

2016 CLINICAL PRACTICE GUIDELINES CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

PURPOSE:

Chronic Obstructive Pulmonary Disease (COPD), a common preventable and treatable disease, is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. Exacerbations and co-morbidities contribute to the overall severity in individual patients.

COPD remains a major public health problem and a leading cause of morbidity and mortality worldwide, resulting in an economic and social burden that is both substantial and increasing. In 2010, the Centers for Disease Control and Prevention (CDC) found that the total national medical costs attributable to COPD were estimated at \$32.1 billion dollars annually. COPD exacerbations account for the greatest proportion of the total COPD burden on the health care system. It is the fourth leading cause of death and further increases in prevalence are predicted in the coming decades. Approximately 16 million people have been diagnosed and there are an estimated 14 million undiagnosed cases.

While there is no current cure, there is strong evidence that early intervention and improved management can impact outcomes. The purpose of these practice guidelines is to support effective diagnosis of patients with COPD, properly classify their severity, and develop appropriate plans of treatment.

Key Points of the Practice Guideline:

1. Assess patient using spirometry, symptoms, and exacerbation risk/history
2. Treat based upon assessment using GOLD classifications into 4 populations of patients
3. Use pharmacologic and non-pharmacologic treatments, smoking cessation, when applicable, and patient education and supports

PRACTICE GUIDELINE:

Blue Cross & Blue Shield of Rhode Island has adopted the COPD guidelines developed through the Global Strategy for the Diagnosis, Management, and Prevention of Chronic Pulmonary Obstructive Disease (GOLD), National Heart, Lung and Blood Institute, World Health Institute Workshop Report, April 1988. Updated July 2003, July 2004 and July 2005, July 2007, December 2009, December 2011, January 2013 and January 2014, and January 2016. The complete version of the GOLD guidelines may be accessed and downloaded at www.goldcopd.org.

The Four Components of COPD Management

An effective COPD management plan includes four components: (1) Assess and Monitor Disease; (2) Reduce Risk Factors; (3) Manage Stable COPD; (4) Manage Exacerbations.

The goals of effective COPD management are to:

- Prevent disease progression
- Relieve symptoms
- Improve exercise tolerance
- Improve health status
- Prevent and treat complications
- Prevent and treat exacerbations
- Reduce mortality.

DIAGNOSIS

A clinical diagnosis of COPD should be considered in any patient who has dyspnea, chronic cough or sputum production, and/or a history of exposure to risk factors for the disease. Spirometry is required to make a clinical diagnosis of COPD; the presence of a post-bronchodilator $FEV_1/FVC < 0.70$ confirms the presence of persistent airflow limitation and thus of COPD.

Spirometry: Spirometry is the most reproducible and objective measurement of airflow limitation available. Peak expiratory flow measurement alone cannot be reliably used as the only diagnostic test, despite its good sensitivity, because of its weak specificity. Good quality spirometric measurement is possible in any health care setting and all health care workers who care for COPD patients should have access to spirometry.

- Spirometry should measure the maximal volume of air forcibly exhaled from the point of maximal inhalation (forced vital capacity, FVC) and the volume of air exhaled during the first second of this maneuver (forced expiratory volume in one second, FEV_1), and the ratio of these two measurements (FEV_1/FVC) should be calculated.
 - The ratio between FEV_1 and slow vital capacity (VC), FEV_1/VC , is sometimes measured instead of the FEV_1/FVC ratio. This will often lead to lower values of the ratio, especially in pronounced airflow limitation; however, the cut-off point of 70 percent should still be applied.

ASSESSMENT OF DISEASE

The goals of COPD assessment are to determine the severity of the disease, its impact on the patient's health status and the risk of future events (such as exacerbations, hospital admissions or death), in order to, eventually guide therapy. COPD assessment must consider the following aspects of the disease separately:

- Symptoms
- Degree of airflow limitation (using spirometry)
- Risk of exacerbations
- Comorbidities

Assess Symptoms: GOLD recommends using validated questionnaires such as the COPD Assessment Test (CAT) or the Modified British Medical Research Council (mMRC) breathlessness scale. Patient classifications are based upon these scales (see Attachment A).

Spirometric Assessment: **Table 1** provides the classification of airflow limitation severity in COPD.

Table 1. Classification of Severity of Airflow Limitation in COPD (Based on Post-Bronchodilator FEV₁)		
In patients with FEV₁/FVC < 0.70:		
GOLD 1:	Mild	FEV ₁ ≥ 80 percent predicted
GOLD 2:	Moderate	50 percent ≤ FEV ₁ < 80 percent predicted
GOLD 3:	Severe	30 percent ≤ FEV ₁ < 50 percent predicted
GOLD 4:	Very Severe	FEV ₁ < 30 percent predicted

Assess Risk of Exacerbations: An exacerbation of COPD is defined as an acute event characterized by a worsening of the patient’s respiratory symptoms that is beyond normal day-to-day variations and leads to a change in medication. The best predictor of having frequent exacerbations (2 or more per year) is a history of previous treated events. In addition, worsening airflow limitation is associated with an increasing prevalence of exacerbations and risk of death.

Assess Comorbidities: Cardiovascular diseases, skeletal muscle dysfunction, metabolic syndrome, osteoporosis, depression and lung cancer among other disease occur frequently in COPD patients. These comorbid conditions may influence mortality and hospitalizations, and should be looked for routinely and treated appropriately.

Combined Assessment of COPD: **Table 2** provides a rubric for combining these assessments to improve management of COPD.

- Symptoms
 - Less Symptoms (mMRC 0-1 or CAT <10): patient is (A) or (C)
 - More symptoms (mMRC ≥ 2 or CAT ≥10): patient is (B) or (D)
- Airflow Limitation
 - Low Risk (GOLD 1 or 2): patients is (A) or (B)
 - High Risk (GOLD 3 or 4): patient is (C) or (D)
- Exacerbations
 - Low Risk (≤ 1 per year): patient is (A) or (B)
 - High Risk (≥ 2 per year): patient is (C) or (D)

Table 2. Model of Symptom/Risk of Evaluation of COPD
 (When assessing risk, choose the highest risk according to GOLD grade or exacerbation history.)

Risk
(GOLD Classification of Airflow Limitation)

4
3
2
1

(C)	(D)
(A)	(B)

Risk
(Exacerbation History)

≥ 2
1
0

Symptoms
(mMRC or CAT score)

mMRC 0-1 mMRC ≥ 2
 CAT < 10 CAT ≥ 10

Patient	Characteristic	Spirometric Classification	Exacerbations per year	mMRC	CAT
A	Low Risk Less Symptoms	GOLD 1-2	≤ 1	0-1	< 10
B	Low Risk More Symptoms	GOLD 1-2	≤ 1	≥ 2	≥ 10
C	High Risk Less Symptoms	GOLD 3-4	≥ 2	0-1	< 10
D	High Risk More Symptoms	GOLD 3-4	≥ 2	≥ 2	≥ 10

THERAPEUTIC OPTIONS

Smoking Prevention and Cessation

Smoking cessation is the single most effective and cost-effective way to reduce the risk of developing COPD and stop its progression. Even a brief, 3-minute period of counseling to urge a smoker to quit can be effective, and at the very least this should be done for every smoker at every visit.

Pharmacologic Therapy for Stable COPD

Pharmacologic therapy is used to prevent and control symptoms, reduce the frequency and severity of exacerbations, improve health status, and improve exercise tolerance. Each treatment regimen needs to be patient-specific as the relationship between the severity of symptoms and the severity of airflow limitation is influenced by other factors such as the frequency and severity of exacerbations, the presence of respiratory failure, co morbidities (cardiovascular disease, osteoporosis, etc.) and general health status (see Table 3).

Table 3. Pharmacologic Management of COPD*			
Patient Group	First Choice	Second Choice	Alternative Choice**
A	Short-acting anticholinergic prn or Short-acting beta ₂ -agonist prn	Long-acting anticholinergic or Long-acting beta ₂ -agonist or Short-acting beta ₂ -agonist and short-acting anticholinergic	Theophylline
B	Long-acting anticholinergic or Long-acting beta ₂ -agonist	Long-acting anticholinergic and long-acting beta ₂ -agonist	Short-acting beta ₂ -agonist and/or short-acting anticholinergic Theophylline
C	Inhaled corticosteroid + long-acting beta ₂ -agonist or Long-acting anticholinergic	Long-acting anticholinergic and long-acting beta ₂ -agonist or Long-acting anticholinergic and phosphodiesterase-4 inhibitor or long-acting beta ₂ agonist and phosphodiesterase-4 inhibitor	Short-acting beta ₂ -agonist and/or short-acting anticholinergic Theophylline
D	Inhaled corticosteroid + long-acting beta ₂ -agonist or Long-acting anticholinergic	Inhaled corticosteroid + long- acting beta ₂ -agonist and long- acting anticholinergic or Inhaled corticosteroid + long- acting beta ₂ -agonist and phosphodiesterase-4 inhibitor or long-acting anticholinergic and long-acting beta ₂ -agonist or long-acting anticholinergic and phosphodiesterase-4 inhibitor	Carbocysteine Short-acting beta ₂ -agonist and/or short-acting anticholinergic Theophylline

*Medications in each box are mentioned in alphabetical order, and therefore, not necessarily in order of preference.

**Medication in this column can be used alone or in combination with other options in the First and Second columns.

Bronchodilators: These medications are central to symptom management in COPD.

- Inhaled therapy is preferred.
- The choice between beta₂-agonists, anticholinergics, theophylline, or combination therapy depends on the availability of medications and each individual's response in terms of symptom relief and side effects.
- Bronchodilators are prescribed PRN or on a regular basis to prevent or reduce symptoms.
- Long-acting inhaled bronchodilators are convenient and more effective at producing maintained symptom relief than short-acting bronchodilators.
- Long-acting inhaled bronchodilators reduce exacerbations and related hospitalizations and improve symptoms and health status, and tiotropium improves the effectiveness of pulmonary rehabilitation.

- Combining bronchodilators of different pharmacological classes may improve efficacy and decrease the risk of side effects compared to increasing the dose of a single bronchodilator.

Inhaled Corticosteroids: In COPD patients with FEV₁ < 60 percent predicted, regular treatment with inhaled corticosteroids improves symptoms, lung function, and quality of life, and reduces the frequency of exacerbations. Inhaled corticosteroid therapy is associated with an increased risk of pneumonia.

Combination Inhaled Corticosteroid/Bronchodilator Therapy: An inhaled corticosteroid combined with a long-acting beta₂-agonist is more effective than either individual component in improving lung function and health status and reducing exacerbations in patients with moderate to very severe COPD. Combination therapy is associated with an increased risk of pneumonia. Addition of a long-acting beta₂-agonist/inhaled glucocorticosteroid to tiotropium appears to provide additional benefits.

Oral Corticosteroids: Long-term treatment with oral corticosteroids is not recommended.

Phosphodiesterase-4 Inhibitors: In GOLD3 and GOLD4 patients with a history of exacerbations and chronic bronchitis, the phosphodiesterase-4 inhibitor roflumilast is added to long-acting bronchodilators; there are no comparison studies with inhaled corticosteroids.

Methylxanthines: Methylxanthines are less effective and less well-tolerated than inhaled long-acting bronchodilators and are not recommended if those drugs are available and affordable. There is evidence for a modest bronchodilator effect and some symptomatic benefit of these medications compared with placebo in stable COPD. Addition of theophylline to salmeterol produces a greater increase in FEV₁ and relief of breathlessness than salmeterol alone. Low-dose theophylline reduces exacerbations, but does not improve post-bronchodilator lung function.

Other Pharmacologic Treatments

Vaccines: Influenza vaccines can reduce serious illness and death in COPD patients. Pneumococcal polysaccharide vaccine is recommended for COPD patients 65 years and older.

Antibiotics: Not recommended except for treatment of infectious exacerbations and other bacterial infections.

Non-Pharmacological Treatment

Rehabilitation: The principal goals of pulmonary rehabilitation are to reduce symptoms, improve quality of life, and increase physical and emotional participation in everyday activities.

Oxygen Therapy: The long-term administration of oxygen (>15 hours per day) to patients with chronic respiratory failure has been shown to increase survival in patients with severe, resting hypoxemia.

Long-term oxygen therapy is indicated for patients who have:

- PaO₂ at or below 7.3 kPa (55 mm Hg) or SaO₂ at or below 88 percent, with or without hypercapnia confirmed twice over a three-week period; *or*
- PaO₂ between 7.3 kPa (55 mm Hg) and 8.0 kPa (60 mm Hg) or SaO₂ of 88%, percent, if there is evidence of pulmonary hypertension, peripheral edema suggesting congestive cardiac failure, or polycythemia (hematocrit > 55 percent).

Ventilatory Support: The combination of non-invasive ventilation with long-term oxygen therapy may be of some use in a selected subset of patients, particularly in those with pronounced daytime hypercapnia. It may improve survival, but does not improve quality of life. There are clear benefits of continuous positive airway pressure (CPAP) on both survival and risk of hospital admission.

Surgical Treatments:

Lung Volume Reduction Surgery (LVRS): advantage over medical therapy in patients with predominantly upper lobe emphysema and low exercise capacity. Higher mortality than medical treatment in patients with severe emphysema.

Lung Transplantation: due to limited organ donors there are very restricted criteria for referral

Bullectomy: removal of large bulla that decompress adjacent lung parenchyma in patients with bullous emphysema.

Management of Stable COPD

Once COPD has been diagnosed, effective management should be based on an individualized assessment of disease in order to reduce both current symptoms and future risks.

In previous versions of the GOLD report, COPD treatment recommendations were based on spirometry only. This is in keeping with the fact that most of the clinical trial evidence about treatment efficacy in COPD is oriented around baseline FEV₁. However, FEV₁ alone is a poor descriptor of disease status and for this reason the treatment strategy for stable COPD should also consider an individual patient's symptoms and future risk of exacerbations.

Management of Exacerbations

COPD is often associated with exacerbations of symptoms. An exacerbation of COPD is defined as an acute event characterized by a worsening of the patient's respiratory symptoms that is beyond normal day-to-day variations and leads to a change in medication.

Treatment Options

Oxygen: Supplemental oxygen should be titrated to improve the patient's hypoxemia with a target saturation of 88-92%.

Bronchodilators: Short-acting inhaled beta₂-agonists with or without short-acting anticholinergics are the preferred bronchodilators for treatment of an exacerbation.

Systemic Corticosteroids: Systemic corticosteroids can shorten recovery time, improve lung function (FEV₁) and arterial hypoxemia (PaO₂), and reduce the risks of early relapse, treatment failure, and length of hospital stay. A dose of Prednisone 40 X 5 days is recommended.

Antibiotics: The use of antibiotics is controversial. Evidence best supports that antibiotics should be given to patients:

- With the following three cardinal symptoms: increased dyspnea, increased sputum volume, increased sputum purulence;
- Increased sputum purulence with one other cardinal symptoms, ;
- Who require mechanical ventilation (invasive and non-invasive).

Implementation

Blue Cross & Blue Shield of Rhode Island offers telephonic Care Coordination for members with complex medical conditions. Members and Providers may call the Care Coordination Triage line 401-459-2273 or 1-800-637-3718 x2273 for further information on these programs and services.

SOURCE

From the *Global Strategy for the Diagnosis, Management and Prevention of COPD*, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Updated 2016. Available online at www.goldcopd.org

REVIEWS AND APPROVALS:

Medical Peer Review Committee: 4/5/2006, 4/2/2008, 4/7/2010, 4/18/2012
Professional Advisory Committee: 3/15/2014, 3/16/2016

Attachment A

Scales for Assessment of Symptoms

- *COPD Assessment Test (CAT)* on following page.
- *Breathlessness Measurement using the Modified British Medical Research Council (mMRC) Questionnaire.* This questionnaire relates well to other measures of health status and predicts future mortality risk (see Table A1).

Table A1. Modified Medical Research Council Questionnaire for Assessing the Severity of Breathlessness	
Please tick in the box that applies to you (one box only)	
mMRC Grade 0. I only get breathless with strenuous exercise.	<input type="checkbox"/>
mMRC Grade 1. I get short of breath when hurrying on the level or walking up a slight hill.	<input type="checkbox"/>
mMRC Grade 2. I walk slower than people of the same age on the level because of breathlessness, or I have to stop for breath when walking on my own pace on the level.	<input type="checkbox"/>
mMRC Grade 3. I stop for breath after walking about 100 meters or after a few minutes on the level.	<input type="checkbox"/>
mMRC Grade 4. I am too breathless to leave the house or I am breathless when dressing or undressing.	<input type="checkbox"/>



Name:

Today's Date:



How is your COPD? Take the COPD Assessment Test (CAT)

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

If you wish to complete the questionnaire by hand on paper, [please click here](#) and then print the questionnaire.

If you complete the questionnaire on-line, for each question below, click your mouse to place a mark (X) in the box that best describes you currently.

Example: I am very happy 0 1 2 3 4 5 I am sad

		SCORE				
I never cough	0 1 2 3 4 5	I cough all the time	<input type="text"/>			
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5	My chest is full of phlegm (mucus)	<input type="text"/>			
My chest does not feel tight at all	0 1 2 3 4 5	My chest feels very tight	<input type="text"/>			
When I walk up a hill or one flight of stairs I am not breathless	0 1 2 3 4 5	When I walk up a hill or one flight of stairs I am very breathless	<input type="text"/>			
I am not limited doing any activities at home	0 1 2 3 4 5	I am very limited doing activities at home	<input type="text"/>			
I am confident leaving my home despite my lung condition	0 1 2 3 4 5	I am not at all confident leaving my home because of my lung condition	<input type="text"/>			
I sleep soundly	0 1 2 3 4 5	I don't sleep soundly because of my lung condition	<input type="text"/>			
I have lots of energy	0 1 2 3 4 5	I have no energy at all	<input type="text"/>			
			<input type="text"/>			

CLICK TO GET YOUR TOTAL SCORE!



Make sure you print your CAT before visiting your healthcare professional!

Last Updated: February 26, 2012

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