Asthma affects a large percentage of Americans. In 1998, about 17 million people in the United States had this chronic disease, resulting in direct and indirect expenses of approximately $11.3 billion. Many managed care organizations have established disease-management programs for asthma as a way to control costs while providing consistent, high-quality care. These programs are often modeled after the National Institutes of Health guidelines for the diagnosis and management of asthma.

As described by O’Connor and supported by recommendations of the 2002 update to the NIH treatment guidelines, much clinical evidence exists supporting the use of an inhaled corticosteroid (ICS) and an inhaled long-acting beta2-agonist (LABA) to treat both the chronic inflammation and bronchoconstriction of asthma in patients with moderate or severe asthma. Less is known about whether the same results hold true in the general population of asthmatics and whether the improved asthma control translates to cost savings.

This paper describes the results of 2 previously published studies with which I was involved that assessed the cost impact of the most commonly prescribed dual-controller regimens for treating asthma in several managed care populations. Phase 1 was a cross-sectional retrospective claims study. Phase 2 was a 2-year retrospective cohort analysis of the efficacy and efficiency of dual-controller therapies.

Cross-Sectional Study

In the phase 1 cross-sectional study, patients with ICD9 codes for asthma between the ages of 12 and 65 years who were continuously enrolled during the 6-month study period in one of 4 geographically diverse health plans were included. The 4 plans were subsidiaries owned by Health Net, Inc (formerly Foundation Health Systems, Inc.). In 1999, the plan on the West Coast covered more than 2 million members, and the Northeast plan had more than 1 million members. The plans in the Southeast and mid-Atlantic regions together had more than 1 million members. The West Coast plan, which is in the heart of managed care territory, primarily pays providers through capitated contracts, while the other 3 plans use a fee-for-service system. Patients with chronic obstructive pulmonary disease were excluded.

For the West Coast and Northeast plans, data were collected from November 1998 through April 1999. Data collection for the other 2 plans occurred from July 1998 through December 1998. Since asthma is affected by various seasons of the year, these staggered data-collection periods ensure that almost the entire year is covered.

Administrative claims databases were the source of data for...
Patients taking one of 3 dual-controller regimens: fluticasone propionate and salmeterol, ICS (excluding fluticasone propionate) and salmeterol, and ICS (including fluticasone propionate) and leukotriene modifier (LTM). The number of patients who fell into the 3 study groups were 967, 2511, and 826, respectively.

Table 1 shows patient characteristics of the 3 groups. The mean age of patients in the ICS and salmeterol group was significantly higher than that of patients in the fluticasone propionate and salmeterol group. The most prevalent comorbid condition was depression (20% of patients). Multivariate analyses controlling for age, gender, plan, and comorbidities were used to estimate the impact of the 3 different regimens on cost.

Table 2 summarizes the mean cost per member for the 6-month study period for patients in the 3 treatment groups for various aspects of care. Hospital, emergency department, and pharmacy costs were determined from their respective data sets, which are highly accurate. Because outpatient care in the West Coast plan was capitated, estimates of statistics requiring outpatient cost data were based on data from the other 3 regions. Asthma management cost is the sum of pharmacy and outpatient costs, which is the plan’s investment in the asthma patient population so that they do not need emergency department visits or hospitalizations.

This study provided just a snapshot of care in 4 managed care plans along with other potential limitations, such as not controlling for race/ethnicity and pretreatment disease severity. The results show that different drug regimens are associated with measurable differences in outcome when both drug costs and use of medical services are taken into account. This study suggests that the fluticasone and salmeterol combination would be preferable to the other 2 regimens in controlling overall asthma care costs.

### Table 1: Characteristics of Patients in Cross-Sectional Comparison of Dual-Controller Regimens*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>FP and Salmeterol (n = 967)</th>
<th>ICS (except FP) and Salmeterol (n = 2511)</th>
<th>ICS and LTM (n = 826)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender (% male)</strong></td>
<td>37.0</td>
<td>39.0</td>
<td>33.8</td>
</tr>
<tr>
<td><strong>Age (year)</strong></td>
<td>43.8 ± 16.0</td>
<td>49.3 ± 17.0†</td>
<td>43.6 ± 16.4</td>
</tr>
<tr>
<td><strong>Presence of comorbidity (%)‡</strong></td>
<td>39.7</td>
<td>41.3</td>
<td>45.6</td>
</tr>
</tbody>
</table>

*Reported as mean (± SD) unless otherwise noted.
†Significantly different than the FP and salmeterol group at P < 0.05.
‡Comorbidities include one or more of the following diseases: cardiovascular disease, congestive heart failure, depression, diabetes, emphysema, hyperlipidemia, hypertension, or other respiratory conditions.

### Table 2: Mean Cost ($) Per Patient in 6-Month Period in Cross-Sectional Comparison of Dual-Controller Regimens*

<table>
<thead>
<tr>
<th>Cost Category</th>
<th>FP and Salmeterol (n = 967)</th>
<th>ICS (except FP) and Salmeterol (n = 2511)</th>
<th>ICS and LTM (n = 826)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pharmacy</strong></td>
<td>297.1 ± 211.3</td>
<td>352.2 ± 217.0*</td>
<td>385.7 ± 253.4*</td>
</tr>
<tr>
<td><strong>Outpatient</strong></td>
<td>80.58 ± 197.6</td>
<td>87.26 ± 181.1</td>
<td>121.80 ± 219.05*</td>
</tr>
<tr>
<td><strong>Asthma management†</strong></td>
<td>381.6 ± 301.3</td>
<td>452.9 ± 298.4*</td>
<td>500.8 ± 336.5*</td>
</tr>
<tr>
<td><strong>Inpatient</strong></td>
<td>20.9 ± 256.0</td>
<td>16.0 ± 228.5</td>
<td>36.1 ± 406.5</td>
</tr>
<tr>
<td><strong>Emergency department</strong></td>
<td>8.9 ± 76.2</td>
<td>10.7 ± 91.0</td>
<td>10.5 ± 77.5</td>
</tr>
<tr>
<td><strong>Asthma treatment failure†</strong></td>
<td>29.9 ± 271.3</td>
<td>26.7 ± 259.0</td>
<td>46.6 ± 420.4</td>
</tr>
<tr>
<td><strong>Total§</strong></td>
<td>408.6 ± 401.9</td>
<td>460.3 ± 445.0*</td>
<td>560.8 ± 627.4*</td>
</tr>
</tbody>
</table>

*Significant results compared with fluticasone propionate and salmeterol using multivariate regressions controlling for age, gender, region, and comorbidities at P < 0.05.
†Includes pharmacy and outpatient costs.
‡Includes inpatient and emergency department costs.
§Total is not always the sum of subcategories because of missing data.

**Retrospective Cohort Analysis**

As phase 2 of this study, we conducted a 2-year retrospective cohort study, again using a large claims database. The purpose of the study was to compare the cost of 3 common dual-controller therapies, controlling for asthma severity by using preindex cost and use measures. We longitudinally followed patients aged 12-65 years with asthma who received an index prescription for one of the dual-controller regimens (salmeterol or LTM) between January 1, 1997, and December 31, 1998. The records of these patients were reviewed for one year before (preindex) and one year after (postindex) the index prescription.

Because of the rigorousness of the study, the sample only included patients from 2 health plans that were subsidiaries of Health Net, Inc., one in the Northeast and the other on the West Coast. Together the 2 plans covered 3.5 million lives.

All patients received at least one prescription for an inhaled corticosteroid in the preindex period. Patients were excluded if...
they had chronic obstructive pulmonary disease or respiratory cancer, resided in a nursing home or intermediate care facility, or used salmeterol or LTM in the preindex period. At the index date, they were switched to dual-controller regimens and categorized into the same 3 groups as used in the cross-sectional study. The n values are smaller than in the previous study: 121 for fluticasone propionate and salmeterol, 844 for ICS (except fluticasone propionate) and salmeterol, and 360 for ICS and LTM.

Table 3 shows the patients’ preindex characteristics. The mean age of patients in the 3 groups ranged from 41 to 47 years, with the fluticasone propionate and salmeterol cohort having a significantly lower age than the other 2 groups. The majority of the patients were female (65-67%). About 80% of patients in the ICS and salmeterol group were enrolled in the West Coast plan. The lower use of this drug combination in the Northeast plan was a result of restricted formulary status for fluticasone propionate during the beginning of the study period, not of an asthma management program. Emergency department cost and medical asthma cost (sum of outpatient, inpatient, and emergency department) were highest in the fluticasone propionate and salmeterol group. In the regression modeling, preindex cost and use variables were used to control for asthma severity.

Table 4 shows a comparison of costs in the preindex and postindex periods. In all 3 groups, pharmacy cost increased in the postindex period after salmeterol or a leukotriene modifier was added to the ICS. Costs for the emergency department, inpatient care, and outpatient care decreased. Despite the substantially higher emergency department and inpatient costs for the fluticasone propionate and salmeterol group, this cohort of patients had the largest reduction in those costs in the postindex period, resulting in an average increase of $22 in total costs. At the same time, the total cost increased $333 in the ICS and salmeterol group and $378 in the ICS and LTM group.

The fluticasone propionate and salmeterol group still had significant savings in total costs compared with the ICS and LTM group when gender, age, plan type, eligibility, and preindex use and cost variables were controlled using multiple regression. The costs were similar between the fluticasone and salmeterol group and the other ICS and salmeterol group. Using multiple regression in which the cost is adjusted for preindex use and cost variables, the 12-month risk-adjusted total cost for the fluticasone propionate and salmeterol group was the lowest at $975, followed...
by $1,089 and $1,268 for the ICS and salmeterol and for the ICS and LTM groups, respectively. Pharmacy costs accounted for most of the risk-adjusted total costs ($814, $841, and $996, respectively).

■ Conclusion

Dual-controller therapy consisting of fluticasone propionate and the long-acting beta₂-agonist, salmeterol, resulted in lower total asthma care costs than a regimen consisting of an ICS with a LTM.

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REFERENCES