

Issues and Challenges for Managed Care in the Treatment of Asthma and Chronic Obstructive Pulmonary Disease

Shellie K. Schoening, MBA, PharmD, RPh

Abstract

Managed care organizations (MCOs) and payers have become increasingly aware of the impact of asthma and chronic obstructive pulmonary disease on healthcare expenditures. The prevalence and incidence of both conditions continue to increase, even as new therapeutic modalities enter the market to offer treatment alternatives for these conditions. Although viewed by most payers as long-term conditions with expenditures that will not diminish, MCOs and payers have become more concerned with controlling costs and ensuring appropriate utilization.

(*Am J Manag Care. 2004;10:S158-S163*)

Asthma and chronic obstructive pulmonary disease (COPD) may have traditionally been viewed as diseases that affect the elderly or those with a lower socioeconomic status. However, these conditions are becoming more common among the middle class.^{1,2} According to the National Health Interview Survey, between 1980 and 1996, self-reported asthma prevalence rose by the largest percentage in individuals aged 15 to 34 years than any other age group in the survey.³ The same survey also estimated that during 1994-1996, adults with asthma missed on average 2.5 work days per year because of asthma complications, which accounted for 14.5 million missed work days overall. In a retrospective study of patients entering the National Jewish Medical and Research Center disease state management program, Tinkelman and colleagues⁴ found that the stereotypical classification of the patient with COPD as elderly and unemployed may not apply to patients currently diagnosed with COPD. In fact, Tinkelman⁴ found that 49.7% of patients were younger than 65 years of age and 46.1% of patients were employed.

In many cases, the severity of the disease dictates resource utilization. Hilleman and

colleagues⁵ conducted a retrospective cost-of-illness analysis on patients with COPD. The authors determined that healthcare resource utilization was highly correlated with disease severity, and as disease severity increased so did healthcare resource utilization. According to the American Thoracic Society⁶ COPD severity stages, stage I disease severity was found in this study to have \$1681 per patient per year in healthcare resource expenditures, stage II was found to be \$5037, and patients with stage III utilized on average \$10 812 in healthcare resources per patient per year. In a cohort of 318 patients, Godard and associates also concluded that the overall costs of asthma (including individual direct costs, indirect costs, and intangible quality-of-life costs) are directly related to the severity of the disease.⁷

This is leading many MCOs and employers to take a harder look at disease management, risk avoidance, and early detection/identification.

Clinical Guidelines

Recognizing that these conditions cannot be cured, but rather managed, the development and use of clinical guidelines has assisted efforts to manage appropriate therapy. For COPD, the American Thoracic Society (ATS) guidelines⁶ were released in 1995 for the diagnosis and care of individuals with COPD. This was followed in 2001 by the World Health Organization and US Strategy for the Diagnosis, Management, and Prevention of Chronic Pulmonary Disease Report that has become known as the "GOLD Guidelines."⁸ Table 1 summarizes the goals of COPD therapy according to the GOLD guidelines. The ambulatory management of patients with COPD includes specific, symptomatic, and secondary therapy.

Treatment may depend on severity. Staging of severity by the ATS is based on forced expiratory volume in 1 second (FEV₁), which correlates best with morbidity and mortality in COPD. **Table 2** summarizes the management strategies for COPD. However, appropriate outpatient management of COPD depends on prescription compliance and adherence to therapy.

The National Asthma Education and Prevention Program (NAEPP) first released guidelines on the management and treatment of asthma in 1991,⁹ followed by a release in 1997,¹⁰ and then an update on selected topics in 2002.¹¹ **Table 3** summarizes the goals of therapy according to the NAEPP guidelines. These guidelines help to categorize asthma based on severity of symptoms and provide treatment recommendations based on disease severity. The guidelines standardize care and promote the use of anti-inflammatory medications. **Table 4** summarizes the treatment guidelines for asthma.

Despite the development and publication of clinical guidelines regarding these disease states, managed care organizations (MCOs) are still plagued with several challenges when it comes to appropriate therapy for asthma and COPD. Appropriate dosage, duration, and agent selection still remain major therapy hurdles. Many physicians have failed to adopt clinical guidelines in the treatment and management of their patients,¹²⁻¹⁴ leading to evidence that many patients have suboptimal therapy management for their disease conditions.¹⁵⁻¹⁷ Anis and colleagues¹⁸ found that excessive use of short-acting β -agonists and underuse of inhaled corticosteroids was a marker for poorly controlled asthma and excessive utilization of healthcare resources. Patients who were inappropriately managed received more prescriptions per year, visited their healthcare provider more frequently, were more likely to be admitted to the hospital, and were more likely to require an emergency department visit.

Recognizing the need for performance monitoring, the National Committee for Quality Assurance (NCQA) developed a set of guidelines to benchmark health plan performance measures in asthma therapy management.¹⁹ The NCQA Health Employer

Table 1. Goals of COPD Management

1. Prevent disease progression
2. Relieve symptoms
3. Improve exercise tolerance
4. Improve health status
5. Prevent and treat complications
6. Prevent and treat exacerbations
7. Reduce mortality
8. Prevent or minimize side effects from treatment

Source: Adapted from reference 8.
COPD indicates chronic obstructive pulmonary disease.

Table 2. Recommended Management Strategies for COPD

- Management of stable COPD**
- Smoking cessation (all patients)
 - General (both effective and cost-effective)
 - Brief tobacco dependence treatment
 - Practical counseling
 - Social support as part of treatment
 - Social support arranged outside of treatment
 - Nicotine replacement therapy
 - Adjunctive agents (bupropion, nortriptyline)
 - Health education (all patients)
 - Self-management skills
 - Coping ability
 - Health status
 - Bronchodilators (for symptom management)
 - β -agonists
 - Anticholinergics
 - Theophylline
 - Combinations
 - Exercise training programs (all stages of disease)
 - Exercise tolerance
 - Dyspnea
 - Fatigue
 - Long-term oxygen therapy (increases survival in selected patients)
- Management of acute exacerbations**
- Bronchodilator therapy (all patients)
 - Inhaled bronchodilators (short-acting β -agonists, anticholinergics)
 - Theophylline
 - Systemic corticosteroids (all patients)
 - Noninvasive positive pressure ventilation (hospitalized patients)
 - Improved arterial blood gases
 - Decreased need for intubation and invasive mechanical ventilation
 - Decreased in-hospital mortality
 - Decreased hospital length of stay

Source: <http://www.rcjournal.com/contents/08.01/08.01/0768.asp>
COPD indicates chronic obstructive pulmonary disease.

Table 3. Goals of Therapy for Asthma Control

<ol style="list-style-type: none"> 1. Maintain near "normal" pulmonary function 2. Maintain normal activity levels (including some exercise and other physical activity) 3. Prevent long-term and troublesome symptoms (eg, coughing or breathlessness in the night, in the early morning, or after exertion) 4. Prevent recurrent exacerbations of asthma and minimize the need for emergency department visits or hospitalization 5. Provide optimal pharmacotherapy with minimal or no adverse effects 6. Meet patients' and families' expectations of and satisfaction with asthma care

Source: Adapted from reference 11.

Data and Information Set provides minimally acceptable therapy measures for asthma that addresses minimally acceptable primary medications for treatment. It is important to note that the NCQA criteria vary from the NAEPP treatment recommendations and should not be viewed as a treatment or a therapy guide, but rather a quality and performance measure guide for MCOs to follow to assist in their efforts to monitor the quality of care for these patients.

Although clinical guidelines have been developed to address patient identification

Table 4. Recommended Therapy for Asthma Based on Disease Severity Classification

Severity Classification	Recommended Therapy
Severe persistent	High-dose inhaled corticosteroids and long-acting β -agonists (if needed oral corticosteroids)
Moderate persistent	Low-to-medium-dose inhaled corticosteroids and long-acting β -agonists; other alternative therapies include medium-dose corticosteroid or low-to-medium-dose corticosteroid and leukotriene modifier/theophylline
Mild persistent	Low-dose inhaled corticosteroids; other alternative therapies include cromolyn, leukotriene modifier, nedocromil, or theophylline
Mild intermediate	No daily medication needed

Source: Adapted from reference 9.

and decisions for treatment, clinical guidelines are slow to incorporate new drug treatments into the therapeutic regimen. These therapies often fall subject to managed care review measures, such as step therapy or prior authorization criteria, before access to coverage is provided. It is a difficult challenge for MCOs to provide a fair balance between cost control and ensuring quality of care for the patient.

Therapy Choice

The ultimate choice of therapy for a patient is a critical factor in determining the success rate that the patient will have in controlling their disease state. Other factors such as trigger exposure, medication adherence, and self-management education also play a major role in determining the success of a patient in disease state control. Clinical guidelines should assist physicians in prescribing the correct agents and/or combination of agents to target the patient's needs based on their disease severity. However, managed care formularies also play a role in determining which particular therapeutic agent a patient may be started on. Many MCOs have adopted formulary review measures that focus on evidence-based clinical guidelines; however, a struggle that MCOs face is the lack of data on comparative efficacy of the available agents. According to the Asthma Committee of the Canadian Thoracic Society's Canadian Asthma Consensus Conference Summary of Guidelines,²⁰ in asthma therapy, 12% or more improvement in FEV₁ after administration of a β ₂-agonist is considered significant, whereas the use of oral corticosteroids for more than 1 week or the use of inhaled corticosteroids for 2 or more weeks should produce an increase of 20% in a patient's FEV₁ response. This presents a challenge to MCOs. How many agents are reviewed on their ability to provide this level of relief and response for patients? Direct comparative data are often sparse and difficult to obtain to conduct a thorough comparative efficacy analysis. Pharmacoeconomic models and analytical decision models need to be developed to support the decision-making processes of comparing new and existing treatments.²¹ MCOs are then faced with the

challenge of providing and proving the clinical and economic outcomes of therapy choices in formulary decisions regarding asthma and COPD medications.

Disease State Management Programs

Outcomes are one of the key challenges for all medical care. All outcomes need to be assessed to ensure a properly designed program. In the short term, an asthma or COPD management program may actually increase pharmaceutical product costs in cases in which patients are receiving sub-optimal therapy because of the need for additional therapies. However, long-term outcomes of decreased hospitalizations and emergency department visits need to be carefully monitored for impact. In addition, reductions in indirect costs due to missed work and school are important to patients and employers.

Patient education can be one of the most successful management techniques for asthma and COPD. A lack of understanding of the patient's disease state can lead to non-compliance or exacerbation of symptoms. Just as the etiology of asthma is multimodal, its management encompasses nonpharmacologic, pharmacologic, and educational components. A broad-based educational platform that includes an overview of the disease state, recognition of triggers and symptoms, an action plan to handle exacerbations, and education on proper inhaler techniques and spacer devices, if needed, are cornerstones of any program. The use of peak flow meters can assist patients in recognizing airway obstruction and then developing an action plan to help control their symptoms and identify triggers. A properly structured asthma and/or COPD education program should take various forms and be administered in many mediums to provide repetition for increased patient comprehension and compliance. Patient engagement of asthma and COPD begins with the recognition that many changes must take place before the trends of increasing morbidity and mortality can be reversed.

Risk modeling and targeting have also become important techniques for MCOs to aid in targeting early interventions to avoid future expenditures. Risk models can satis-

factorily predict future patient outcomes in asthma when models take into account risk factors for disease progression based on patient demographics, symptom severity, comorbid conditions, and concurrent medication usage.²²

MCOs have proved to be successful at implementing therapy compliance programs that monitor patient medication compliance ratios or engage in refill reminder programs.²³ Disease state management programs need to be designed to ensure ease of patient access to care, ensure dose and duration appropriateness of pharmacologic agents, and include a management program that incorporates pharmacologic treatment and institutes ongoing monitoring of patient outcomes. MCOs have the daunting challenge of developing asthma and COPD management programs that minimize costs and maximize the quality of care for the patient.

Preventive Care Measures

Prevention is one of the best opportunities for MCOs to make an impact on conditions such as asthma and COPD. Maternal smoking during pregnancy is a proposed risk factor for asthma development in children, as well as active smoking in adolescents and young adults.²⁴ Smoking cessation is extremely important to prevent disease exacerbation and potential development of COPD. Multitargeted strategies are most effective; establishment of a quit date, behavior modification techniques, group sessions, and nicotine therapy are useful. After smokers give up their smoking habit, their FEV₁ increases slightly for a few years, then follows a path similar to that of nonsmokers. Of course, this depends on when they quit and how much they smoked. After smoking cessation, cough and expectoration diminish over a few months; sputum may become more viscid. Lost lung function is not regained, but smoking cessation delays the onset of exertional dyspnea and decreases the risk of developing or dying from COPD.

The fear for MCOs and payers is that the inclusion of coverage for smoking cessation programs would increase budgets and drug spending. Although the benefits of long-term smoking cessation are well documented, the short-term benefits may not be as recogniza-

ble for MCOs and payers. A study conducted by Ringen and colleagues²⁵ on a subset of blue collar workers found the costs associated with a smoking cessation program to be \$1025.28 per smoker who quit or \$11.78 per full-time equivalent employee per year.²⁵ The overall savings in healthcare resource utilization was expected to be 15 times the cost of the program, yielding an annual return on investment of 27.6%.

Preventive care measures can be one of the most cost-effective measures for MCOs. Some causes of COPD, such as smoking, are targeted. For example, environmental irritants in the workplace or elsewhere may be evaluated, and patients would then be advised of ways to avoid them. Influenza vaccine should be given annually because the risk of serious complications from influenza is greater in these patients.¹⁹ Pneumococcal vaccine should be given once and may be repeated after 5 to 10 years in higher-risk patients.²⁰

Although the benefits seem obvious, the challenge for MCOs is to encourage employer adaptation of smoking cessation and preventive care programs for their workforce. Many strategies can be employed; however, support from the employer is key to the success of any work-site smoking cessation or preventive care program.

Summary

MCOs and payers face many unique challenges in the management and treatment of asthma and COPD, such as clinical guideline acceptance and use, clinical and economic therapy choices, outcomes measurement and assessment, as well as incorporation of preventive care measures. Although newer pharmacologic treatment modalities are becoming available, and even newer agents are on the horizon, MCOs face the tough challenge of balancing access and cost drivers to ensure optimal patient outcomes. To reverse the increase in morbidity and mortality, and overall healthcare resource utilization, a paradigm shift needs to occur in the management of asthma and COPD. The focus needs to shift to early detection, disease prevention, adherence to medication therapy, and the use of evidence-based clinical guidelines for pharmacotherapy.

REFERENCES

1. **Yawn B.** The increasing prevalence and incidence of asthma in white middle class America: it's not just an inner city issue. Presented at: 2001 Annual Meeting of the American College of Allergy, Asthma & Immunology; November 15-20, 2001; Orlando, Fla.
2. **Joseph LMJ, Ownby DR, Peterson EL, et al.** Racial differences in physiologic parameters related to asthma among middle-class children. *Chest.* 2000;117:1336-1344.
3. **Mannino DM, Homa DM, Akinbami LJ, Moorman JE, Gwynn C, Redd SC.** Surveillance for asthma—United States, 1980-1999. *MMWR Surveill Summ.* 2002;51:1-13.
4. **Tinkelman O, Corsello P.** Chronic obstructive pulmonary disease: the impact occurs earlier than we think. *Am J Manag Care.* 2003;9:767-773.
5. **Hilleman DE, Dewan N, Malesker M, Friedman M.** Pharmacoeconomic evaluation of COPD. *Chest.* 2000; 118:1278-1285.
6. Standards for the diagnosis and care of patients with chronic obstructive pulmonary disease. American Thoracic Society. *Am J Respir Crit Care Med.* 1995;152:S77-S121.
7. **Godard P, Chanez P, Siraudin L, Nicoloyannis N, Duru G.** Costs of asthma are correlated with severity: a 1-year prospective study. *Eur Respir J.* 2002;19:62-67.
8. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: NHLBI/WHO Workshop Report. Bethesda, Md: DHHS, National Institutes of Health; 2001. NIH Publication 01-2701.
9. **National Heart, Lung, and Blood Institute.** Guidelines for the Diagnosis and Management of Asthma: Expert Panel Report. Bethesda, Md: National Heart, Lung, and Blood Institute; 1991. NIH Publication 91-3042.
10. **National Heart, Lung, and Blood Institute.** Guidelines for the Diagnosis and Management of Asthma: Expert Panel Report No. 2. Bethesda, Md: National Heart, Lung, and Blood Institute; 1997. NIH Publication 97-4051.
11. **National Asthma Education and Prevention Program.** Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma Update on Selected Topics—2002. *J Allergy Clin Immunol.* 2002;110(5 suppl):S141-S219.
12. **Legorreta AP, Christian-Herman J, O'Connor RD, Hasan MM, Evans R, Leung KM.** Compliance with national asthma management guidelines and specialty care: a health maintenance organization experience. *Arch Intern Med.* 1998;158:457-464.
13. **Doerschug KC, Peterson MW, Dayton CS, Kline JN.** Asthma guidelines: an assessment of physician understanding and practice. *Am J Respir Crit Care Med.* 1999; 159:1735-1741.
14. **Crim C.** Clinical practice guidelines vs actual clinical practice: the asthma paradigm. *Chest.* 2000;118:62S-64S.
15. **Ramsey SD.** Suboptimal medical therapy in COPD: exploring the causes and consequences. *Chest.* 2000; 117;(2 suppl):33S-37S.
16. **Wolfenden LL, Diette GB, Krishnan JA, Skinner EA, Steinwachs DM, Wu AW.** Lower physician estimate of underlying asthma severity leads to undertreatment. *Arch Intern Med.* 2003;163:231-236.
17. **Diette GB, Wu AW, Skinner EA, et al.** Treatment patterns among adult patients with asthma: factors associated with overuse of inhaled beta agonists and underuse of inhaled corticosteroids. *Arch Intern Med.* 1999; 159:2697-2704.

- 18. Anis AH, Lynd LD, Wang X, et al.** Double trouble: impact of inappropriate use of asthma medication on the use of health care resources. *CMAJ*. 2001;164:625-631.
- 19. National Committee for Quality Assurance.** HEDIS 2000. Volume 3: Specifications for Survey Measures. Washington, DC: National Committee for Quality Assurance; 1999.
- 20. Ernst P, Fitzgerald JM, Spier S.** Canadian Asthma Consensus Conference Summary of Recommendations. *Can Respir J*. 1996;3:89-100.
- 21. Price MJ, Briggs AH.** Development of an economic model to assess the cost effectiveness of asthma management strategies. *Pharmacoeconomics*. 2002;20:183-194.
- 22. Yurk RA, Diette GB, Skinner EA, et al.** Predicting patient-reported asthma outcomes for adults in managed care. *Am J Manag Care*. 2004;10:321-328.
- 23. Feifer RA, Gutierrez B, Verbrugge RR.** Impacts of PBM-based disease management program on asthma medication use. *J Manag Care Pharm*. 2001;7:460-467.
- 24. Strachan DP, Butland BK, Anderson HR.** Incidence and prognosis of asthma and wheezing illness from early childhood to age 33 in a national British cohort. *BMJ*. 1996;312:1195-1199.
- 25. Ringen K, Anderson N, McAfee T, Zbikowski SM, Fales D.** Smoking cessation in a blue-collar population: results from an evidence-based pilot program. *Am J Ind Med*. 2002;42:367-377.