

## Patterns of Anti-Inflammatory Therapy in the Post-Guidelines Era: A Retrospective Claims Analysis of Managed Care Members

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### **Abstract**

Published and widely disseminated guidelines for the care and management of asthma characterize asthma as a chronic, inflammatory disease and propose specific recommendations for therapy with inhaled anti-inflammatory medications. In a retrospective analysis of medical and pharmacy claims data of approximately 28,000 asthmatic members from five managed care settings, the dominant pattern of pharmacologic therapy that emerged was the use of bronchodilators without inhaled anti-inflammatory drug therapy. In addition, a significant proportion of asthmatic patients received no prescription drug therapy for asthma. Less than one third of asthmatic patients received any anti-inflammatory therapy and the majority of these received one or two prescriptions per year. Specialist physicians were two to three times more likely than non-specialists during a study period of 1 year to prescribe an anti-inflammatory medication, and were half as likely to have their asthmatic patients experience an emergency department or hospital event. This database analysis suggests that greater conformity with guidelines and/or access to specialist physician care for asthmatic members will lead to improved patient outcomes.

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In 1991, *Guidelines for the Diagnosis and Management of Asthma* was released by the National Institutes of Health (NIH)<sup>1</sup>; in 1992 an expert panel presented the *International Consensus Report on Diagnosis and Treatment of Asthma*.<sup>2</sup> Both documents characterize asthma as a chronic, inflammatory disease and recommend monotherapy with an inhaled short-acting  $\beta_2$ -agonist only for patients with mild, intermittent symp-

oms. Patients using more than six inhalations per week of an inhaled short-acting  $\beta_2$ -agonist on a regular basis are candidates for the addition of inhaled anti-inflammatory medications.<sup>2</sup> Some authorities go beyond the recommendations of these initial guidelines to suggest that chronic asthma requires anti-inflammatory inhalation therapy as first-line therapy.<sup>3,4</sup>

Recent articles reviewing medical records and medical and pharmacy claims analysis have indicated that the guideline recommendations regarding combined anti-inflammatory and  $\beta_2$ -agonist pharmacologic therapy are not being followed, especially for asthmatic patients using high-dose  $\beta_2$ -agonists. The present study characterizes the dominant patterns of pharmacologic therapy in the years following publication of these two guidelines, employing a retrospective analysis of a claims database involving almost 28,000 asthmatic patients.

Although these guidelines have not been tested in a randomized, prospective study, recent analyses point to the relation between following the approach to asthma treatment recommended by these guidelines and positive benefits in terms of reduced emergency department visits and hospitalizations of asthmatics.<sup>7</sup> Programs to improve asthma management that educate physicians about the guidelines<sup>8</sup> and are associated with increased use of anti-inflammatory agents produce benefits to asthmatic patients in terms of enhanced control of asthma symptoms<sup>9</sup> and reductions in hospitalization and emergency department visits.<sup>8</sup>

### ... METHODS ...

#### The Research Database

The research database for this study was constructed using integrated paid medical and pharmacy claims taken from the administrative files of five geographically diverse managed care plans with annual enrollment of approximately 870,000 members. The database included member enrollment information, provider information, medical claims (provider and facility), and pharmacy claims. All files were linked by

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a member number assigned by the health plan. The claims for covered benefits submitted by approved providers included medical claims with asthma diagnosis codes as defined by the International Classification of Disease (ICD-9-CM)<sup>10</sup>; selected medical procedures associated with asthma using Current Procedural Terminology (CPT-4)<sup>11</sup> procedure codes; selected supplies associated with asthma HCFA Common Procedures Coding System (HCPCS)<sup>12</sup> codes; and selected classes of pharmaceutical drugs according to their National Drug Classification (NDC)<sup>13</sup> codes.

### Patient Identification

The study population was comprised of all members who had medical claims evidence of asthma (specifically a medical claim with an ICD-9-CM diagnosis code of 493.xxx) or, in the absence of a claim with an asthma-diagnosis code, members who had two or more claims in a 12-month period for pharmaceutical agents used in the treatment of asthma. In addition, members were excluded if they showed any claims evidence of other pulmonary disorders, such as chronic obstructive pulmonary disease (COPD), cystic fibrosis, chronic bronchitis, or bronchiolitis. The pharmaceutical drugs that defined the population included: oral and/or inhaled  $\beta_2$ -agonist agents, oral inhaled corticosteroid agents, other oral inhaled anti-inflammatory agents (cromolyn and nedocromil), and theophylline and related agents. Ipratropium was used as a surrogate marker of COPD and members using this drug were not included in the analysis.

These medical- and pharmacy-claims criteria identified approximately 28,000 asthmatics in the calendar

year of July 1, 1993–June 30, 1994. This represents an overall prevalence rate for asthma of about 3%. Approximately two thirds of this asthma population was defined by at least one medical claim with a diagnosis of asthma and the remainder through pharmacy claims alone.

### ... RESULTS ...

The dominant pattern of pharmacologic therapy among asthmatic patients defined by pharmacy and/or medical claims is the use of bronchodilators without inhaled anti-inflammatory drug therapy. Asthmatic patients are treated with  $\beta_2$ -agonists alone, with the dosage form varying according to the age of the patient, or coupled with oral tablet or liquid corticosteroids. For patients defined by the linked medical and pharmacy claims, slightly less than two-thirds of adult asthmatics, slightly more than two-thirds of children, and more than three-quarters of the infants and toddlers rely on bronchodilator therapy or receive no drug treatment (Table 1). For patients defined by medical claims only, 22% to 31% receive no prescription drug therapy for asthma at all (Figure 1). Age groupings are defined in relation to the prescription drug labeling of the most commonly used anti-asthmatic medications.

The proportion of asthmatics receiving any inhaled anti-inflammatory agent increases with age from a low of 12% for asthmatics under age 2 to a high of 41% among asthmatics age 40 and older. On average, less than one in three asthmatics receive one or more prescriptions for any inhaled anti-inflammatory medicine. The class of inhaled anti-inflammatory medicine also

**Table 1.** Dominant Patterns of Pharmacologic Therapy Among Asthmatics\*: Use of Bronchodilators Without Inhaled Anti-Inflammatory Agents

Variable	Age of Patient					
	0-1 (N=967)	2-5 (N=2,884)	6-11 (N=4,309)	12-19 (N=4,734)	20-39 (N=8,385)	40-64 (N=6,555)
No Drug Therapy	14%	15%	16%	19%	21%	19%
Beta Agonist Alone	48%	38%	27%	32%	29%	19%
Beta Agonist with Oral Corticosteroid	21%	19%	12%	7%	6%	4%
Other Bronchodilator Combinations	5%	5%	9%	11%	12%	17%
<b>TOTAL</b>	<b>88%</b>	<b>77%</b>	<b>64%</b>	<b>69%</b>	<b>68%</b>	<b>59%</b>

\*Asthmatics are defined by pharmacy and/or medical claims.

is age related, with children under 12 receiving predominantly cromolyn products and adults age 20 and older receiving oral inhaled steroids. Therapy for adolescents is split between the two classes of anti-inflammatory medications (Table 2). Teens and young adults receive anti-inflammatory therapy at a slightly lower rate, in part because a drop-off in cromolyn use is not entirely replaced by prescriptions for inhaled corticosteroids in those age groups.

In addition to the low frequency of anti-inflammatory therapy for asthmatic members, the majority of asthmatic patients (50% to 80%, depending on age) receive two or fewer canisters of anti-inflammatory medication per year. Less than 15% of adults (20-64 years of age) and less than 12% of children and adolescents (6-19 years of age) receive seven or more canisters of these medications, which may suggest a level of chronic use (Table 3). Significant use of inhaled oral steroid therapy, as measured by the proportions of asthmatics receiving this agent and those with a frequency of claims that suggests chronic use, does not begin until asthmatics are at least 40 years of age.

### Specialist Versus Nonspecialist Treatment

A different prescribing pattern emerges for the asthmatics whose primary asthma care physician is a specialist. Allergists and pulmonologists are the predominant specialists caring for asthmatic patients in this population. Nonspecialist care includes services provided by family or general practitioners, pediatricians, internists, and emergency medicine physicians. The primary asthma care physician is defined by associating the majority of claims for asthma treatment with a particular provider. Among the asthmatics in the study population, 26% receive their primary asthma care from a specialist (Figure 2). Specialists are twice as likely as nonspecialists to prescribe an anti-inflammatory for an asthmatic patient in their care, and they are two to three times more likely to prescribe an inhaled corticosteroid for their astmat-

ic patient (Figure 3).

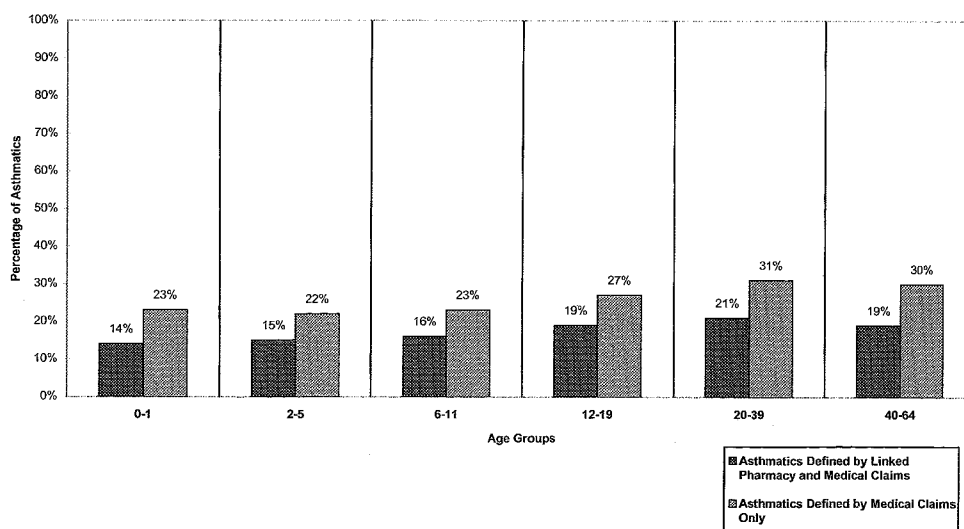
Emergency department or hospitalization events increase the rate of anti-inflammatory and inhaled corticosteroid use in the patients of specialists, but not for the asthmatics seen by nonspecialists. Nonspecialists, on average, do not appear to change their prescribing for asthmatics who have had at least one emergency event (Figure 4).

Asthma patients who are treated primarily by nonspecialists for their asthma are twice as likely to have an emergency department or hospital event as are patients treated by a specialist. The proportion of asthmatics treated by a nonspecialist who had an emergency event was 13.4% in the calendar year ending June 1994; the proportion treated by a specialist was 6.5%. Figure 5 illustrates the inverse correlation of hospital or emergency department asthma events and the use of inhaled corticosteroids. Age appears to be a factor associated with both increasing use of inhaled corticosteroids and decreasing emergency department visits and hospitalizations.

### ... DISCUSSION ...

This database analysis presents additional population-based evidence that although some changes have occurred in therapy post-publication of the guidelines,

**Figure 1.** Asthmatics with No Claims Evidence of Drug Therapy Under Two Claims-Based Definitions of Asthma



asthmatics are still not receiving the recommended anti-inflammatory medication.<sup>14,15</sup> The results indicate that physicians in the United States continue to under use anti-inflammatory medications, particularly oral inhaled corticosteroids, and fail to demonstrate any increase in use after major adverse episodes—unless they are specialists. Thus, 3 years after publication of the NIH guidelines and 2 years after publication of the International Consensus guidelines, most asthmatics continue to be treated symptomatically—relying on bronchodilators at best or receiving no prescribed drug therapy at all. Claims for bronchodilators appear to occur at expected frequency. A lower level of claims for anti-inflammatory agents may reflect lower prescribing rates for these medicines and/or failure to educate patients to the importance of compliance with this

medication.

The lack of prescription drug therapy among a fairly constant proportion of asthmatics may reflect the inherent limitations of claims-data analysis. Lack of claims could suggest missing data/claims due to patient noncompliance with the filling or refilling of prescriptions, use of prescription drug samples, coverage of drug therapy from other sources such as dual benefits, or simply timing of the filling and payment of the claim. However, all members in the analysis had prescription drug coverage with minimal copayments.

Another limitation of claims-data analysis is the absence of definitions of clinical severity and, therefore, the ability to assess appropriateness of therapy. Nonetheless, the similarity in rates of inhaled anti-inflammatory prescribing of asthmatic members with

**Table 2.** Any Use of Inhaled Anti-inflammatory Agents

Variable	Age of Patient					
	0-1 (N=967)	2-5 (N=2,884)	6-11 (N=4,309)	12-19 (N=4,734)	20-39 (N=8,385)	40-64 (N=6,555)
Inhaled Corticosteroid	1%	4%	15%	19%	28%	38%
Cromolyn or Nedocromil	11%	21%	26%	16%	6%	7%
Any Anti-inflammatory (One or Both)	12%	23%	36%	31%	32%	41%

**Table 3.** Frequency of Claim Activity for Anti-inflammatory Agents (Among Asthmatics Receiving One)

Variable	Age of Patient					
	0-1	2-5	6-11	12-19	20-39	40-64
<b>Number of Anti-inflammatory Claims:</b>						
1-2 Rx Claims	80%	62%	56%	70%	64%	50%
3-6 Rx Claims	14%	28%	30%	23%	26%	30%
7 or More Claims	4%	10%	14%	8%	10%	19%

Rx=prescription.

and without hospital and emergency events raises questions concerning appropriate use of anti-inflammatory medications.

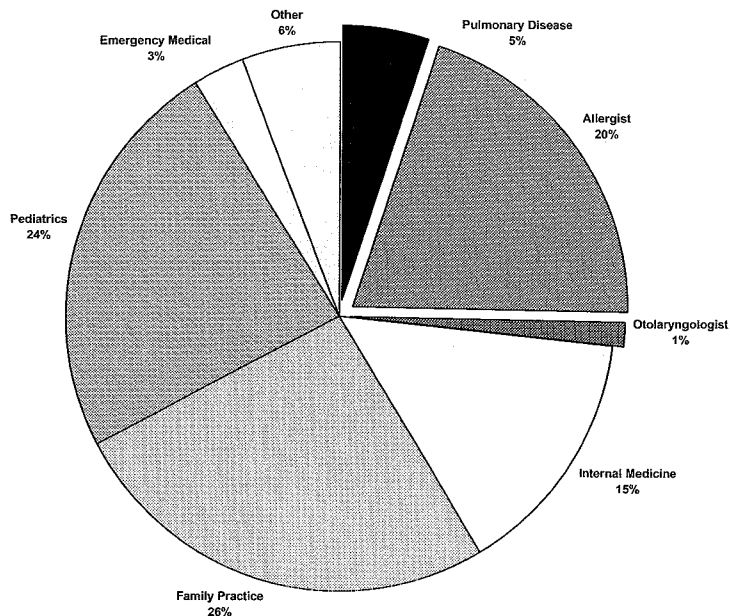
The pattern of infrequent prescription drug claims for inhaled anti-inflammatory therapy suggests a lack of focus on preventive therapy among providers and patients. Comparing the annual prescribing rates during the 3 years after publication of the guidelines, the rate of anti-inflammatory prescribing increased just 4% to 5% in these five health plans.

In the year ending June 1994, about one third of the population of asthmatics received one or more prescriptions for any inhaled anti-inflammatory, but the vast majority of them received just 1 or 2 months of therapy. Less than one third of the one in three asthmatics receiving any anti-inflammatory therapy received three or more anti-inflammatory prescriptions (1 in 9 asthmatics). Half of these received an oral inhaled steroid as the anti-inflammatory therapy. Based on this evidence, less than 1 in 18 asthmatics had pharmacy claims suggesting at least limited chronic therapy with an oral inhaled steroid.

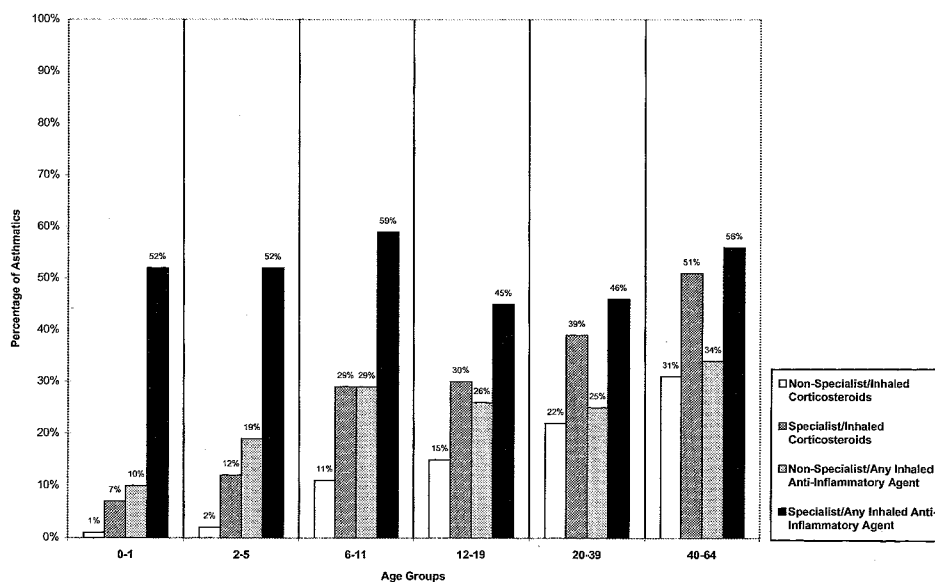
An important indicator of the extent of undertreatment is shown by the comparison of specialist to non-specialist prescribing. Even assuming that specialists tend to treat patients with more severe disease, the difference in therapy among patients with an emergency event cannot be

explained by severity of disease alone. This analysis documents, as in previous studies, that specialists prescribe significantly more inhaled anti-inflammatory

**Figure 2.** Primary Asthma Care Physician



**Figure 3.** Use of Inhaled Anti-Inflammatory Agents: Comparison of Specialist to Non-Specialist Primary Asthma Care Physicians

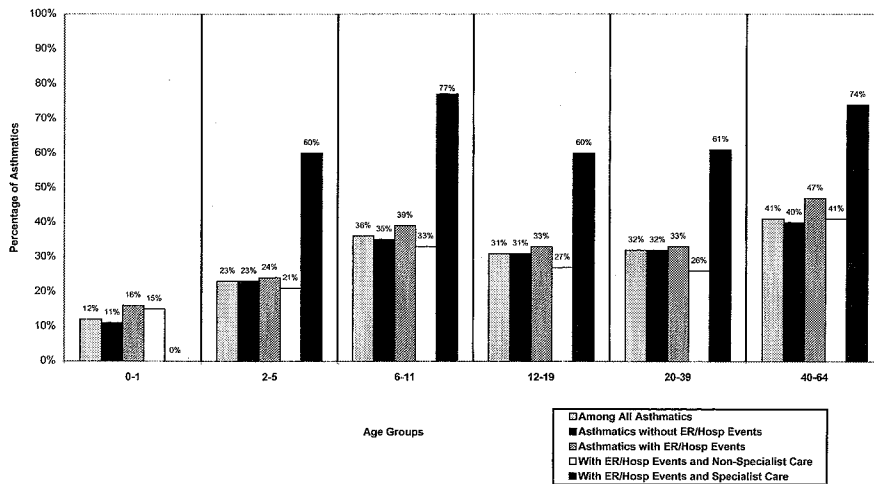


medication, especially oral inhaled steroids. In addition, treatment by specialists correlates with fewer adverse events, such as hospitalizations and emer-

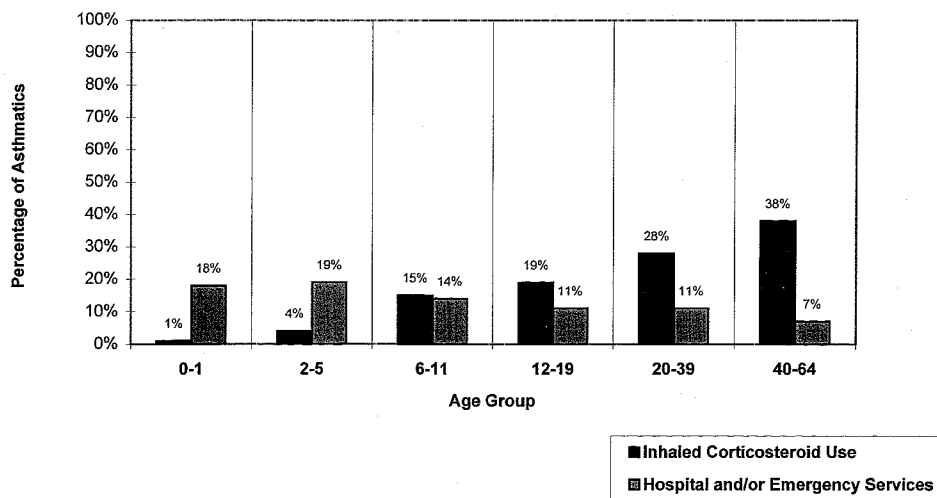
gency department visits. For example, Zeiger and associates<sup>16</sup> and Mahr and Evans<sup>17</sup> showed a reduction in these events when care was provided by an asthma specialist, specifically an allergist, as compared with nonspecialist care. Indeed, a major factor that distinguishes asthma specialist care is significantly greater use of anti-inflammatory therapy. The experiences in the previously mentioned studies reflect small cohorts of patients with recent emergency department or hospital events. The present retrospective study is a much larger study of all—not merely selected—high risk asthmatic patients, and confirms these earlier results.

This research provides broad, population-based support that the guidelines offer an appropriate therapeutic approach. By using preventive therapy, specialists succeed in achieving a lower rate of emergency department and hospital admissions. If the asthma patients in this study who received treatment by nonspecialists had received the typical treatment provided by specialists, 1300 to 1400 emergency department and/or hospital admissions might have been avoided in 1 year alone based on the differing rates of emergency events between specialists and non-specialists.

**Figure 4.** Use of Anti-Inflammatory Agents Under Varying Conditions of Hospital and Emergency Department Events and Primary Asthma Care Physician



**Figure 5.** Inhaled Corticosteroid Use and Use of Hospital and/or Emergency Services



... CONCLUSIONS ...

Greater conformity to the guidelines along with access to specialist

care may lead to improved patient outcomes. Managed care medical policy that limits appropriate pharmacologic therapy or access to specialist care may lead to adverse patient outcomes and increased costs. Recent events, however, suggest trends in the opposite direction. The National Committee for Quality Assurance, the nonprofit managed care accreditation organization, has released *Health Plan Employer Data and Information Set 3.0*, the latest edition of its health plan performance measurement system.<sup>18</sup> An important quality indicator suggested for testing in this system will be to measure the proportion of asthmatics receiving inhaled anti-inflammatory medication. In addition, a number of large managed care plans are now considering lifting restrictions on access to specialist care (*USA Today*, June 25, 1996:12A). Nevertheless, these data suggest that while the consensus guidelines appear to have wide acceptance, actual implementation requires better patient and provider education before the goals of the guidelines can be achieved.

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