Obstructive Lung Diseases – Asthma and Chronic Obstructive Pulmonary Disease: Managing The Patient and the Costs

Based on the proceedings of a satellite symposium held in conjunction with the Academy of Managed Care Pharmacy’s 17th Annual Meeting and Showcase, in Denver, on April 20, 2005

HIGHLIGHTS

• The health plan’s perspective on care management
• Clinical perspectives on obstructive lung disease
• Treatment guidelines and performance indicators
• Burden of illness in Medicaid and managed care populations
• Question and Answer Session: The challenges of managing patients with obstructive lung disease

Continuing education for physicians and pharmacists sponsored by Medical Education Resources Inc.

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INTRODUCTION

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Obstructive lung diseases (OLD) such as asthma and chronic obstructive lung disease (COPD) are a serious financial and resource burden for managed care organizations. In 2002, the number of noninstitutionalized adults in the United States who had ever been diagnosed with asthma reached almost 22 million (NCHS 2002a). In that same year, asthma accounted for approximately 1.9 million emergency department visits (NCHS 2002b), 500,000 hospitalizations (NCHS 2002c), and 5,000 deaths (NCHS 2002d), with estimated direct and indirect costs exceeding $14.5 billion (NHLBI/NIH 2002). The National Heart, Lung, and Blood Institute estimated that in 2002, COPD was responsible for more than 1.5 million emergency department visits, 726,000 hospitalizations, and more than $32.1 billion in direct and indirect costs (NHLBI/NIH 2002). Asthma can strike at any age, and COPD affects many working-age people, often before they have begun their fifth decade. Many patients can present with both diseases concomitantly. Consequently, successful treatment and medical management of these patients are a necessity for MCOs.

Correctly diagnosing and treating these diseases has proved difficult for medical providers because of limited testing, the potential for presenting with concomitant diseases, and the similarities among diseases. Despite their similarities, however, each of these conditions has an extremely different pathogenesis, prognosis, treatment, and set of pharmacotherapy guidelines. Making an early and accurate differential diagnosis is essential to the proper and cost-effective treatment of these patients. Studies have shown that in patients with concomitant diseases, airflow obstruction is significantly higher, making treatment all the more challenging and costly.

This publication serves to educate readers on the most recent guidelines pertaining to the prevalence and costs associated with, challenges relating to the proper diagnosis of, and the benefits of early treatment of OLD. Comprehensive knowledge and understanding of these diseases, guidelines, treatment options, cost consequences, and the challenges they present to managed health care plans are all critical to the success of relevant disease management and cost-control programs.

I hope that you will take advantage of the continuing education credit for this supplement that is being made available through Medical Education Resources and that you will find the information herein to be extremely useful in your daily responsibilities.

References

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SELF-STUDY CONTINUING EDUCATION ACTIVITY
Obstructive Lung Diseases – Asthma and Chronic Obstructive Pulmonary Disease: Managing the Patient and the Costs

ABOUT THIS PUBLICATION
This publication has been derived from the proceedings of a satellite symposium held in conjunction with the Academy of Managed Care Pharmacy’s 17th Annual Meeting and Showcase, at the Colorado Convention Center, in Denver, April 20, 2005. The symposium faculty, whose presentations form the basis of the articles herein, provide an overview of obstructive lung diseases, asthma, and chronic obstructive pulmonary disease; highlight updates on treatment guidelines from the Global Initiative for Asthma (GINA) as well as the Global Initiative for Chronic Obstructive Lung Disease (GOLD); look at emerging treatment trends; describe proposed performance indicators from the National Committee for Quality Assurance and the Physician’s Consortium; and discuss the financial implications of certain treatment approaches in various subpopulations.

Program release date: July 15, 2005
Program expiration date: July 15, 2006

Target audience
This program has been designed to educate managed care pharmacy directors, pharmacists, and medical directors on recent and upcoming changes in asthma management guidelines and to help them improve the quality of care and to reduce the burden of illness that is associated with specific subpopulations affected by these conditions.

Learning objectives
After reading this supplement, the participant should be able to:

• Describe the prevalence, costs, and quality-of-life issues related to obstructive lung diseases.
• Define the most recent guidelines related to diagnosis, treatment, and management of obstructive lung diseases.
• Analyze the different pharmacotherapies and pharmacoconomics of obstructive lung diseases.
• Identify the importance of differential diagnosis in patients with obstructive lung diseases.

To receive credit
The physician or pharmacist must read the material on pages 4 through 26 of this publication, successfully complete the post-test and evaluation form, and mail or fax the completed form to:

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The faculty reported the following: Burton I. Orland, BS, RPh, reports no relationships to disclose as posing potential conflicts of interest. Nicola A. Hanania, MD, reports receiving grants and research support from GlaxoSmithKline, Boehringer-Ingelheim, Sepracor, and AstraZeneca. He has declared that he has served as a consultant to GlaxoSmithKline and Dex, and acknowledges that he has participated in speakers’ bureaus for GlaxoSmithKline and Boehringer-Ingelheim. Sean D. Sullivan, RPh, PhD, reports receiving grants and research support from AstraZeneca, Genentech, and Novartis. He acknowledges that he has served as a consultant to AstraZeneca, Genentech, Merck, Novartis, Pfizer, and Altana Pharma. Fadia T. Shaya, PhD, MPH, reports that she has received grants and research support from Roche, Pfizer, and Bayer.

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Managed Care Viewpoint: The Challenges Of Obstructive Lung Diseases

B R U T O N  I. O R L A N D, B S, R P H
V ice President, Pharmacy, Oxford Health Plans, Trumbull, Conn.

Obstructive lung diseases pose many clinical and patient management challenges. These include diagnosing the disease correctly; deciding on treatment options from among the many different drugs and approaches available; developing effective disease management programs; properly considering concomitant medications used in treating patients with concurrent diseases; establishing consistent guidelines, which is particularly important if one intends to use evidence-based medicine as a primary form of diagnosis and treatment; and predicting outcome and cost.

Asthma and chronic obstructive pulmonary disease (COPD) continue to be significant health care problems in the United States from clinical, treatment, and cost perspectives. Consider these numbers: Asthma affects 26 million people in the United States, and each year it accounts for over 1.8 million emergency room visits, approximately 500,000 hospitalizations, and about 5,000 deaths. It also reaches $14.5 billion in total annual costs (Mannino 2002). COPD affects about 20 million people, of whom only 10.5 million have been diagnosed. Each year COPD accounts for approximately 1.5 million emergency room visits, 726,000 hospitalizations, and approximately 120,000 deaths — amounting to total annual costs of $32.1 billion (CDC 2005, NIH/NHLBI 2002). There is consensus throughout the health care community that such high levels of morbidity and mortality could be reduced with improved disease management.

The direct costs of COPD and asthma are $18.0 billion and $9.4 billion, respectively — costs shared by nursing home care, home health care, physician services, hospital care, and prescriptions drugs (Figure 1) (NIH/NHLBI 2002). Clearly, obstructive lung disease affects everyone’s budget.

This article presents the national managed care perspective on asthma and COPD using the efforts underway at Oxford Health Plans as a case study. Two considerations are particularly important in developing and maintaining effective long-term care programs for asthma patients and COPD patients. One is being able to monitor and ensure compliance while appropriately adjusting treatment regimens for patients. This means that physicians must be provided with a variety of treatment options and current information about treatment administration. The second key point, as with other diseases and therapeutic areas, is that it is critical to be able to link financial and medical data to track exactly what the cost centers are. Our experience has been that predictive modeling, using appropriate and well-correlated data, permits funds to be allocated more effectively so that physicians can provide patients with treatment options that facilitate long-term compliance and better overall health.

Long-term compliance and cost reduction

First, to put the situation in context, background information will be provided here. Oxford has 78,000 members who are receiving care for asthma, at a total cost of about $45 million, which averages to about $550 to $600 per person per year. Oxford has 17,000 members being treated for COPD, but this is at an annual cost of $17 million or about $1,000 per member per year. So the costs are substantially different in these programs. This is why it is critical to be able to predict the costs these patients incur over time, which largely is a function of how well they adhere to their controller medication regimens, and how this will affect a managed care organization’s total budget.

To do so, Oxford looks at the number of patients we are treating for these diseases, breaks out that number by age groups, and then looks at the overall risk score for each member to determine a predictive model for costs for the coming year (Table 1). Direct costs are broken out further by ancillary costs, facility or inpatient costs, pharmacy, professional services, and types of services. Facility inpatient and outpatient care, pharmacy, and professional services all are documented and linked together, providing a comprehensive picture of how effectively these different measures are affecting both patient health and health care expenditures (Table 2).

A key indicator is the appropriate use of long-term controller medications among patients, which is impor-
tant to patient health as well as program effectiveness. At least one recent study has shown that patients with low adherence to controller medication had a significantly higher risk of an emergency room visit or hospitalization compared to those with moderate or high adherence to controller medication (Berger 2004). Recognizing significant variation in the way that providers treat asthma patients, the study authors sought to assess the utility of the asthma Health Plan Employer Data and Information Set (HEDIS) measure in predicting asthma-related outcomes. They came to the conclusion that the HEDIS measure does not always correctly identify patients with persistent asthma and often mislabels people with intermittent asthma as having persistent asthma. As HEDIS also is used in pay-for-performance reimbursement models for physicians, a systematic and continual evaluation of the measure is recommended.

At Oxford, to monitor and attempt to effect better compliance with medication regimens, we looked at the change in HEDIS methodology devised by the National Committee for Quality Assurance (NCQA) in 2003 for the use of appropriate long-term controller medications. Several interventions were identified, particularly to address the pediatric population, which was a major goal.
“Better Breathing” program

Oxford initiated in 1997 and rolled over in 2005 a comprehensive disease management program called “Asthma Better Breathing.” This program is designed to help manage, assist, and educate children and adults who have asthma. Its purpose is to complement the care that members receive from their doctors by providing answers to questions about their condition. Members in this program can learn more about the triggers of asthma and how to avoid them, can learn the proper way to administer their medication, and can receive general support to help manage their condition. There currently are 54,000 asthmatics in the Asthma Better Breathing program.

The pediatric population is an especially important focus of the Better Breathing program. A number of messages are addressed in the campaign, including: children with asthma can lead full active, normal lives; if a child you care for has asthma, don’t smoke; everyone can help reduce the daily environmental factors that make asthma worse; asthma can be controlled; work with your doctor to manage your asthma; and take your anti-inflammatory asthma medications every day.

As part of the Better Breathing program, Oxford developed a three-tier open formulary for treating obstructive lung disease that gives physicians sufficient clinical choices so that they do not need to be limited by the drugs in the formulary. The plan offers five types of xanthin preparations, three oral beta-agonists, seven beta-agonists, three inhaled corticosteroids, four intranasal steroids, as well as several miscellaneous pulmonary agents.

The program includes a patient mailing list comprising all members who have been diagnosed with asthma. Members receive a self-help guide, a complimentary peak flow meter, a spacer, and an asthma action plan. Oxford also mailed out an asthma trigger postcard, which included general information on the agents that can cause an asthma episode, as well as a checklist for members to assess their own triggers. The postcards were sent to 53,000 members, and the newly identified asthmatics mailing was sent out to 23,000 members. These mailings have been sent to all persistent asthmatics, not just those on long-term controller medications. Members also received two brochures from the American Academy of Allergy, Asthma and Immunology (AAAAI) providing education about the different types of pharmacotherapy; this targeted mailing affected 2,000 members in 2004. The patient clinical update is a list of persistent asthmatic patients who are not on long-term controller medications and who have had an emergency room visit or an inpatient visit, and those were targeted as well.

Pediatric interventions involved an educational puppet kit that targeted members with asthma who were within the age range of 3 to 6 and who had one or more emergency room visits or inpatient visits in the past 12 months. Called the “Rory the Lion” asthma educational tool kit, it included a storybook, a parent packet, and a puppet. These kits were sent to 1,800 members. Oxford sent an asthma CD-ROM game to affected members within the age range of 7 to 15 who had one or more emergency room visits or patient visits in the past 12 months. The mailing was scheduled for late fourth quarter and went out to approximately 1,300 members.

The program also includes a flu reminder by telephone, from the company Televox, for members with asthma who were within the age range of 5 to 17, in which representatives, among other aspects of care, discussed the importance of influenza vaccines for chil-

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**TABLE 2 Asthma and chronic obstructive pulmonary disease: direct utilization costs**

<table>
<thead>
<tr>
<th></th>
<th><strong>Asthma — direct utilization</strong></th>
<th><strong>COPD — direct utilization</strong></th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Oxford Commercial Book of Business</td>
<td>Oxford Commercial Book of Business</td>
</tr>
<tr>
<td></td>
<td>12 months ending September 2004</td>
<td>12 months ending September 2004</td>
</tr>
<tr>
<td>Ages: 0 to 75+</td>
<td>Total no. of members: 78,856</td>
<td>Total no. of members: 17,599</td>
</tr>
<tr>
<td>Ancillary</td>
<td>Allowed amount: $1,656,358</td>
<td>Allowed amount: $991,508</td>
</tr>
<tr>
<td>Facility inpatient</td>
<td>Allowed amount: $2,875,175</td>
<td>Allowed amount: $5,397,783</td>
</tr>
<tr>
<td></td>
<td>Inpatient days: 2,122</td>
<td>Inpatient days: 4,240</td>
</tr>
<tr>
<td>Facility outpatient</td>
<td>Allowed amount: $3,111,952</td>
<td>Allowed amount: $1,166,807</td>
</tr>
<tr>
<td>Pharmacy*</td>
<td>Allowed amount: $25,266,189</td>
<td>Allowed amount: $5,195,842</td>
</tr>
<tr>
<td>Professional services</td>
<td>Allowed amount: $12,679,603</td>
<td>Allowed amount: $4,375,325</td>
</tr>
<tr>
<td>Total type of service</td>
<td>Total allowed amount: $45,589,277</td>
<td>Total allowed amount: $17,127,264</td>
</tr>
</tbody>
</table>

*Asthma plus all comorbidities.

**SOURCE:** OXFORD HEALTH PLANS 2005

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Members receive a self-help guide, a complimentary peak flow meter, a spacer, and an asthma action plan. Oxford also mailed out an asthma trigger postcard, which included general information on the agents that can cause an asthma episode, as well as a checklist for members to assess their own triggers. The postcards were sent to 53,000 members, and the newly identified asthmatics mailing was sent out to 23,000 members. These mailings have been sent to all persistent asthmatics, not just those on long-term controller medications. Members also received two brochures from the American Academy of Allergy, Asthma and Immunology (AAAAI) providing education about the different types of pharmacotherapy; this targeted mailing affected 2,000 members in 2004. The patient clinical update is a list of persistent asthmatic patients who are not on long-term controller medications and who have had an emergency room visit or an inpatient visit, and those were targeted as well.

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The program also includes a flu reminder by telephone, from the company Televox, for members with asthma who were within the age range of 5 to 17, in which representatives, among other aspects of care, discussed the importance of influenza vaccines for chil-
dren with asthma. Calls were made to 14,000 members in the third quarter of 2004, and vaccination rates have shown improvement since.

This program has received positive feedback by all those who have been involved. Under consideration for 2005 is an expansion of the pediatric outpatient program with bimonthly educational mailings and a “Take Asthma to Camp” mailing, featuring a list of local asthma camps for children to enjoy.

Return on investment

Oxford analyzed the outcomes of these interventions, evaluated the educational information regarding the importance of using both short-term and long-term asthma medications, and provided a clinical update to physicians and patients deemed to be using inappropriate medications.

These initiatives clearly have been successful, in terms of both cost control and patient compliance. Regardless of whether one views the HEDIS measure as the standard of care, Oxford’s Better Breathing program has brought about a rise in the appropriate use of long-term controller medications. In the 5- to 9-year old age group, the number of patients showing appropriate use of long-term controller medications increased to 75 percent from 68 percent in 2004. Similar successes are being realized in other age groups: 10- to 17-year olds are up to 72 percent from 62 percent; 18- to 56-year olds are up to 76 percent from 67 percent. Cumulatively, all ages are up to 75 percent from 67 percent. Thus, we have shown a definite increase in the correct utilization of medication. The results of the analysis also showed that 41 percent of these members whose asthma is active are now on maintenance drugs.

The Better Breathing program cost Oxford about $29,000 in 2004 for the members who were involved, which brought a return on the investment in the program. Our goal for 2005 is to continue the targeted mailing for those who are not on appropriate medications — the self-help mailing, the asthma trigger mailing, the pediatric focus mailings and interventions, and the provider clinical updates.

Overall, our efforts have shown that it is critical to link the provider and the member together so that everyone stays abreast of the latest information and treatment developments. Because of the many variables involved with obstructive lung disease, including the many ways that the disease manifests and the numerous options available to treat these variations, communication and systematic reevaluation of our treatment arsenal are the best means of assuring more positive patient outcomes.

References


Although chronic obstructive pulmonary disease (COPD) is the fourth leading cause of death in the United States, in 2020 it is expected to become the third leading cause of death for U.S. males and females (NHLBI 2003) and fifth in worldwide disease burden (GOLD 1998). Many patients with asthma have characteristics of COPD, and this distinct overlap between the two diseases can make it difficult to establish an accurate diagnosis (Figure 1). Both asthma and COPD are characterized by airflow obstruction and chronic persistent airway inflammation. They differ, however, in their cellular mechanisms, inflammatory mediators, inflammatory effects, and response to treatment (Barnes 2000).

The distinct similarities between COPD and asthma were noted in the 1960s with the introduction of the Dutch hypothesis stating that various types of airway obstruction are different expressions of a single disease spectrum (Postma 2004, Donohue 2003). Furthermore, it recognized that a predisposition is needed for onset of both asthma and COPD. More specifically, this hypothesis suggested that genetic factors and other host factors such as airway hyperresponsiveness (AHR), atopy, gender, and age, along with exogenous factors — such as allergens, infections, and smoking — all contribute to the pathogenesis of this chronic nonspecific lung disease (Orie 1961, Postma 2004). Scientists within the United States and the United Kingdom originally rejected the hypothesis, which now is reemerging.

In 1995, the American Thoracic Society (ATS) issued a statement supporting the overlap of these two chronic lung diseases: “It may be impossible to differentiate patients with asthma whose airflow obstruction does not remit completely from persons with chronic bronchitis and emphysema with partially reversible airflow obstruction and bronchial hyperresponsiveness.”

A 2004 statement from the ATS and European Respiratory Society (ERS) also supports this position, suggesting that both diseases often coexist because of their high prevalence in the general population (Celli 2004). In some patients, airflow does not return to normal with treatment and often can worsen over time. The ATS/ERS guidelines recommend that clinicians always treat such patients as asthmatics (Celli 2004).

A recent epidemiologic study comprising 3,099 adult subjects suggests that asthma might indeed be a risk factor for the future development of COPD. Results from this long-term, cohort study conducted in Tucson, Ariz., showed that the two diseases developed markedly similar characteristics over the course of 2 decades. Compared to those with inactive asthma, patients with active asthma had a tenfold risk of acquiring symptoms of chronic bronchitis, 17 times the risk of being diagnosed with emphysema, and 12.5 times the risk of meeting diagnostic criteria for COPD (Silva 2004).

Despite the shared characterization of these two lung diseases, the minimal attention that has been given to COPD (Barnes 2000) contrasts sharply with the great strides made in the understanding of the pathophysiology of asthma. This article will present the important similarities and differences between COPD and asthma to strengthen the understanding of COPD and its optimal management, thereby attempting to curtail its morbidity and mortality.
treatment. The onset of asthma, unlike COPD, generally occurs early in life, though some patients also may present with asthma for the first time in late adulthood.

**Diagnosis: clinical features and spirometry**

A diagnosis of COPD should be suspected in any patient presenting with a chronic cough; sputum production, or exertional dyspnea, with a history of exposure to cigarette smoke. The diagnosis should always be documented by measurement of lung function using spirometry (Mannino 2002). A confirmation is determined if the postbronchodilator forced expiratory volume in one second (FEV₁)/forced vital capacity (FVC) is less than or equal to 0.7, indicating the presence of airflow obstruction that is not completely reversible (Celli 2004).

Spirometry is also key for staging the disease. The ATS/ERS guidelines recommend spirometric classification of severity using a 5-stage system (Stage 0: at risk, Stage 1: mild, Stage 2: moderate, Stage 3: severe, Stage 4: very severe). In addition to spirometry, obtaining a chest radiograph is recommended in the initial assessment to help establish a differential diagnosis (Celli 2004).

Clinical features of asthma include wheezing, shortness of breath, chest tightness, and cough. The diagnosis of asthma also should be confirmed by spirometry. In patients with symptoms of asthma and normal spirometry, a bronchoprovocation test (methacholine challenge test) may be needed to confirm the diagnosis. COPD should be considered when determining a differential diagnosis if the patient is a current or former smoker who is over 40 years old, with persistent and slowly progressive symptoms, and a limited response to asthma treatment (GPIAG, undated).

The saying “all that wheezes is not asthma” is especially relevant in older individuals. Diagnosis of asthma through objective pulmonary measurement is particularly important in the elderly, in whom the disease is often overlooked and can be confused with COPD. (Braman 2003).

**Risk factors and triggers**

Airflow obstruction in COPD is associated with an abnormal inflammatory response of the lungs to toxic particles or gases, particularly tobacco smoke. Approximately 90 percent of patients with COPD are heavy smokers or have smoked upon diagnosis; therefore, smoking cessation is considered the most important step toward preventing COPD and halting its progression (Scanlon 2000), which is particularly true for women (Connett 2003). Other risk factors for COPD include secondhand smoke and occupational exposure to dust (e.g., coal, asbestos) and chemicals (NHLBI 2003, Donohue 2003).

Although respiratory tract infection during early childhood may be a risk factor for acquiring COPD, it is a major trigger for COPD exacerbation. Genetics also play an important role in the pathogenesis of COPD as only 20 percent of smokers acquire this disease (Donohue 2003). Several susceptibility genes are currently being investigated. A less common genetic predisposition for emphysema is alpha-1-antitrypsin deficiency.

Similar to COPD, asthma development in childhood can be influenced by exposure to secondhand tobacco smoke, but it is more typically precipitated by allergens. Of most importance to asthma onset is the interaction of genetic susceptibility and environmental exposure, especially to indoor allergens. Environmental triggers are the predominant triggers of asthma, with approximately 70 percent of asthmatics who are allergic to some indoor or outdoor allergen. Other triggers common to both diseases include exposure to certain weather conditions, exercise, and air pollution. Emotional and endocrine factors contribute to asthma but not to COPD. Women are particularly susceptible to hormonal triggers.

**Prevalence of COPD and asthma**

Based on data collected by the National Health and Nutrition Examination Surveys from 1971 through 2000, COPD is clearly underdiagnosed. In 2000, approximately...
10 million American adults reported physician-diagnosed COPD. Data from NHANES III (1991–1994), however, estimated that approximately 24 million U.S. adults have evidence of impaired lung function. The prevalence of asthma is similar, with approximately 20 million Americans — including children and adults — affected (NCHS 2005) (Figure 2).

Over this same period, the death rate from COPD in women showed the most dramatic change, increasing from 2.1 per 100,000 in 1980 to 56.7 per 100,000 in 2000 compared with the smaller increase in the death rate for men, from 73.0 per 100,000 to 82.6 per 100,000. These numbers should help to dispel the misconception that COPD affects more men than women. In fact, for the first time, the number of deaths in women surpassed the number of deaths in men (59,936 vs. 59,118) (Mannino 2002). Still, the age-adjusted COPD death rate in 2000 was approximately 46 percent higher in males than in females and 63 percent higher in whites than in African Americans (NHLBI 2003).

In 2001, the prevalence of chronic bronchitis was highest in African American women and white women, at about 12 and 9 percent, respectively. These percentages represented another shift in the populations affected by COPD, from those older than 65 years to those between ages 45 and 65 (NHLBI 2003). Deaths from asthma were considerably lower, with approximately 4,200 in 2002 (NCHS 2005). This number, though much higher than that seen in the past, fortunately has plateaued.

The economic burden
Considering the high prevalence of COPD and asthma, direct medical expenditures and indirect costs of morbidity and premature mortality take an enormous toll on society, economically and socially, and on public and private insurance payers. Direct costs include the value of health care resources needed for diagnosis and medical management of the disease. Indirect costs represent the disability, missed work and school, premature mortality, and caregiver or family expenses attributable to the illness (GOLD 1998).

The health care costs that are associated with physician visits, hospitalizations, prescription drugs, home health care, and nursing home care for COPD and asthma amount to billions of dollars. The data for 2002 show that the direct costs for COPD and asthma were $18 billion and $9.4 billion, respectively, and indirect costs were $14.1 and $4.6, respectively (Mannino 2002).

The cost to employers exemplifies the indirect costs of chronic lung disease. A study of employer cost of asthma showed that use of health care services and rate of disability were substantially higher in asthmatic patients vs. controls. Annual per capita employer expenditures for asthmatic patients were approximately 2.5 times those for controls ($5,385 vs. $2,121).

Further, wage replacement costs for asthma patients for workdays that were lost as a result of disability and sporadic absenteeism were similar to those that were due to medical care (40 percent and 43 percent, respectively) (Birnbaum 2002). Similarly, Medicare expenses for COPD were nearly 2.5 times the expenses for all other patients (NHLBI 2003).

The majority of asthma costs are attributable to 20 percent of asthmatics — the high utilizers with severe asthma who account for 20 percent of the affected patient population. If their disease is diagnosed early, asthmatics can be controlled effectively with minimal intervention. To shift these disturbing cost statistics, then, physi-
Mechanisms of inflammation
Although bronchial inflammation characterizes COPD and asthma, the pathogenic inflammatory processes of these diseases differ vastly (Table 1) (Barnes 2000). AHR is the characteristic physiologic abnormality in asthma. It is associated with eosinophilic inflammation that affects all the small airways. Bronchial biopsies, bronchoalveolar lavage, and induced sputum show an increase in activated and degranulating eosinophils. Also, there is an increase in CD4+ T lymphocytes (T-helper type 2 cells) that appear to orchestrate the eosinophilic inflammation and degranulated mast cells fundamental to the fast and episodic bronchoconstrictor responses that characterize acute asthma.

In COPD, however, AHR may be present in some but not all patients. Neutrophilic inflammation is predominant in the peripheral airways and the alveoli. Increased numbers of neutrophils also have been found in bronchoalveolar lavage. Parenchymal damage is a significant irreversible feature of COPD patients with emphysema. In contrast to asthma, the airway lymphocytes found in COPD are generally CD8+ rather than CD4+ cells. Although neutrophils, macrophages, and lymphocytes are predominant in inflammation in COPD, eosinophils may be present in the airway walls and lumens during a COPD exacerbation. A recent study has demonstrated that inflammation in small airways in COPD correlate with the severity of the disease and with the thickening of the airway wall (remodeling) (Hogg 2004).

Management guidelines for COPD and asthma
In 2004, the ATS/ERS updated their 1995 standards for treating COPD patients, motivated by the increased prevalence and research advances. The ATS/ERS guidelines recognize the 2001 recommendations of the Global Initiative for Chronic Obstructive Lung Disease (GOLD), but the revised guidelines specifically address management of stable COPD and exacerbations using oxygen therapy, pulmonary rehabilitation, noninvasive ventilation, and surgery for COPD, such as transplantation and lung volume reduction surgery. These evidence-based guidelines are Web-based and include a patient education component «www.thoracic.org/copd».

Pharmacologic approaches: COPD. Bronchodilator therapy is pivotal in the management of patients with COPD. Inhaled long-acting bronchodilators are preferred agents over oral and short-acting agents. Both long-acting beta-agonists (salmeterol and formoterol) and the long-acting anticholinergic (tiotropium) have been shown to cause sustained improvement in lung function, improvement in health status and exercise tolerance, and a reduction in COPD exacerbations. Use of inhaled corticosteroid alone is not currently approved by the U.S. Food and Drug Administration and remains a subject of debate due to conflicting findings. Nonetheless, in a meta-analysis, inhaled corticosteroids for treatment of at least 2 years had a modest effect on the rate of lung function deterioration in patients with moderate to severe airflow limitation (Sutherland 2003). Another meta-analysis demonstrated a 30 percent reduction in the relative risk of exacerbations in patients treated with inhaled corticosteroids compared to placebo (Alsaeedi 2002).

Systemic corticosteroids should be limited to the treatment of COPD exacerbations only, where they have been shown to cause a moderate improvement in hospitalized patients compared to placebo (Niewoehner 1999).

More recently, the treatment guidelines support the use of combinations of drugs of different classes to achieve improved outcomes. Specifically, the combination of a long-acting inhaled beta-agonist and inhaled corticosteroid is recommended. When administered in combination in a single inhaler, fluticasone and salmeterol, compared with fluticasone or salmeterol alone, resulted in an improvement in morning lung function.

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Inflammation – differences between asthma and COPD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asthma</strong></td>
<td><strong>COPD</strong></td>
</tr>
<tr>
<td><strong>Inflammatory cells</strong></td>
<td>Mast cells, EOS, CD4+ (Th2) cells, macrophages +</td>
</tr>
<tr>
<td></td>
<td>LTB4, histamine, IL-4, IL-5, IL-13, eotaxin, RANTES</td>
</tr>
<tr>
<td><strong>Inflammatory mediators</strong></td>
<td>Neutrophils, CD8+ (Tc) cells</td>
</tr>
<tr>
<td></td>
<td>macrophages ++</td>
</tr>
<tr>
<td></td>
<td>LTB4, TNF-alpha, IL-8, GRO,</td>
</tr>
<tr>
<td><strong>Inflammatory effects</strong></td>
<td>Peripheral airways and alveoli</td>
</tr>
<tr>
<td></td>
<td>Epithelial metaplasia, fibrosis ++, parenchymal destruction, mucus</td>
</tr>
<tr>
<td></td>
<td>All airways</td>
</tr>
<tr>
<td></td>
<td>Epithelial shedding, fibrosis +,</td>
</tr>
<tr>
<td></td>
<td>No parenchymal involvement, mucus</td>
</tr>
</tbody>
</table>

RANTES=regulated on activation, normal T expressed and secreted; TNF=tumor necrosis factor.
SOURCE: BARNES 2000
that was maintained for 24 weeks (Hanania 2003). Additionally, in a retrospective study in a primary care practice, regular use of the inhaled corticosteroid fluticasone and/or the long-acting beta agonist salmeterol improved survival in patients with COPD (Soriano 2002). A 3-year prospective study (TORCH 2004) is underway to further evaluate this finding.

Little or no evidence was found by the authors of the ATS/ERS guidelines to support use of maintenance antibiotic therapy, vasodilators, immunoregulators, or leukotriene receptor antagonists. An algorithm for pharmacologic treatment of COPD that was developed by the ATS/ERS is presented in Figure 3.

**Pharmacologic approaches: asthma.** Based on the guidelines established by the Global Initiative for Asthma (GINA), a rapid acting inhaled beta-2 agonist should be used as needed for most patients with mild intermittent asthma. For mild persistent asthma, the guidelines recommend controller medication daily, primarily inhaled glucocorticoids. In patients with mild persistent asthma, long-term, once-daily treatment with low-dose budesonide decreased the risk of severe exacerbations (Pauwels 2003). Moderate persistent disease should be treated with low-to-medium dose inhaled corticosteroids and long-acting beta agonists. In a recent meta-analysis, inhaled glucocorticoids proved to be more effective than leukotriene receptor antagonists in adult patients with mild or moderate disease (Ducharme 2003). Severe persistent asthma necessitates the use of high-dose inhaled steroids, a long-acting bronchodilator, and an oral steroid. For all levels of disease severity, a rapid-acting inhaled beta-2 agonist should be used as needed (GINA 2005) (Figure 4).

**Nonpharmacologic approaches: COPD and asthma.** Smoking cessation is central to the guidelines. The ATS/ERS view cigarette smoking as an addiction and chronic relapsing condition per the guidelines of the U.S. Department of Health and Human Services and the World Health Organization. Accordingly, they recommend that physicians offer available pharmacotherapies, such as bupropion SR, a nicotine inhaler, or a nicotine nasal spray or patch, to patients who cannot stop smoking without the use of drugs. Treatment should be repeated until the patient has abstained from smoking for a prolonged period (Celli 2004). The ATS/ERS also recommend that activities and support services for smoking cessation be integrated into the health care system. Additionally, the guidelines support use of influenza vaccination for all patients with COPD.

Pulmonary rehabilitation is designed to address secondary conditions associated with COPD, such as cardiac deconditioning, peripheral muscle dysfunction, and reduction in total and lean body mass, anxiety, and poor coping skills. A healthy lifestyle, physical activity, and

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**FIGURE 3** ATS/ERS algorithm for pharmacologic treatment in COPD

![Diagram](https://example.com/diagram.png)

**SOURCE:** CELLI 2004

adherence to therapy are encouraged. Although pulmonary rehabilitation has a minimal effect on pulmonary function values, it does improve dyspnea, exercise ability, and health status, and it reduces health care utilization. The ATS/ERS guidelines also focus on oxygen desaturation during sleep, air travel evaluation to determine oxygen needs, and end-of-life care (Celli 2004). Long-term oxygen therapy is recommended to improve survival, exercise, sleep, and cognition in patients with hypoxemia.

Avoiding exposure to environmental triggers is important in management of both COPD and asthma. In asthma, those conditions that might affect symptom control, such as allergic rhinitis, sinusitis, and gastroesophageal reflux disease, should be treated. Additionally, patient education is an important aspect of asthma and COPD management. Nonpharmacologic approaches in COPD management, which were described previously, include smoking cessation, optimum nutrition, pulmonary rehabilitation, and surgical interventions.

**Conclusion**

Although COPD and asthma are two different forms of chronic lung disease, there is considerable overlap in presentation and in management. Both are caused by gene-environment interaction. Their pathophysiology involves multiple components, including airway inflammation, obstruction, as well as hyperresponsiveness. Treatment of these diseases is somewhat similar in that they can be managed both pharmacologically and non-pharmacologically. Management strategies for both diseases should focus on treating both components — bronchoconstriction and airway inflammation. Only through increased understanding of their similarities and differences can there be progress in simplifying the differential diagnosis of these two disease entities.
References


Global diagnosis and management guidelines for asthma and chronic obstructive pulmonary disease have been issued. This article introduces the current treatment recommendations of the Global Initiative in Asthma (GINA) and Global Initiative for Obstructive Lung Disease (GOLD). Full reports and supporting documentation for clinicians and patients are available through the initiative Web sites. The scientific review committees of GINA and GOLD currently are revising the guidelines and soon will be issuing a revised report. Accepted treatment guidelines have influenced the development of performance indicators for physicians and health plans. The National Committee on Quality Assurance (NCQA) has promulgated quality of care indicators for a number of diseases, including asthma, and currently is reviewing possible quality indicators for chronic obstructive pulmonary disease (COPD). The Physician Consortium for Performance Improvement, convened and staffed by the American Medical Association, also is developing COPD performance indicators for use by physicians. A general description of the draft indicators is presented in this article.

The GINA guidelines
GINA started as a joint venture between the National Institutes of Health (NIH) in the United States and the World Health Organization (GINA 2005). These organizations historically have shared management of the GINA initiative. Two committees govern the work of the GINA initiative: the scientific committee, which is responsible for continuously evaluating emerging literature on asthma, and the executive committee, which makes final decisions on the recommendations. The objectives of GINA are to increase appreciation for this disease as a global problem, to present evidence-based diagnosis and management recommendations, to provide strategies that clinicians, patients, and health plans can use to undertake self-management, and to identify areas where there are gaps in the available scientific literature.

Asthma is extremely common worldwide, its prevalence is increasing (ISAAC 1998), particularly in children, and the societal burden is quite high (Nakagami 1994, Weiss 2000). The GINA guidelines attempt to address the burden of asthma disease through evidence-based diagnosis and treatment recommendations that can be disseminated and implemented within health care systems. The discussion that follows summarizes the treatment recommendations of GINA. Figure 1 depicts the asthma management goals put forward by GINA. In short, these comprehensive recommendations consist of equal parts physician and patient education as well as therapeutic recommendations for the prevention and treatment of asthma symptoms and morbidities. The use of pharmaceuticals to control disease burden is guided by a stepped therapy algorithm that takes into account the nature and severity of disease. Treatment recommendations are made for children and adults. There are particular patient subgroups to which the general recommendations may not apply, however. For example, specific approaches are required when treating asthma during pregnancy, treating patients with comorbid disease, or for those with exercised-induced bronchospasm. The GINA scientific committee has issued guidance for these and other special circumstances.

Asthma can be controlled effectively with current self-management and pharmaceutical treatments, though it cannot be cured. Effective asthma management programs, including patient education, environmental control, and pharmacologic therapy, are components of a comprehensive approach to control of disease. The main objective is to accomplish the goals of therapy with the least possible amount of medication. The availability of varying forms of treatment, cultural preferences, and differing health care systems need to be considered.

GINA currently is being revised so that it will reflect more recent evidence on diagnostic and therapeutic approaches. New evidence will be considered on emerging treatments, such as anti-IgE and fixed-dose combination therapies. Nevertheless, control of disease will re-
The GOLD guidelines
COPD is the fourth leading cause of morbidity and mortality worldwide. The age-adjusted death rate of persons with COPD in the United States has climbed steadily since 1965, while death rates for coronary heart disease, stroke, and many other diseases have fallen (Figure 2). This can be attributed to historical patterns of smoking and the lack of effective treatments to alter the progression of disease. Tobacco use is a major cause of COPD but is not the only culprit. The increasing use of biomass fuels for cooking and heating has been linked to growth in the incidence of COPD in nonsmoking populations. Our knowledge about the pathophysiology and mechanisms of COPD has increased in recent years. Yet, in spite of this, COPD remains underdiagnosed in the community.

In an effort to provide some guidance to clinicians, patients, and the general public, GOLD was established in April 2001 to bring awareness, improve diagnosis and management, and stimulate research into chronic obstructive lung diseases (GOLD 1998). GOLD is organized in much the same way as GINA. One committee undertakes a thorough and ongoing scientific review of the literature, and the executive committee issues diagnosis and treatment guidelines.

An update to the GOLD guidelines was issued in 2003; specific diagnosis and treatment recommendations are available for review on the GOLD Web site. The major modifications include: a change to the severity classification, an expansion of the role of long-acting bronchodilators, an expansion of the role of inhaled corticosteroids, improved evidence of pulmonary rehabilitation, and an expanded role for nurse-administered home care for exacerbations. The changes to the severity classification include the addition of “with or without chronic symptoms.” Also, the original 2a and 2b subcategories have been replaced (Table 1).

Quality of care indicators for asthma and COPD
The Institute of Medicine — through its publication “Crossing the Quality Chasm” — as well as the NCQA and other nongovernment organizations have acutely focused attention in the United States on the quality of health care provision (IOM 2001). One important NCQA activity focuses on development, dissemination, and reporting on quality of care performance indicators (www.ncqa.org). The NCQA Health Plan Employer Data and Information Set (HEDIS) contains 60 process and outcome measures that commercial health plans and government-sponsored health plans can use to assess the quality of care that they provide to enrolled members.
HEDIS measures are developed with practical utility for purchasers of care in mind. New HEDIS indicators, therefore, must be based on accepted clinical guidelines, clear evidence of benefit to patients, and feasibility for both private and government-sponsored health plans. Figure 3 shows the life cycle of a HEDIS measure.

A HEDIS drug therapy measure for asthma was developed in 2000. It was designed to determine the proportion of patients with persistent asthma in a health plan population receiving at least one prescription for appropriate guideline-based therapy. This measure has undergone revision to keep current with GINA and other treatment recommendations for persistent asthma. Table 2 shows the definitions of the numerator and denominator for the asthma HEDIS measure. Summary statistics from health plans reporting data to NCQA on the asthma measure indicate that roughly 60 to 65 percent of asthma patients had at least one dispensation for an appropriate controller therapy in the past 12 months (Figure 4). The NCQA recently issued a draft document illustrating a change to the asthma quality of care indicator. The public comment period closed in the spring of 2005. By the end of 2005, a decision on the new measure is expected.

The NCQA does not currently have a HEDIS measure for COPD. The Committee on Performance Measurement assembled a technical advisory group (TAG) in 2003 to begin the process of developing appropriate quality indicators for COPD. The TAG has proposed several measures, including appropriate diagnostic and treatment indicators. These measures are undergoing field testing and public review.

### TABLE 1 COPD: classification by severity

<table>
<thead>
<tr>
<th>Stage</th>
<th>Characteristics</th>
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| 0: At risk | Normal spirometry  
| | Chronic symptoms (e.g., cough, sputum) |
| I: Mild | \( \text{FEV}_1 / \text{FVC} < 70\% \); \( \text{FEV}_1 \geq 80\% \) predicted  
| | With or without chronic symptoms |
| II: Moderate | \( \text{FEV}_1 / \text{FVC} < 70\% \); \( 50\% \leq \text{FEV}_1 < 80\% \) predicted  
| | With or without chronic symptoms |
| III: Severe | \( \text{FEV}_1 / \text{FVC} < 70\% \); \( 30\% \leq \text{FEV}_1 < 50\% \) predicted  
| | With or without chronic symptoms |
| IV: Very severe | \( \text{FEV}_1 / \text{FVC} < 70\% \); \( \text{FEV}_1 < 30\% \) predicted or \( \text{FEV}_1 < 50\% \) predicted plus chronic respiratory failure |

**SOURCE:** GOLD 1998

### TABLE 2 HEDIS — asthma specification

- Percentage of enrollees ages 5 to 56 years identified as having persistent asthma, with at least 1 dispensed prescription in the measurement year for:
  - inhaled corticosteroids
  - nedocromil
  - cromolyn sodium
  - leukotriene modifiers* or
  - methylxanthines
- Age stratified for 5–9, 10–17, 18–56 years

### HEDIS — Persistent asthma

- Members are identified as having persistent asthma if they have any of the following in each of 2 consecutive years (year prior plus measurement year):
  - At least 4 asthma—medication-dispensing events*
  - At least 1 emergency room visit for asthma
  - At least 1 inpatient discharge for asthma, or
  - At least 4 outpatient visits for asthma, and at least 2 asthma—medication-dispensing events
- Defined by utilization, for logistical and feasibility reasons

* For members for whom leukotriene modifiers were the sole asthma medication dispensed, the member must meet any of the other 3 eligibility criteria OR have at least 1 diagnosis of asthma in any setting during the 2 years.

**SOURCE:** NCQA 2005

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Figure 3 shows the life cycle of a HEDIS measure.
Conclusion

Asthma and COPD are receiving substantial attention from clinical experts and quality improvement organizations. The hope is that this attention will lead to improvements in patient and population health. The immediate challenge is to effectively disseminate and implement evidence-based guidelines and quality improvement indicators in routine practice.

References


The Physician Consortium for Performance Improvement, convened and staffed by the American Medical Association, includes methodology and data collection experts; measurement development consultants; and members of national medical specialty societies, state medical societies, federal organizations, the Agency for Healthcare Research and Quality, the Council of Medical Societies, and the NCQA. The goal of the Consortium is that there be physician-driven, evidence-based, standardized clinical performance measures that could be used for various quality improvement and pay-for-performance activities. The Consortium wants evidence-based approaches that reflect cross-specialty representation and consensus. Presently, the Consortium is developing a number of COPD measures. These are expected to be announced at the end of 2005.
Obstructive lung diseases, specifically asthma and chronic obstructive pulmonary disease (COPD), continue to place a significant drain on Medicaid and Medicare programs (Grasso 1998). This is because these diseases often are misdiagnosed or under-diagnosed, result in a disproportionate number of physician and hospital visits, necessitate long-term pharmacotherapeutic maintenance, and are characterized by a lack of awareness that hampers the implementation of preventive programs.

With changes on the horizon to the Medicare prescription drug plan in 2006, it is important to examine utilization patterns among Medicare and Medicaid patients and to determine how these patterns affect the cost distributions for providers, employers, and patients. As the fourth most common cause of mortality in the United States (NCHS 2002a), obstructive lung disease needs to be better controlled, or the entire health care community will incur major expenses in seeking to ensure that patients lead healthy, productive lives. A key to this change will be shifting the burden of care from inpatient hospitalizations through better drug management and improved preventative programs that might increase the cost effectiveness of caring for these patients.

The Center on Drugs and Public Policy at the University of Maryland is conducting a number of studies on cost and resource utilization in a COPD Medicaid population. The research presented herein aims to track utilization patterns of COPD patients, assess the burden of COPD in Medicaid and managed care, examine patient programs and their effects on costs and outcomes, and look at the effect of the Medicare drug benefit being managed by pharmacy benefit management (PBM) services and regional health plans in states. These studies compare COPD patients to a matched cohort of non-COPD patients and to the overall Medicaid population. Such comparisons are important to health plans because they provide insight into how patients fare in the real world in terms of medication compliance and adherence.

A key item from these observational studies (Lapane 1998) is the fact that COPD patients might be unaware that they are afflicted or they might not even recognize the name of their condition. There is a severe need for a major awareness campaign to be undertaken. According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria and suggestions, the objectives of good management of patients with COPD are to raise awareness, to improve management of the disease, and to stimulate interest in COPD research. Medicaid plans in Maryland have been focusing on the burden of COPD in their populations, but any such investigation is confounded by the fact that some patients are not seeking care because they are unaware of their disease or they do not recognize its severity.

COPD can be described as a disease characterized by airflow limitation that is not fully reversible and is associated with an abnormal inflammatory response. The treatment goal is to slow disease progression. Prevalence in general has been documented at 6.8 percent per year for the year 2000, meaning approximately 10 million Americans had a clinical diagnosis of COPD in the year 2000. Further, approximately 1.5 times that many patients are as yet undiagnosed (Mannino 2002).

Data from the Centers for Disease Control and Prevention (Adams 1996) suggest that 70 percent of patients are under 65 years old, which makes this the fastest-rising disease in the working-age population. This has direct relevance to the Health Plan Employer Data and Information Set (HEDIS) measures and the employer-based programs, because employers are purchasing insurance for their members. Patients are more likely to be in the working-age group and no longer fit the false profile of COPD patients who are in their retirement years.

A look at a Medicaid population

The goals of our study were to capture health care resource utilization patterns and trends among Medicaid COPD patients, and to then compare the data to those of a matching cohort. We examined all medical and pharmacy claims from Medicaid COPD patients in Maryland who were continuously enrolled between January 1, 2001 and December 31, 2003; patients were selected if they had at least one claim with COPD (ICD-9 codes 491, 492, or 496), as a 1-, 2- or 3-year diagnosis. The study involved

The Burden of Obstructive Lung Disease in Medicaid and Managed Care Populations

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a total of 13,924 COPD patients, 60 percent of whom were male, 69 percent of whom were older than age 40, 49 percent of whom were white, and 36 percent of whom lived in the city.

We wanted to determine how patients actually used their medications and the services that are available to them, whether they go to the physician or to the emergency room. Prevalence was predominantly male, which is interesting for our population that is about 75 percent female. So the prevalence of male patients is much higher than what we would expect in a random Medicaid population, but probably lower than what we would expect in the general U.S. population. All the numbers in the study are slightly shifted toward a younger age group, as Medicaid populations tend to be younger than the national average.

In examining utilization patterns of inpatient emergency visits and pharmacy claims, an interesting trend emerges: Emergency room visits peak between the third and the fourth quarter of every year, with that rate declining again in the first 2 quarters of the following year (Figure 1). We have been unable to label these exacerbations because these are claims data, which contain no clinical information to provide performance indicators. In totaling all claims within COPD patients, we still find a substantial percentage of claims attributed to inpatient hospitalization. More than half comprise office and outpatient claims; drug prescriptions constitute approximately 28 percent of claims (Figure 2).

With the matching cohort of non-COPD patients, there is a shift away from inpatient hospital claims compared to COPD patients. We see a smaller percentage attributed to office and outpatient claims, down to about 43 percent in the non-COPD group, from over 50 percent in the COPD group. Most of these claims are for pharmaceutical treatment. Regardless of whether it is appropriate management, treatment of COPD patients is shifting from inpatient care to drug prescriptions. For comparable patients in Medicaid, COPD patients still claim a higher share of inpatient hospitalizations as well as office and outpatient services.

In looking at the average number of claims per patient with COPD vs. those for a patient with no respiratory dis-
ease, the average number of claims per patient for outpatient and office visits was 4 times higher for patients with COPD. Inpatient claims were also 4 times higher for patients with COPD, and claims for prescription drugs were 2 times higher for these patients (Figure 3). Further, the direct costs of COPD were about twice those for asthma. The indirect costs of COPD are believed to be many times those of asthma (Leigh 2002), which raises questions with important connotations for Medicaid and managed care: how can plans develop budgets when the costs and prevalence of COPD are underestimated?

Kesten et al (2001) analyzed the effects of COPD in a nationwide managed care population and estimated the cost at $1,100 per month per patient with COPD, whereas the average cost for all members was estimated at $179 per patient per month. Looking at comparisons of burden between Medicaid patients, Medicare patients, and chronic bronchitis and emphysema and asthma, according to the National Health Interview Survey, the overall prevalence in Medicaid populations is much higher than in Medicare populations for asthma and for chronic bronchitis and emphysema (NCHS 2002b).

The need for preventive programs

Many programs have been proposed for managing COPD in patients, and of these, perhaps the most promising are the pulmonary rehabilitation (PR) programs. These programs potentially can have the greatest effect on reducing patient claims and, ultimately, slowing disease progression. PRs are multidisciplinary care programs, tailored to patients with a chronic respiratory impairment, and they are designed to optimize physical and social performance as well as to retain the patients’ autonomy. It’s important to look at actual clinical indicators and quality of life as well as the survey results obtained from the patient. These involve functional outcomes, general quality of life outcomes, and disease-specific outcomes. The components of PR include exercise training; patient education, to assist with recognition of the disease and its severity; psychological and behavioral interventions; and outcome assessment.

PR programs are available in approximately 56 percent of facilities in the United States vs. 74 percent in Europe (Kida 1998). Most U.S. programs are implemented in the outpatient setting, compared with only 55 percent in Europe. Many studies have looked at the effectiveness of these programs. One study has shown that PR can reduce the number of emergency room visits, physician office visits, and calls to physicians (Bria 1987). The same study also showed that PR reduces the rate of primary care visits and the rate of hospitalizations, as well as the length of hospital stay. Given the shift of COPD prevalence from an elderly population to the working-age population, employers might be more interested now in considering support of these programs, because they have been shown to affect variables and indicators of high relevance to their population.

The new HEDIS measures seek to correlate any programs or interventions, clinical and otherwise, to some improvements in quality of life. In a study performed in the United Kingdom, the authors showed a positive effect on quality of life after implementation of the PR programs (Singh 1998).

As to the cost implications of PR, Goldstein and his team of investigators (1997) looked at this in a respiratory unit in Canada and found that 90 percent of the costs were associated with the initial cause of hospitalization. In these programs, the incremental cost of rehab was just over $11,000 Canadian.

Golmohammadi et al (2004) have evaluated the direct costs and disease-specific quality of life outcomes of community-based PR programs for COPD patients in Canada, and have shown significant health improvements. This is about a 30 percent decrease in the cost for those patients, from the preprogram phase to the post-program phase. Smoking cessation is probably the most effective intervention and the one that could be reasonably correlated with slowing the progress of the disease.

In terms of the cost-benefit analysis, Griffiths et al (2001) assessed the costs and benefits of a 6-week outpatient PR program in a hospital in England and showed that, for that program involving 20 patients, the costs were about £12,000 or U.S.$21,847. The mean incremental cost of adding a rehabilitation plan to standard
care was about £152 or U.S.$276.77 per patient, a significant improvement compared to the standard of care.

**The prescription drug benefit**

Another important consideration for employers and managed care providers is the Medicare drug prescription benefit, which will be effective in January 2006. This will include a $250 deductible and a 25 percent coinsurance liability on the part of the patient, up to $2,250. It is estimated that currently from Medicare only about 20 percent of patients will incur drug costs exceeding $3,000 per year. The threshold of $2,250 kicks in at what is known as the “donut hole,” where patients would have to pay out-of-pocket expenses up to the point at which Medicare covers about 95 percent of the drug costs. This will affect patients who are currently in Medicaid and who also are eligible for Medicare — the “dually eligible.”

Between 2004 and 2013, under the prescription drug plan, about $407 billion will go directly to benefit Medicare beneficiaries, including those dually eligible who would be eligible now under Medicaid. More than half of this $407 billion would directly benefit patients. Consider these statistics from a recent PricewaterhouseCoopers study (Stell 2004): approximately 35 percent of these funds would be attributable to the reduced beneficiary cost sharing. Approximately 16 percent would be attributable to the reduced patient. About 18 percent would be from the increased use of the drugs that has come to be expected with an increased drug utilization benefit. Subsidies to employers would represent 27 percent. The net subsidies to Medicaid state plans are only at 4 percent, because many of the savings that these programs accumulate might be given back to federal plans.

**Conclusion**

With increasing prevalence and earlier diagnosis of COPD and OLD, and reaching into younger age groups, Medicaid plans and Medicare need to explore effective ways of managing these diseases. Pulmonary rehabilitation programs have been proposed to assist in clinical management. Utilization trends show that a large portion of the spending is accounted for by prescription drugs. The implications of the new Medicare prescription drug benefit, scheduled to take effect in January 2006, are multifaceted. This new benefit is bound to change not only the utilization, likely boosting it, but also to lower average drug prices and probably average spending by patients.

**Acknowledgements**

Dr. Shaya gratefully acknowledges the assistance of Antoine El Khoury PhD, postdoctoral fellow at the University of Maryland School of Pharmacy in preparing this article.

**References**


BURTON I. ORLAND, BS, RPh: What is your opinion on [the recent] news from the New England Journal of Medicine suggesting that mild asthmatics should be treated as needed with steroids and short-acting beta-agonists?

NICK HANANIA, MD: It’s an interesting paper. Obviously, the group that did this study is highly respected, the Asthma Clinical Research Network or ACRN. Nonetheless, within the study conclusion, the authors themselves are only cautiously optimistic about their findings.

To generalize from the results of such studies does a disfavor to all the asthmatic patients whom we’re treating now. Most studies on the anti-inflammatory effects of inhaled steroids show that continuous treatment is needed. As to why the results are different in this study, I cannot explain it. Yet it is worth mentioning that daily inhaled corticosteroid therapy was superior to intermittent steroids in most of the secondary endpoints in this study. It is taking us much time to convince primary care physicians to start anti-inflammatory therapy early. I would not generalize the results of this paper to my practice until I see more studies. I showed you data from the START trial where inhaled steroids were used once daily instead of twice daily and showing some effect compared to placebo. This, however, is the first study demonstrating that intermittent use of inhaled steroids might work.

SEAN D. SULLIVAN, RPh, PhD: I agree that the ACRN is an accomplished group of investigators. They posed an extremely interesting question regarding 1-year outcomes of various monotherapy treatments in very mild persistent asthma. The study concludes that patients who use their inhaled steroids less than daily are not harmed in terms of lung function during 1 year. The caveat, however, is that this was a 1-year study, not a 3- or a 5-year study. Also, it showed that patients on inhaled corticosteroid [ICS] therapy had improvements in symptom-free days at the exact same magnitude as what we found in the START [Inhaled Steroid as Regular Therapy in Early Asthma]. This is only one study, but it will probably get repeated, as it’s raised interest in the clinical and research community.

HANANIA: The new asthma guidelines will focus on asthma control rather than severity based on FEV₁ [forced expiratory volume in one second]. Obviously FEV₁ is important, but mild, persistent asthmatics may not always be mild. Patients with FEV₁ greater than 90 percent at one time will not necessarily maintain lung function over the year.

ORLAND: Is there evidence that many patients are failing to adhere to treatment regimens?

HANANIA: In my practice, there is. Adherence is a big problem with chronic diseases, particularly asthma. Due to the episodic nature of the disease, patients don’t adhere to their controller medications and they tend to overuse their rescue medications. Also, the rescue medication gives them symptom relief immediately, whereas controllers usually take time to provide a benefit. That underscores the importance of patient education about the two types of medications. When I first see patients and ask what they’ve been using, the first thing they pull out is the rescue medicine.

FADIA T. SHAYA, PhD, MPH: I agree that the delivery system hampers adherence and that there is a need to educate both patient and physician. As we introduce new treatments and regimens, patients must be better educated and monitored more closely.

SULLIVAN: The HEDIS methodology has, like any other...
diagnostic test, characteristics of sensitivity and specificity and predictive value. The HEDIS performance measure for asthma is only somewhat valid for identifying patients who are persistent asthmatics, without an allergy component or exercise-induced disease. So there are mixed populations in the persistent group, which leads us to question the interpretability of the current HEDIS measure.

**ORLAND:** Given the overlapping diagnoses, how can HEDIS work?

**SULLIVAN:** COPD coexists with many conditions. Optimal treatment and management has to be thought through carefully in terms of patient comorbidities.

**ORLAND:** Recognizing the importance of smoking cessation in COPD, what about employer groups and managed care, which commonly exclude coverage of OTC and prescription smoking-cessation products?

**HANANIA:** In our county hospital, I cannot prescribe any OTC nicotine agents or bupropion for COPD patients who smoke. They must go through a weekly smoking-cessation class, run by an internist — which is good in that it offers counseling, plus participants get prescriptions for nicotine agents. Getting these patients to class is a challenge, however. Without question, the practice guidelines for smoking cessation emphasize the fact that pharmacotherapy must be offered to every patient who smokes and wants to quit. I certainly think we should enforce this.

**SULLIVAN:** It takes a sustained smoker more than 20 attempts to achieve sustained abstinence from smoking. Those attempts are either by going cold turkey or using counseling, telephone lines, pharmacotherapy, etc. Smoking cessation is the most effective and cost-effective way of preventing this disease. We should be covering interventions that prevent this disease cost-effectively.

**SHAYA:** Perhaps with evidence that patients who go through such programs succeed, these patients might eventually comply better with pharmacological treatment; we’ll have an argument for improved coverage for these programs because of the fringe benefits.

**ORLAND:** Is there evidence that outdoor grilling is a COPD factor?

**SULLIVAN:** Given the density of wood smoke and other biomass smoke, and the particulate matter in it, and given that some people cook that way daily, it is a factor for developing COPD. It’s as poisonous to the lungs as cigarette or tobacco smoke.

**HANANIA:** Also, the concentration of nitrogen oxide and particulate matter around a gas stove is much higher than in any other area in the house. Indoor exposure is a real concern relative to these two diseases.

**SULLIVAN:** It’s the exposure in cooking in a closed environment with fossil fuels, propane, butane, and with wood and animal dung.

**HANANIA:** Also, diesel exposure is a potential exacerbating factor for asthma.

**ORLAND:** What about ICSs and long-acting beta-agonists vs. tiotropium in reducing COPD exacerbation?

**HANANIA:** Both an inhaled steroid/long-acting beta-agonist combination and tiotropium have been shown in separate studies to reduce the number of COPD exacerbations. But no head-to-head studies comparing the agents have been published. For many of my severe patients with COPD, I do use both concomitantly, and I believe that there is a strong rationale in using both in extremely severe disease. Cost and the need for more than one inhaler are issues.

**SULLIVAN:** The GOLD guidelines say, rather than push the dose of the long-acting beta-agonists, combine it with another bronchodilator to balance efficacy with side effects.

**ORLAND:** What is the place for omalizumab in moderate to severe persistent asthma?

**HANANIA:** Obviously, it has an important role in patients who failed routine therapies, which are inhaled steroid, long-acting beta-agonists, or leukotriene modifiers. Cost is a drawback, but it is important in patients who have allergic asthma, who have IgE levels that are high, and also those who demonstrate allergy to certain allergens. Improvement in lung function is modest, but these patients are already on several other medications. FDA approval of this drug was based on the reduction in exacerbations. Several publications in the last 3 years show that those likely to respond to this medication are those with recurrent exacerbations, those with severe asthma. There are good Venn diagrams showing the odds ratio of the likelihood of response from those patients.

**ORLAND:** What would make inhalers more effective?

**HANANIA:** One study involved a survey on asthmatics and asked if they prefer a pill or an inhaler and whether they prefer an inhaler 1, 2, or 4 times a day. Whether it was a pill or an inhaler, it did not matter, but patients preferred once or twice a day over 4 times a day therapy. Fortunately, the new devices and medications have reduced the number of doses per day. Also, most of the devices are now much easier to use than the MDI [metered dose inhaler], with better and targeted drug delivery. The drawback is having to keep up with recently marketed devices, so that we can educate patients appropriately. Also, regarding delivery systems, as of December 2008, we will not have any MDIs containing CFCs [chlorofluorocarbons]. There will be a shift toward dry-powder or HFA [hydrofluoroalkane-134a] -containing devices, and costs of using rescue medication might rise. So, while we hope to one day be using one medication for asthma and one medication for COPD, that’s not the case now.
ORLAND: When does reactive airway disease become asthma?

HANANIA: There is no such thing as reactive airway disease in adult pulmonary medicine. RADS, reactive airway dysfunction syndrome, is a totally different disease that is related to acute occupational exposure to gases such as chlorine. Even insurance companies know that RAD equals asthma. I believe physicians use that term when they don’t want their patient to be labeled as asthmatic.

ORLAND: Physician and/or parental resistance to use of inhaled corticosteroids continues to be a significant impediment to the appropriate diagnosis of pediatric asthma. How do you change that?

SULLIVAN: I think physician resistance is decreasing, particularly in the pediatric physician community. The parents, of course, are concerned. We should never have called these agents steroids, because of the confusion it generates. The term used in the guidelines is “controller therapy.”

ORLAND: Dr. Shaya, how do you feel about the likelihood of managed care’s increasing reduction in the number of therapeutic options in different categories for treating Medicare members?

SHAYA: One clause of the prescription drug benefit is that these benefits will be managed by private payers that will eventually develop formularies. It certainly has been cost effective to deliver effective therapies with improved compliance. Yet the trade-off is that these patients now face many choices from different plans, and perhaps may find that certain medications are not on a particular formulary. That might be disconcerting to the patients. But we are gaining understanding as we go, and the more education patients receive, the more these patients become engaged in their own care and the better the outlook for these formularies.

ORLAND: Sean, how will placement of these drugs on formulary affect HEDIS or NCQA guidelines development for COPD?

SULLIVAN: This was not a consideration, because there were no recommendations for specific drugs. The only pharmacotherapeutic recommendation was to make sure that all patients diagnosed with COPD are on long-acting beta-agonists as first-line therapy.

ORLAND: I understand that short-acting inhalers will need different delivery mechanisms, for example, to be propellant. How will this affect cost of therapy?

HANANIA: I mentioned earlier that HFA is the only formulation we will have with the MDI in 2008. I am more concerned about albuterol, because that’s generic and inexpensive now. At least three formulations of HFA albuterol are available, but they are more expensive than the CFC-containing product. As to the concern about the environment, it is worth noting that the Montreal Protocol has been adopted worldwide, with the exception of this country.

SHAYA: If we consider costs alone, it is a daunting prospect, but looking at effectiveness and perhaps savings — not only savings generated by hospitalization avoided, but also through improved productivity and quality of life — we would see more of a cost justification.

SULLIVAN: Actually, it makes a big difference for patients, because it’s going to alter the formulary status of albuterol.

HANANIA: There was one question about long-term studies in COPD. One large 4-year study on the effect of tiotropium on lung-function decline in COPD is underway. That’s the UPLIFT [Understanding Potential Long-term Impacts on Function with Tiotropium] study. Another study, TORCH [Towards a revolution in COPD health], is looking at the effect of the combination of inhaled steroid and long-acting beta-agonists on mortality in COPD over 3 years.

ORLAND: I truly appreciate everybody’s questions. We thank our panel and thank you all for attending. We hope that the information shared through this discussion will be useful to you in your day-to-day responsibilities.
CONTINUING EDUCATION POST-TEST
Obstructive Lung Diseases – Asthma and Chronic Obstructive Pulmonary Disease: Managing the Patient and the Costs

Please tear out the combined answer sheet/evaluation form on page 28. On the answer sheet, place an X through the box of the letter corresponding with the correct response for each question. There is only one correct answer to each question.

1. Each year in the United States, asthma accounts for approximately how many emergency room visits?
   a. 4 million.
   b. 1.5 million.
   c. 1.8 million.
   d. 2.4 million.

2. According to recent statistics from National Institutes of Health and the National Heart Lung, and Blood Institute, the total annual direct costs related to asthma are almost double the direct costs associated with chronic obstructive pulmonary disease.
   a. True.
   b. False.

3. The percentage of patients currently in Oxford’s Asthma Better Breathing program who have successfully shifted from long-term controller medications to maintenance drugs is _____.
   b. 57.
   c. 63.
   d. 41.

4. The three-tier open formulary Oxford developed for its Better Breathing program includes how many different types of xanthin preparations?
   a. Three.
   b. Seven.
   c. Four.
   d. Five.

5. Asthma cannot be controlled effectively with current self-management and pharmaceutical treatments.
   a. True.
   b. False.

6. Which of the following is not an objective of GINA?
   a. Identify areas in which information on COPD is needed.
   b. Present evidence-based recommendations.
   c. Increase awareness of COPD as a problem primarily in developing nations.
   d. Provide treatment strategies for clinicians and health plans.

7. According to Sullivan, new HEDIS indicators must be based on:
   a. Clear evidence of benefit to patients.
   b. Accepted clinical guidelines.
   c. Feasibility for private and government-sponsored health plans.
   d. All the above.
   e. Answers “a” and “b” only.

8. In the 2003 GOLD guidelines update, the major modifications include:
   a. An expansion of the role of long-acting bronchodilators.
   b. A reduction of the role of inhaled corticosteroids.
   c. Improved evidence of pulmonary rehabilitation.
   d. All the above.
   e. Answers “a” and “c” only.

9. What was the documented prevalence of COPD in the general population in 2000?
   a. 6.8 percent per year.
   b. 41 percent per year.
   c. 9.6 percent per year.
   d. 70 percent per year.

10. Pulmonary rehabilitation programs are available in managed care facilities in the United States and in Europe at percent and percent, respectively.
    a. 42, 56.
    b. 56, 74.
    c. 23, 32.
    d. 70, 30.

11. Pulmonary rehabilitation programs are:
    a. Tailored to patients with an acute respiratory impairment.
    b. Multidisciplinary care programs.
    c. Designed to retain patient autonomy.
    d. All the above.
    e. Answers “b” and “c” only.

12. Asthma and COPD differ with respect to the following:
    a. Cellular mechanisms.
    b. Inflammatory mediators and inflammatory effects.
    d. All the above.
    e. Answers “b” and “c” only.

13. COPD, which typically presents in midlife, is characterized by:
    b. Airway inflammation.
    c. A rapid and reversible loss in lung function.
    d. All the above.
    e. Answers “a” and “b” only.

14. Spirometry is useful in confirming the diagnosis of asthma and in the staging of COPD.
    a. True.
    b. False.

15. Indirect costs of COPD and asthma are.
    a. The disability.
    b. Missed work and school.
    c. Premature mortality.
    d. Caregiver or family expenses attributable to the illness.
    e. All the above.
CONTINUING EDUCATION ANSWER SHEET/EVALUATION/CERTIFICATE REQUEST
Obstructive Lung Diseases – Asthma and Chronic Obstructive Pulmonary Disease: Managing the Patient and the Costs

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EXAMINATION: Place an X through the box of the letter that represents the best answer to each question on page 27. There is only ONE correct answer per question. Place all answers on this form:

A. B. C. D. E.
1. ☐ ☐ ☐ ☐ ☐
2. ☐ ☐ ☐ ☐ ☐
3. ☐ ☐ ☐ ☐ ☐
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15. ☐ ☐ ☐ ☐ ☐

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To receive continuing education credit, please provide all information requested below. This assures prompt and accurate issuance of your continuing education certificate.

Have the activity’s objectives been met?

1. Describe the prevalence, costs, and quality-of-life issues related to obstructive lung diseases. ☐ Yes ☐ No
2. Define the most recent guidelines related to diagnosis, treatment, and management of obstructive lung diseases. ☐ Yes ☐ No
3. Analyze the different pharmacotherapies and pharmacoeconomics of obstructive lung diseases. ☐ Yes ☐ No
4. Identify the importance of differential diagnosis in patients with obstructive lung diseases. ☐ Yes ☐ No

Was this publication fair, balanced, and free of commercial bias? ☐ Yes ☐ No

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Agree _______________ 4
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Treat/manage patients?
5 4 3 2 1 N/A

Communicate with patients?
5 4 3 2 1 N/A

Manage my medical practice?
5 4 3 2 1 N/A

Other ______________________________
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Effectiveness of this method of presentation:

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5 4 3 2 1

What other topics would you like to see addressed?
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