521)	HIRD (N = 1786)
Age, mean $\pm$ SD	38.8 $\pm$ 12.6	44.6 $\pm$ 14.0	47.3 $\pm$ 15.6
Age categories, N (%)			
12–17 years	92 (12.6%)	261 (7.4%)	132 (7.4%)
$\geq$ 18 years	639 (87.4%)	3260 (92.6%)	1654 (92.6%)
Male, N (%)	227 (31.1%)	1273 (36.2%)	697 (39.0%)
Region, N (%)			
Midwest	—	812 (23.1%)	349 (19.5%)
Northeast	—	401 (11.4%)	408 (22.8%)
South	—	1628 (46.2%)	520 (29.1%)
West	—	665 (18.9%)	509 (28.5%)
Unknown	—	15 (0.4%)	—
Florida	273 (37.4%)	—	—
Iowa	5 (0.7%)	—	—
Kansas	49 (6.7%)	—	—
Missouri	241 (33.0%)	—	—
New Jersey	163 (22.3%)	—	—
Year of index date, N (%)			
2003	56 (7.7%)	126 (3.6%)	9 (0.5%)
2004	181 (24.8%)	447 (12.7%)	156 (8.7%)
2005	175 (23.9%)	801 (22.8%)	650 (36.4%)
2006	151 (20.7%)	609 (17.3%)	293 (16.4%)
2007	111 (15.2%)	622 (17.7%)	233 (13.1%)
2008	55 (7.5%)	638 (18.1%)	213 (11.9%)
2009	2 (0.3%)	278 (7.9%)	217 (12.2%)
2010	—	—	15 (0.8%)

Notes: HIRD, HealthCore Integrated Research Database; SD, standard deviation.

TABLE 3.—Clinical characteristics of the study population.

	Medicaid (N = 731)	MarketScan (N = 3521)	HIRD (N = 1786)
Number of distinct asthma claims ^a			
2 claims	67 (9.2%)	407 (11.6%)	150 (8.4%)
3–4 claims	108 (14.8%)	835 (23.7%)	297 (16.6%)
5 or more	556 (76.1%)	2279 (64.7%)	1339 (75.0%)
Asthma-related events ^a , mean $\pm$ SD	12.8 $\pm$ 20.5	8.8 $\pm$ 7.5	—
ER visits ^b , N (%)	247 (33.8%)	590 (16.8%)	293 (16.4%)
Number of visits, mean $\pm$ SD	0.9 $\pm$ 2.2	0.3 $\pm$ 0.7	0.3 $\pm$ 0.8
Hospitalization visits ^c , N (%)	260 (35.6%)	488 (13.9%)	368 (20.6%)
Number of hospitalizations, mean $\pm$ SD	0.9 $\pm$ 1.7	0.2 $\pm$ 0.7	0.3 $\pm$ 0.8
Outpatient visits, N (%)	718 (98.2%)	3504 (99.5%)	1775 (99.4%)
Number of visits, mean $\pm$ SD	11.0 $\pm$ 19.8	7.5 $\pm$ 6.6	10.8 $\pm$ 9.0
Other visits, N (%)	13 (1.8%)	1373 (39.0%)	1701 (95.2%)
Number of visits, mean $\pm$ SD	0.0 $\pm$ 0.4	0.9 $\pm$ 2.1	6.4 $\pm$ 5.4
Number of non-overlapping days with prescribed asthma medication, mean $\pm$ SD			
ICS ^d	200.9 $\pm$ 112.1	179.6 $\pm$ 122.1	165.2 $\pm$ 99.2
All asthma controllers ^e	236.2 $\pm$ 108.1	220.1 $\pm$ 118.1	220.6 $\pm$ 107.7
Number of days of supply of prescribed asthma medication, mean $\pm$ SD			
ICS ^d	349.7 $\pm$ 279.2	289.4 $\pm$ 258.3	211.6 $\pm$ 156.5
All asthma controllers ^e	495.3 $\pm$ 344.7	408.3 $\pm$ 304.3	346.3 $\pm$ 232.7

Notes: ER, emergency room; ICS, inhaled corticosteroids; HIRD, HealthCore Integrated Research Database; LABA, long-acting beta₂ agonist.

^aEvaluated during the 12 months prior to index date.

^bMultiple ER services recorded on two consecutive days were considered as a hospitalization visit.

^cHospitalizations with a length of stay of 1 day were considered as an outpatient visit.

^dICS includes the following drugs: beclomethasone dipropionate, budesonide, ciclesonide, dexamethasone, flunisolide, fluticasone, mometasone, triamcinolone, and combination of ICS + LABA (salmeterol–fluticasone, budesonide–formoterol).

^eAsthma controller medications include the following classes of drugs: ICS, leukotriene modifiers, LABA, oral corticosteroids, and mast cell stabilizers (cromolyn and nedocromil).

Concomitant Asthma Medication Use

Concomitant asthma medication use among omalizumab users is summarized in Figure 2a and 2b. During the 12-month time period prior to initiating omalizumab, the vast majority of patients (Medicaid: 96%; MarketScan:

89%; HIRD: 86%; Figure 2a) received three or more concomitant asthma medication classes. Concomitant ICS use was observed in 95%, 89%, and 86% of Medicaid, MarketScan, and HIRD patients, respectively. Nearly all (Medicaid: 99%; MarketScan: 97%; HIRD: 97%) of the

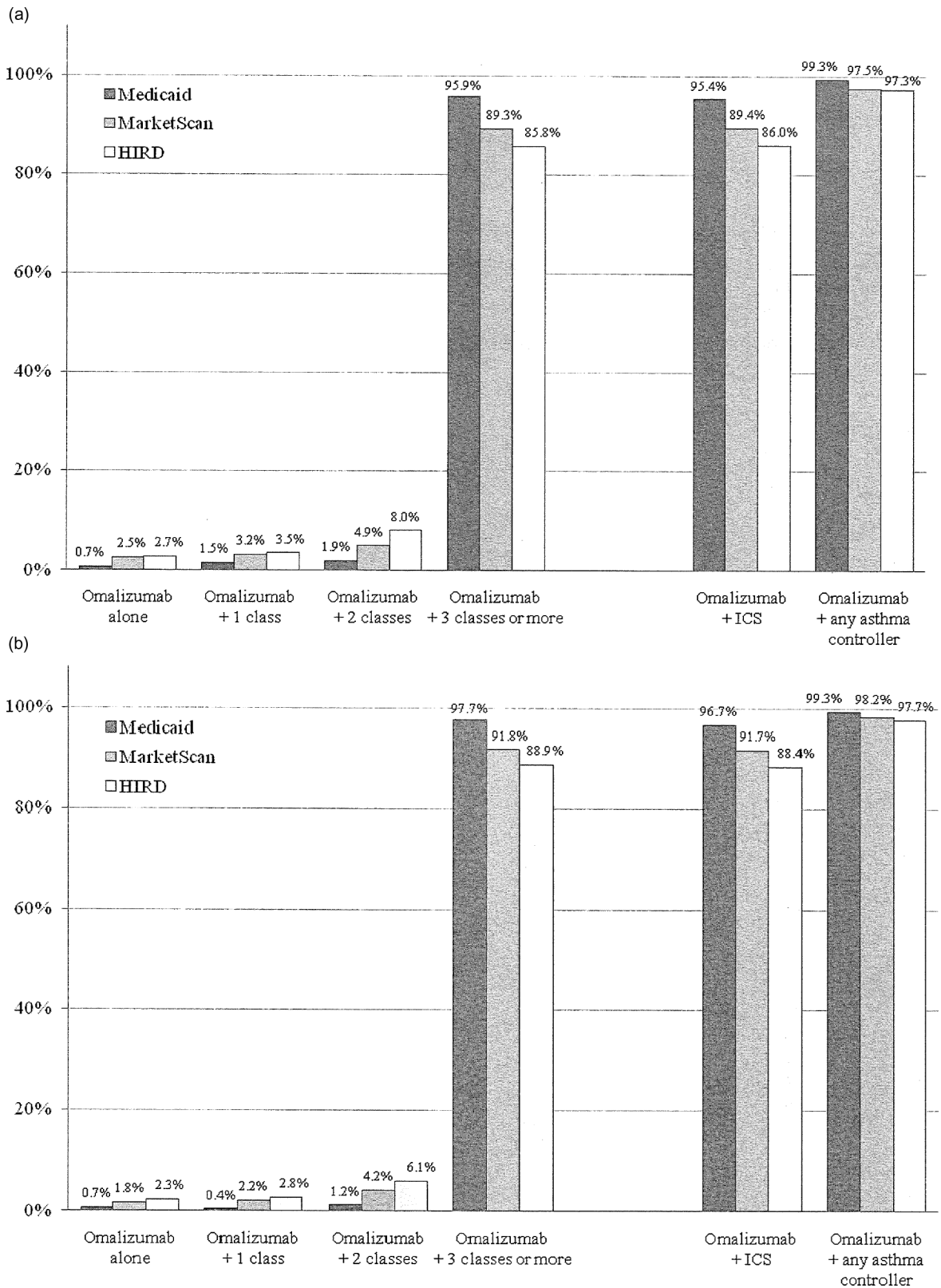


FIGURE 2.—(a) Prior and concomitant asthma medication use—12 months prior to and including index date. (b) Prior and concomitant asthma medication use—12 months prior to and 6 months after index date.

Notes: ICS, inhaled corticosteroids; HIRD, HealthCore Integrated Research Database; LABA, long-acting beta₂ agonist. ICS includes the following drugs: beclomethasone, budesonide, ciclesonide, dexamethasone, flunisolide, fluticasone, mometasone, triamcinolone, and combination of ICS + LABA (salmeterol–fluticasone, budesonide–formoterol). Asthma controller medications include the following classes of drugs: ICS, leukotriene modifiers, LABA, oral corticosteroids, and mast cell stabilizers (cromolyn and nedocromil).

patients were treated with omalizumab and some other asthma medications. The results of the sensitivity analysis were very similar (Figure 2b).

Table 4 shows the most frequent asthma medication combinations used by omalizumab users. In all databases, the combination of ICS, LABA, leukotriene modifiers, SABA, and oral corticosteroids, with or without anticholinergics, represented the most frequent combination, used by 63% of the Medicaid patients, 47% of the MarketScan patients, and 41% of the HIRD patients. Adding 6 months post-index to the time period yielded similar results.

Medical Chart Data

Table 5 displays the results of the medical chart data extraction of HIRD patients with no evidence of other asthma-related medication. Of the 1786 new users of omalizumab identified from the HIRD during the intake period, 48 (2.7%) were identified as having no other asthma-related medication in the 12 months prior to the index date and targeted for medical chart extraction. Among them, 44 patients had provider contact information identified in their medical or pharmacy claims data and their chart data were requested for extraction. From these 44 chart requests, 34 medical charts were obtained. The data extracted from these charts confirmed omalizumab use for 20 patients and could not confirm it for the other 14 patients. Of the 20 confirmed omalizumab patients, 17 patients had a documented history of asthma-related medication use during the pre-index period and 3 patients had no other asthma-related medication documented during this period in their medical chart. Concomitant use of ICS was confirmed for 15 patients, of which 14 patients were also receiving LABA.

DISCUSSION

The current study of 6038 asthma patients using omalizumab from three distinct large databases demonstrated that omalizumab was mainly administered to patients heavily pre-treated with other asthma medications. The vast majority of patients received at least one medication other than omalizumab during the year prior to their first omalizumab dispensing. Furthermore, most of the studied patients used at least three medication classes or more in the year prior to omalizumab initiation, and more than half of the study population used at least five medication classes. Additionally, the rates of asthma-related ER visits and hospitalization were high, patients often consulted a physician, and the majority of them had five or more medical claims associated with an asthma diagnosis in the year prior to their first omalizumab dispensing.

This real-world observational study shows that physicians prescribed omalizumab after patients had been treated with other controller medications and suggests that clinical guidelines were followed in the majority of cases (5). Indeed, omalizumab is indicated for patients with moderate to severe persistent asthma that is inadequately

controlled with ICS (9). The results of our study demonstrate that most patients had been treated with ICS prior to omalizumab. Moreover, patients used significant asthma-related healthcare resources during the year prior to omalizumab, suggesting their asthma conditions were inadequately controlled.

This analysis adds to the literature in multiple ways. First, it used three distinct large databases covering different populations (government and private insurers) and showed consistent results throughout data sources. Additionally, the data used comprised the complete medical history of patients for a given period of time, encompassing the full portrait of asthma medication treatment of the patients. Moreover, this study linked administrative claims data to medical chart data for a subset of patients, where available, to further assess asthma medication therapy patterns among omalizumab users in order to provide a more comprehensive view of these patients. Furthermore, the study design used for the analysis ensured that we were studying newly initiated patients, and therefore allowed for a more comprehensive portrait of patients when they started using omalizumab.

A recent study using Wolters Kluwer's Health Source[®] Lx database reported that 29% of omalizumab patients did not receive other asthma medication along with their omalizumab prescription in 2008 (8). However, the Wolters Kluwer's Health Source database is a provider-based database that is limited in the ability to link patient claims across different providers because unique patient IDs might be assigned by each provider or pharmacist. In addition, this data source does not capture patients' eligibility to determine exposure periods. Therefore, an absence of claims cannot ensure the absence of medical services. Furthermore, not all providers and pharmacists provide information to the database; therefore, information might be incomplete even when patients are eligible for insurance coverage. These data limitations, which are not part of the current study using health insurance claims with complete medical history of patients, can explain the important discrepancy between the proportions of patients using omalizumab alone in the current study and in the study that was based on the Wolters Kluwer's Health Source database.

The healthcare utilization results of this study are consistent with findings reported in the previous literature on severe asthma patients. For example, an analysis conducted by Colice et al. (10) using an administrative claims database showed that patients (<65 years old) with severe asthma had similar rates of ER visits (16%), hospitalizations (35%), and outpatient visits (99.0%) when compared with our results. Similarly, the PERSIST study, a clinical trial analyzing omalizumab patients under "real-life" conditions, reported similar healthcare services utilization rates (ER visits: 14%, hospitalizations: 41%) (11). This further corroborates the assumption that patients in our study, when they started omalizumab therapy, suffered from severe uncontrolled asthma.

TABLE 4.—Five most frequent asthma medication combinations.

Database	Time period considered	Five most frequent combinations	N	%
Medicaid	12 months prior to and including index date	Anticholinergics, ICS, LABA, leukotriene modifiers, SABA, oral corticosteroids	261	35.7
		ICS, LABA, leukotriene modifiers, SABA, oral corticosteroids	198	27.1
		ICS, LABA, leukotriene modifiers, SABA	30	4.1
		Anticholinergics, ICS, LABA, SABA, oral corticosteroids	28	3.8
		ICS, LABA, leukotriene modifiers, mast cell stabilizers, SABA, oral corticosteroids	22	3.0
	12 months prior to and 6 months after index date	Anticholinergics, ICS, LABA, leukotriene modifiers, SABA, oral corticosteroids	293	40.1
		ICS, LABA, leukotriene modifiers, SABA, oral corticosteroids	197	26.9
		Anticholinergics, ICS, LABA, leukotriene modifiers, mast cell stabilizers, SABA, oral corticosteroids	33	4.5
		Anticholinergics, ICS, LABA, SABA, oral corticosteroids	31	4.2
		ICS, LABA, leukotriene modifiers, SABA	23	3.1
MarketScan	12 months prior to and including index date	ICS, LABA, leukotriene modifiers, SABA, oral corticosteroids	875	24.9
		Anticholinergics, ICS, LABA, leukotriene modifiers, SABA, oral corticosteroids	768	21.8
		ICS, LABA, SABA, oral corticosteroids	185	5.3
		ICS, LABA, leukotriene modifiers, SABA	154	4.4
		Anticholinergics, ICS, LABA, SABA, oral corticosteroids	136	3.9
	12 months prior to and 6 months after index date	ICS, LABA, leukotriene modifiers, SABA, oral corticosteroids	927	26.3
		Anticholinergics, ICS, LABA, leukotriene modifiers, SABA, oral corticosteroids	900	25.6
		ICS, LABA, SABA, oral corticosteroids	184	5.2
		ICS, LABA, leukotriene modifiers, SABA	139	3.9
		Anticholinergics, ICS, LABA, SABA, oral corticosteroids	142	4.0
HIRD	12 months prior to and including index date	ICS, LABA, leukotriene modifiers, SABA, oral corticosteroids	453	27.3
		Anticholinergics, ICS, LABA, leukotriene modifiers, SABA, oral corticosteroids	226	13.5
		ICS, LABA, SABA, oral corticosteroids	149	8.9
		ICS, LABA, leukotriene modifiers, SABA	101	6.0
		ICS, LABA, leukotriene modifiers, oral corticosteroids	77	4.6
	12 months prior to and 6 months after index date	ICS, LABA, leukotriene modifiers, SABA, oral corticosteroids	492	29.0
		Anticholinergics, ICS, LABA, leukotriene modifiers, SABA, oral corticosteroids	275	16.2
		ICS, LABA, SABA, oral corticosteroids	155	9.1
		ICS, LABA, leukotriene modifiers, SABA	90	5.3
		ICS, LABA, leukotriene modifiers, oral corticosteroids	65	3.8

Notes: ICS, inhaled corticosteroids; HIRD, HealthCore Integrated Research Database; LABA, long-acting beta₂ agonist; SABA, short-acting beta₂ agonist.

The present study is subject to several limitations that are worth noting, and are mostly inherent in the analysis of health insurance claims data. First, claims data do not include certain information such as reasons for treatment or disease severity, which would be available in clinical trial studies. In addition, data on the prescribers (e.g., physician specialty) was not available for the majority of omalizumab users. However, an

analysis of health insurance claims data can reveal treatment patterns in a real-world setting. Additionally, claims data may be subject to inaccuracies in billing information and missing data. To address this issue, we extracted additional information through medical charts for a subset of patients. However, it is important to note that the medical chart data were collected from one treating physician for each patient and there may have

TABLE 5.—Medical chart data: asthma medication use in patients with no evidence of asthma medication use from HIRD.

Patient population	N	% ^a
Omalizumab patients in HIRD	1786	
Omalizumab patients with no other asthma medication from HIRD	48	2.7%
Patients for which medical chart data were obtained	34	70.8%
Patients with confirmed use of omalizumab	20	58.8%
Prior and concomitant asthma medication use based on medical chart abstraction		
0 class	3	15.0%
1 class	2	10.0%
2 classes	0	0.0%
3 classes or more	15	75%
Omalizumab + ICS	15	75%

Notes: ICS, inhaled corticosteroids; HIRD, HealthCore Integrated Research Database.

^aPercentages were calculated using the upper category as the denominator.

been additional data not captured from other providers. The consistency of results across the three distinct databases that we used adds to the validity and robustness of the results.

CONCLUSIONS

Based on health insurance claims obtained from three databases, this large observational study found evidence that nearly all omalizumab users (>97%) had received other asthma medication prior to initiating omalizumab. The proportion of patients with prior asthma medication use further increased when medical chart data for a subgroup of patients were extracted. The 6038 omalizumab patients studied used multiple asthma medications prior to their initiation to omalizumab, as well as many asthma-related healthcare services. This study of real-world treatment patterns of asthma patients showed that omalizumab is mainly used when patients have already tried other controller medications and suggests that physicians follow the published clinical guidelines on asthma management for the majority of patients.

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DECLARATION OF INTEREST

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