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Chronic Obstructive Pulmonary Disease From a Payer and Provider Lens

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During the National Association of Managed Care Physicians' Fall Managed Care Forum held in Las Vegas, Nevada (November 8-9, 2012), Dr Johnson discussed medical costs associated with chronic obstructive pulmonary disease, current gaps in treatment, and the ensuing updated treatment recommendations. The following is a summary of his presentation.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a progressive obstruction of the lung that is not fully reversible with treatment and manifests as airflow limitation caused by airspace or airway disease.¹ Patients and doctors may use terms such as chronic bronchitis, emphysema, or smoker's lung to describe COPD.¹ According to Dr Johnson, very few people have just COPD; it often occurs in conjunction with other chronic diseases.

An abnormal inflammatory response to repeated inhalation of cigarette smoke has been cited as the primary cause of COPD in 85% of cases, with environmental toxins such as fumes, gases, and dust playing a smaller role.¹ The symptoms of COPD include breathlessness, persistent cough, and excess mucous production. A diagnosis of COPD is generally made in patients over 40 years old through the use of spirometry, a safe, accurate, and simple test that is often underused in the primary care setting, resulting in an underuse of available treatments such as short- and long-acting bronchodilators. The underdiagnosis and undertreatment of COPD may be attributed to the incorrect belief that treatments are not effective. Knowledge deficits among healthcare providers may also be to blame; despite the recent surge in the availability of COPD treatment guidelines, approximately 45% of primary care physicians and 6% of pulmonologists are unaware of such guidelines, a statistic that is perhaps even more troubling after considering that COPD ranks as the third-leading cause of death in the United States.^{1,2}

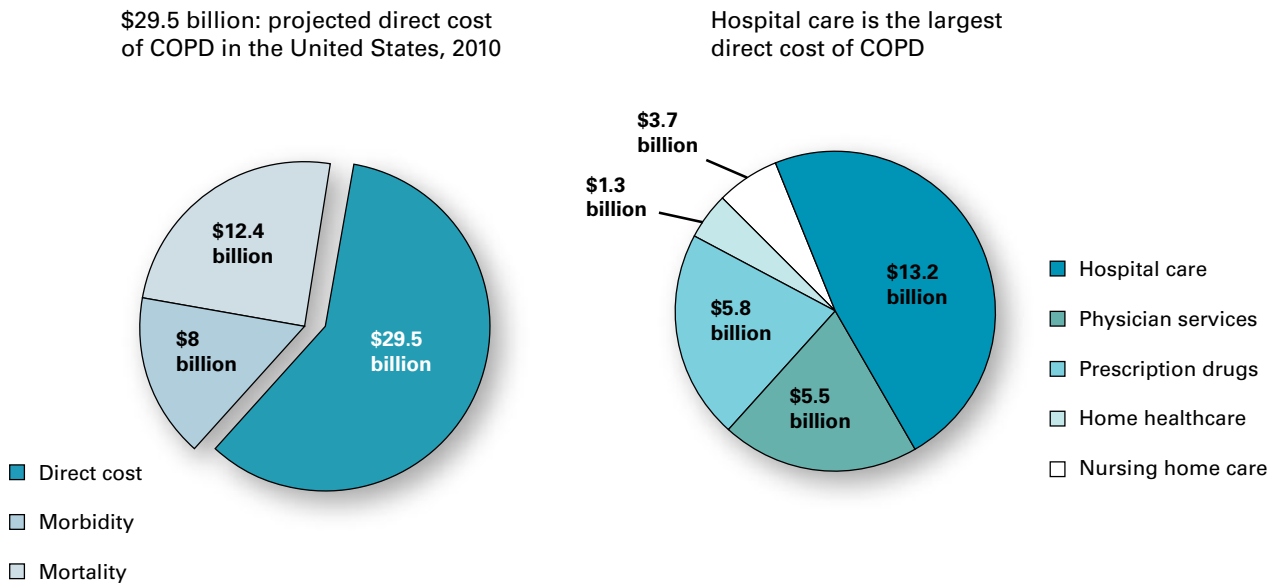
ECONOMIC IMPACT AND BURDEN OF DISEASE

The significant burden caused by COPD has statistically been summarized by the number "15." That is, 15 million people are affected in the United States, with 1.5 million emergency department visits annually, 150 million lost days of work, and \$15 billion in direct costs.¹ Without question, the costs associated with COPD impose a significant burden on the US healthcare system. In 2010, the projected cost of COPD in the United States was \$49.9 billion (**Figure 1**), with hospital care accounting for the largest portion of direct costs.³ In 2006, COPD resulted in 670,000 hospitalizations with an average length of stay of 4.4 days and 16,343,000 physician office visits. In this same year, the incidence of hospitalization, office visits, and death associated with COPD exceeded those associated with asthma.

Perhaps what is most alarming is that the mortality rates due to COPD continue to rise. According to a study that analyzed trends in death rates from the 6 leading causes of death in the United States, mortality attributable to COPD has doubled from 1970 to 2002, while deaths caused by heart disease and cancer have decreased.⁴ In a similar fashion, a study conducted by the Centers for Disease Control (CDC) reported that the rate of COPD-related deaths has increased by 67% over a 20-year period (1980 to 2000).⁵ The reason for this increase in COPD deaths is most likely related to the effects of tobacco smoking.⁶ The CDC also found that from 1980 to 2000, the COPD-associated death rate for US women increased significantly compared with that of men.⁵ Moreover,



Figure 1. The Economic Burden of COPD³



COPD indicates chronic obstructive pulmonary disease.

the rate of COPD deaths in women tripled during this time period, and in 2000, for the first time, the number of deaths caused by COPD was higher in women than in men.

GAPS IN DIAGNOSIS AND CARE

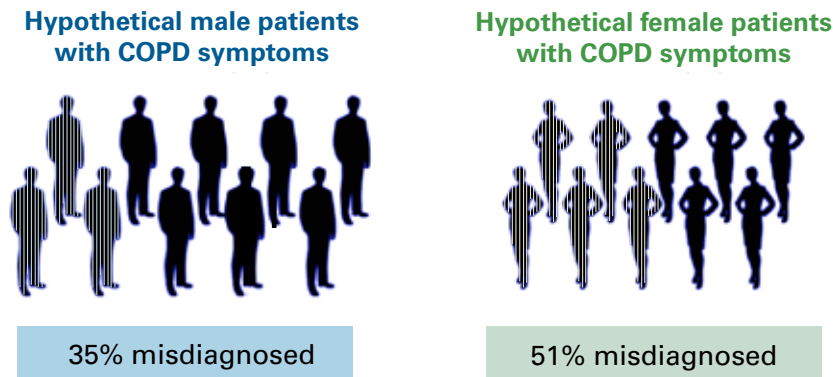
Although women are as likely as men to have COPD, the diagnosis is more common in men than women, possibly due to a sex bias among physicians when diagnosing respiratory illnesses.⁷ Because of this disparity, a recent study set out to determine the effects of sex bias on the diagnosis of COPD. The study also evaluated the percentage of patients with COPD who may be misdiagnosed and evaluated the physician's test-ordering behavior. To obtain more insight into these behaviors, physicians were presented with a hypothetical case study involving a male or female patient with a 40 pack-year history of smoking, a 4-year history of persistent morning cough that increased following viral infection, breathlessness on moderate exertion, and wheezing.

Physicians were then asked what the probable diagnosis was and what diagnostic tests should be ordered. After receiving their answers, regardless of what they were, diagnostic test results were provided to the physicians showing that the patient exhibited abnormalities on spirometry. The physicians were also shown that patients failed steroid therapy, and that steroids did not reverse their symptoms. Findings from this trial showed that misdiagnosis of COPD is common when patient assessments are based on history and physical alone (Figure 2) without the use of spirometry.⁷ The study also found that more female patients who presented with COPD symptoms were misdiagnosed compared with male patients when spirometry was not utilized. After reviewing the history and physical examination findings, only 23% of the physicians ordered spirometry testing whereas 80% requested a chest radiograph. Low rates of spirometry testing have also been reported among patients with newly diagnosed COPD or

newly active COPD by the National Committee for Quality Assurance, an organization that publishes a yearly report to call attention to healthcare quality issues in the United States (Figure 3).⁸

Low rates of spirometry may possibly explain why inhaled steroid use is substantially greater than beta-agonist use in patients who require respiratory treatments.⁹ A recent pharmacy benefit report comprising data supplied by commercial, Medicare Part D, and Medicaid plans reported on the use of respiratory medications as a part of overall drug expenditures. Table 1 provides an overview of 2010 per-member per-year expenditures and prescription use per 1000 members according to insurance plan. As shown, spending on steroids was approximately 3 to 6 times that of beta agonists (expenditure data include both brand and generic drugs). Dr Johnson noted that these data likely indicate that health plans are spending more on inhaled corticosteroids because beta agonists are not being used correctly.

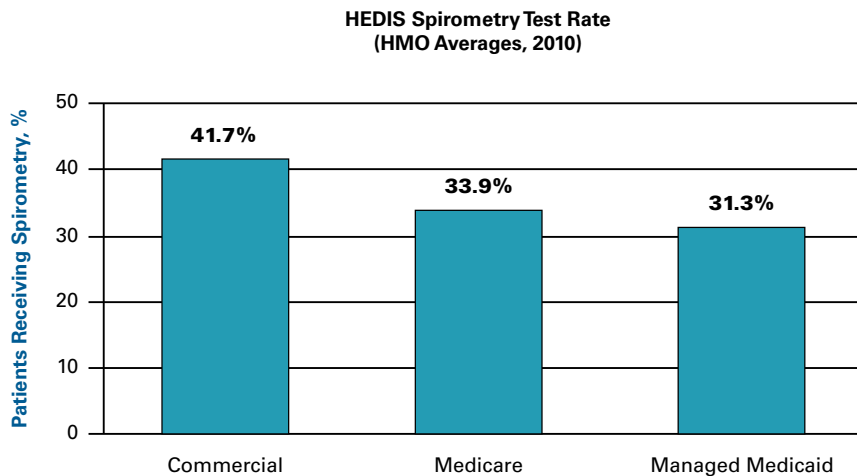
Figure 2. Percentage of Hypothetical Patients With COPD Misdiagnosed During a Survey of Physicians⁷



(Inverse of COPD diagnosis = percentage misdiagnosed)

COPD indicates chronic obstructive pulmonary disease.

Figure 3. The Use of Spirometry in Patients With COPD to Confirm the Diagnosis⁸



COPD indicates chronic obstructive pulmonary disease; HEDIS, Healthcare Effectiveness Data and Information Set; HMO, health maintenance organization.

2011 GLOBAL INITIATIVE FOR CHRONIC OBSTRUCTIVE LUNG DISEASE GUIDELINES

Despite a somewhat increased awareness of COPD over the past several decades, the topic of COPD has largely remained overlooked by the public and medical community. Moreover, Dr Johnson stated that the needed resources (both educa-

tional and financial) have not been available. Based on this observation, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) was founded by a group of committed scientists in 1998 to simultaneously increase awareness of COPD management and aid the millions of patients who suffer and die prematurely from COPD or its com-

plications.¹⁰ The group released its first GOLD practice recommendations in 2001 with annual updates subsequently communicated via its website. In 2009, because a considerable amount of new information had become available in the COPD literature relating to both its management and diagnosis, the group began developing a heavily



Table 1. Spending and Utilization of Inhaled Steroids and Beta Agonists Stratified by Insurance Type⁹

Beta Agonists: PMPY Expenditures and Rx/1000			
	<i>Commercial/Group</i>	<i>Medicare Part D</i>	<i>Medicaid</i>
PMPY expenditures (\$)	5.34	15.07	12.02
Rx/1000 members	120.5	265.7	367.4
Inhaled Steroids and Others: PMPY Expenditures and Rx/1000			
	<i>Commercial/Group</i>	<i>Medicare Part D</i>	<i>Medicaid</i>
PMPY expenditures (\$)	22.09	100.30	31.35
Rx/1000 members	108.8	478.9	194.0

PMPY indicates per member per year; Rx, prescription.

revised guideline and launched this major revision in November 2011. A few of the most salient points include the compulsory use of spirometry to diagnose COPD, a new chapter reviewing the treatment of COPD, and new recommendations for the grading and management of COPD that are based upon COPD risk category. To assess COPD, the 2011 GOLD grading system utilizes a combination of symptomatic assessment (modified Medical Research Council [mMRC] scale and/or COPD Assessment Test [CAT]), spirometric classification (ie, GOLD category), and/or future risk of exacerbations to assign COPD severity to a patient group (Figure 4).¹⁰ The mMRC and CAT are 2 patient questionnaires designed to evaluate COPD symptoms. The mMRC only assesses disability due to breathlessness. The CAT is an 8-item questionnaire that provides a more global assessment of the impact of COPD on patients' daily life and well being. The original strategy for classifying COPD was a much more simple system based upon forced expiratory volume in 1 second (FEV₁) alone and it was referred to as a staging system because, at the time, it was believed that the majority of patients with COPD followed a path of disease progression in which the severity of the disease increased in accordance with the severity of the airflow limitation. The new grading system, using patient groups, promotes a more complete understand-

ing of the impact of COPD since it incorporates symptoms and risk of exacerbations together with the GOLD category component. The GOLD category component is defined according to postbronchodilator FEV₁ in patients with an FEV₁/FVC less than 0.70: GOLD 1 (mild, FEV₁≥80% predicted); GOLD 2 (moderate, 50%≤FEV₁<80% predicted); GOLD 3 (severe, 30%≤FEV₁<50% predicted); GOLD 4 (very severe, FEV₁<30% predicted).

The GOLD guidelines define the 4 patient groups as follows¹⁰:

- Patient Group A: low risk, fewer symptoms—typically GOLD 1 or GOLD 2 (mild or moderate airflow limitation) and/or no more than 1 exacerbation per year *and* an mMRC grade 0 to 1 or CAT score less than 10
- Patient Group B: low risk, more symptoms—typically GOLD 1 or GOLD 2 (mild or moderate airflow limitation) and/or no more than 1 exacerbation per year *and* an mMRC grade of at least 2 or CAT score of at least 10
- Patient Group C: high risk, fewer symptoms—typically GOLD 3 or GOLD 4 (severe or very severe airflow limitation) and/or at least 2 exacerbations per year *and* an mMRC grade 0 to 1 or CAT score less than 10
- Patient Group D: high risk, more symptoms—typically GOLD 3 or GOLD 4 (severe or very severe

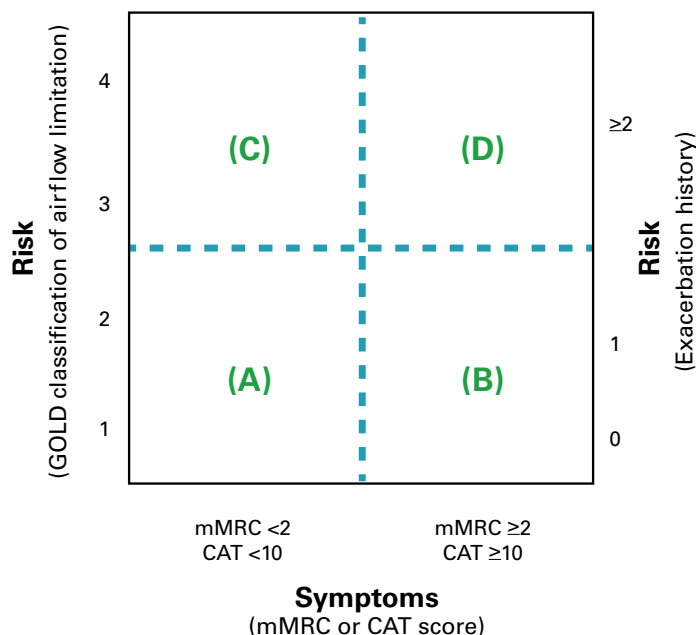
airflow limitation) and/or at least 2 exacerbations per year and an mMRC grade of at least 2 or CAT score of at least 10

It is worthwhile to note that most clinical trials of pharmacologic treatment have been limited mostly to patients with high-risk COPD, although the UPLIFT (Understanding Potential Long-term Impacts on Function with Tiotropium) trial contained more than 2000 patients with GOLD category 2 COPD.^{10,11}

Table 2 summarizes recommendations from the GOLD guidelines for initial pharmacologic management of COPD according to patient group.¹⁰ As shown, the most recent GOLD pharmacologic treatment guidelines position bronchodilators as central to the management of COPD. The guidelines also advise that when choosing a bronchodilator, long-acting formulations are preferred over short-acting formulations for both beta agonists and anticholinergics. Furthermore, the guidelines advise that inhaled formulations are always preferred over oral bronchodilators. The use of combination therapy is also addressed. In patients with severe or very severe COPD and frequent exacerbations who are not adequately controlled by long-term bronchodilators, the concomitant use of long-term inhaled corticosteroids is recommended. However, it is important to note that long-term monotherapy with inhaled corticosteroids is not recommended because this regimen is not as effective as the combination



Figure 4. GOLD Patient Groups: Relationship Between Symptoms and Risk¹⁰



CAT indicates COPD Assessment Test; COPD, chronic obstructive pulmonary disease; GOLD, Global Initiative for Chronic Obstructive Lung Disease; mMRC, modified Medical Research Council.

Reprinted with permission from Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of COPD. http://www.goldcopd.org/uploads/users/files/GOLD_Report_2011_Feb21.pdf.

Revised 2011. Accessed November 20, 2012.

of inhaled corticosteroids and long-acting beta₂-adrenergic agonists. In selected patients treated with bronchodilators alone, the combination of a short or long-acting beta₂-adrenergic agonist and an anticholinergic may be useful if symptoms do not improve with single-agent therapy. Of note, smoking cessation remains a crucial intervention in patients with COPD who continue to smoke. However, Dr Johnson noted that “Tobacco cessation is very difficult to implement with this population.”

AMERICAN COLLEGE OF PHYSICIANS GUIDELINES

Additional guidelines for the treatment of COPD have been published by the American College of Physicians (ACP) following a joint effort with 3 other professional physician organizations—the American College of Chest Physicians, the American Thoracic Society, and the European Respiratory Society.¹² The 2011 ACP guidelines

were developed based on a review of updated evidence on the diagnosis and management of stable COPD. They are an update to the 2007 ACP clinical practice guideline, and were developed to clarify recommendations for when to administer therapy to patients with stable COPD and detail how to select the appropriate monotherapy. The new guidelines were developed to answer questions about the value of history and physical examination for predicting airflow obstruction, the value of using spirometry in patients with no symptoms, the appropriate patients for treatment, and effective management strategies for the treatment of COPD.

Although history and physical examination findings were found to be poor predictors of airflow obstruction, airflow obstruction (defined as a post-bronchodilator FEV₁/FVC ratio <0.70) can be predicted in a patient who demonstrates all 3 of the following: (1) a greater than 55-year history of smoking; (2) wheezing on auscultation; and

(3) self-reported wheezing.¹² In patients with symptoms of airway obstruction, spirometry is used to diagnose COPD when airflow obstruction is not fully reversible and to identify appropriate candidates for pharmacologic therapy. Spirometry is not warranted to screen for airflow obstruction in patients without respiratory symptoms and may lead to additional unneeded testing and unnecessary increases in costs and resource utilization. The use of spirometry has not been effective in persuading patients to quit smoking.

Regardless of presence or absence of airway obstruction or its risk factors, there is no benefit in treating patients who do not exhibit symptoms.¹² There is insufficient evidence from randomized controlled trials to demonstrate that FEV₁ reductions or COPD symptoms can be prevented by treating patients who exhibit spirometric evidence of airflow obstruction, regardless of the presence or absence of risk factors. Overall, treatment recommendations are



Table 2. Suggested Initial Treatment of COPD According to the Individualized Assessment of Risk Group^{10,a}

Patient Group	First Choice	Second Choice	Alternative Choice ^b
A. Low risk, less symptoms	SA anticholinergic <i>or</i> SA beta ₂ agonist, as needed	LA anticholinergic <i>or</i> LA beta ₂ agonist <i>or</i> SA beta ₂ agonist and SA anticholinergic	Theophylline
B. Low risk, more symptoms	LA anticholinergic <i>or</i> LA beta ₂ agonist	LA anticholinergic and LA beta ₂ agonist	SA beta ₂ agonist <i>and/</i> <i>or</i> SA anticholinergic Theophylline
C. High risk, less symptoms	ICS + LA beta ₂ agonist <i>or</i> LA anticholinergic	LA anticholinergic and LA beta ₂ agonist	PDE-4 inhibitor SA beta ₂ agonist <i>and/</i> <i>or</i> SA anticholinergic Theophylline
D. High risk, more symptoms	ICS + LA beta ₂ agonist <i>or</i> LA anticholinergic	ICS and LA anticholinergic <i>or</i> ICS + LA beta ₂ agonist and LA anticholinergic <i>or</i> ICS + LA beta ₂ agonist and PDE-4 inhibitor <i>or</i> LA anticholinergic and LA beta ₂ agonist <i>or</i> LA anticholinergic and PDE-4 inhibitor	Carbocysteine SA beta ₂ agonist <i>and/</i> <i>or</i> SA anticholinergic Theophylline

COPD indicates chronic obstructive pulmonary disease; ICS, inhaled corticosteroid; LA, long-acting; PDE-4, phosphodiesterase type 4; SA, short-acting.

^aMedications in each box are listed in alphabetical order and, therefore, not necessarily in order of preference.

^bMedications in this column can be used alone or in combination with medications in the first and second columns.

Adapted from Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of COPD. Revised 2011. http://www.goldcopd.org/uploads/users/files/GOLD_Report_2011_Feb21.pdf. Accessed November 20, 2012.

similar between the ACP and GOLD guidelines, with both guidelines recommending bronchodilators as the treatment of choice for symptomatic patients with at least a moderate level of COPD, with long-acting formulations preferred over short-acting.^{10,12} One notable difference between the ACP and GOLD guidelines is in their approach to assessing COPD disease severity. As previously discussed, the GOLD guidelines advise clinicians to define COPD severity by considering several disease factors that include the future risk of exacerbations, symptoms, and FEV₁. By comparison, the ACP recommendations for stable COPD are more focused on FEV₁ alone.¹²

The ACP guidelines include the following 7 key recommendations¹²:

- Recommendation 1: Spirometry should be obtained to diagnose airflow obstruction in patients with respiratory symptoms. Spirometry should not be used to screen for airflow obstruction in individuals without respiratory symptoms (strong recommendation, moderate-quality evidence)
- Recommendation 2: For patients with stable COPD with respiratory symptoms and an FEV₁ between 60% and 80% predicted, the guideline suggests that

inhaled bronchodilators can be used (weak recommendation, low-quality evidence)

- Recommendation 3: For patients with stable COPD with respiratory symptoms and an FEV₁ less than 60% predicted, the guideline recommends treatment with inhaled bronchodilators (strong recommendation, moderate-quality evidence)
- Recommendation 4: Clinicians should prescribe monotherapy with a long-acting inhaled anticholinergic or a long-acting inhaled beta₂-adrenergic agonist for symptomatic patients with



COPD and an FEV₁ less than 60% predicted (strong recommendation, moderate-quality evidence). Clinicians should base the choice of specific monotherapy on patient preference, cost, and adverse event profile

- Recommendation 5: Clinicians may administer combination inhaled therapies (long-acting bronchodilators or inhaled corticosteroids) for symptomatic patients with stable COPD and an FEV₁ less than 60% predicted (weak recommendation, moderate-quality evidence)
- Recommendation 6: Clinicians prescribe pulmonary rehabilitation for symptomatic patients with an FEV₁ less than 50% predicted (strong recommendation, moderate-quality evidence). Clinicians may consider pulmonary rehabilitation for symptomatic or exercise-limited patients with an FEV₁ greater than 50% predicted (weak recommendation, moderate-quality evidence)
- Recommendation 7: Clinicians prescribe continuous oxygen therapy in patients with COPD who have severe resting hypoxemia (arterial oxygen partial pressure ≤ 55 mm Hg or saturation of peripheral oxygen $\leq 88\%$) (strong recommendation, moderate-quality evidence)

SUMMARY

COPD is a common disease that is associated with substantial mortality and a number of uncomfortable symptoms, yet a large number of patients with COPD remain undiagnosed and without available treatment to ease their symptoms. Together, these observations clearly show that a paradigm shift is needed in the diagnosis, treatment, and management of patients with COPD. Recent guidelines are available that contain well-defined recommendations for patients with COPD, based upon their risk for exacerbations and level of airway obstruction. Goals to improve COPD

IMPROVING OUTCOMES IN COPD

According to Dr Johnson, providers and payers need to identify gaps in COPD care and develop management strategies. This can be best accomplished using input from specialists and primary care physicians. He suggested 3 areas that are crucial to improving outcomes in COPD:

1. Increased patient education
2. Better rehabilitation services (eg, pulmonary clinics)
3. More patient copay assistance programs

outcomes should include enhancing early detection through the required use of spirometry by primary care physicians in outpatient clinics among patients with symptoms and a history that suggests the possibility of COPD. Furthermore, short- and long-acting bronchodilators should be used in accordance with the newly revised GOLD guidelines, which also discourage the use of inhaled corticosteroids in patient groups A to B. Of note, preparations should be made in anticipation of the upcoming Medicare COPD quality requirements, which are set to reduce payments, starting in 2013, for patients who have high rates of hospital readmission for COPD. Physicians and healthcare systems are collaborating on process improvements. Some systems have already demonstrated measurable improvements benefitting those with COPD.

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