Chronic Obstructive Pulmonary Disease (COPD) Clinical Guideline

These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients. They are not intended to replace a clinician’s judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.

GUIDELINE HISTORY and APPROVAL

<table>
<thead>
<tr>
<th>ACTION</th>
<th>SEED GUIDELINE and/or MAIN INFORMATION &amp; GROUP SOURCE(S)</th>
<th>DATE</th>
<th>ORGANIZATION</th>
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<tbody>
<tr>
<td>Guideline reviewed, revised and approved</td>
<td>Same</td>
<td>Jan 25, 2001</td>
<td>Geisinger Health Plan/Quality Improvement Committee</td>
</tr>
<tr>
<td>Guideline reviewed, revised and approved</td>
<td>Same</td>
<td>Jan. 22, 2003</td>
<td>Geisinger Health Plan/Quality Improvement Committee</td>
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<td>Oct. 22, 2003</td>
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<td>July 27, 2005</td>
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<td>July 25, 2007</td>
<td>Geisinger Health Plan/Quality Improvement Committee</td>
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OVERVIEW

COPD (chronic obstructive pulmonary disease) includes both emphysema and chronic obstructive bronchitis. COPD is the fourth leading cause of death in the United States and is the only common chronic illness for which mortality rates, social burden and economic burden continue to increase.

According to the American Lung Association’s fact sheet* on Chronic Obstructive Pulmonary Disease (COPD), the disease includes emphysema and chronic bronchitis – diseases that are characterized by obstruction to airflow. Emphysema and chronic bronchitis frequently coexist. Thus physicians prefer the term COPD. It does not include other obstructive diseases such as asthma. Approximately 12 million Americans suffer from COPD, which is the fourth leading cause of death, claiming the lives of 130,933 Americans in 2005.

The annual cost to the nation for COPD is approximately $49.9 billion, including health care expenditures of $29.5 billion and $20.4 billion in indirect costs such as lost wages.
Outpatient Management of COPD

1. Establish Diagnosis (Tables 1 and 2)
   Refer to GHP Disease Management Program

2. Ask and advise patient regarding tobacco use and offer cessation support (Table 3)

3. Stable Disease?
   - Yes
     - Pharmacologic Management (Table 4)
     - Non-pharmacologic Treatment (Table 5)
       - Oxygen Therapy
       - Pulmonary Rehab
       - Surgical Interventions
   - No
     - Ongoing Management (Table 6)

4. Acute Exacerbation Evaluation

5. Treatment (Table 7)
   - Yes
     - Positive Response?
       - Yes
         - Follow Up and Ongoing Management
       - No
         - Hospital Admission (Table 8)
   - No

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### TABLE 1

**Symptoms:**
- Chronic cough greater than 3 months with or without sputum
- Chronic sputum production
- Dyspnea with or without wheezing
- Wheezing, rhonchi or cough
- “Pursed-lip” breathing
- Use of accessory muscles
- Neck vein distention
- Lower extremity edema
- Increased pulmonic component of the second heart sound

**Risk factors:**
- Asthma
- History of tobacco smoking or prolonged exposure to second-hand smoke
- Occupational exposure to smoke, dust or chemicals
- Chronic respiratory infections
- Genetic factors (Alpha 1-antitrypsin deficiency)

**Laboratory Testing**
- Chest X-ray – diagnostic only in severe emphysema but essential to exclude other lung diseases
- Pulse oximetry
- Arterial blood gas should be considered to assess severity of an exacerbation
- Alpha 1-antitrypsin deficiency screening is appropriate in Caucasians who develop COPD at a young age (less than 45 years) or who have a family history of diagnosed A1AD disease.
- Sputum culture in patients with persistent purulent sputum or during recurrent infectious exacerbations to rule out TB or other infections
- Pulmonary function testing in patients with suspected emphysema
- EKG to assess for heart disease
- CBC to assess for anemia or polycythemia

**Spirometry:**

Medical history and physical exam may support the diagnosis of COPD, however, spirometry is required to confirm the diagnosis and establish the presence of persistent airflow limitation.

**Spirometry Overview**

A. Spirometry confirms a diagnosis of COPD, stages COPD severity, and guides treatment.

B. Spirometry measurements used for the diagnosis of COPD include: a) FVC (forced exhaled capacity: maximum volume of air that can be exhaled during a normal forced maneuver; b) FEV₁ (forced expiratory volume in one second): volume expired in the first second of maximal expiration after a maximal inspiration. This is a measure of how quickly the lungs can be emptied; c) FEV₁/FVC: FEV₁ expressed as a percentage of FVC gives a clinically useful index of airflow limitation.

C. To order spirometry, indicate FVC Screen Spirometry with Interpretation. Consider ordering FVC Screen Spirometry Post-Bronchodilator for FEV₁/FVC < 70% predicted. If obstruction with bronchodilator does not produce reversibility, usually indicates COPD.
D. After a baseline spirometry is obtained, repeat testing with bronchodilator is indicated if symptoms worsen or the patient is symptomatic. The intervals between spirometry measurements should be at least twelve (12) months apart to monitor disease progression.

E. FVC Screen Spirometry takes ten (10) to forty (40) minutes. Up to eight (8) breathing tests may be needed (with adequate rest in between) in order to obtain accurate results.

### TABLE 2

<table>
<thead>
<tr>
<th>Stage of COPD</th>
<th>FEV₁/FVC &lt;0.70 and FEV₁ % Predicted</th>
<th>Signs and Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild GOLD 1</td>
<td>FEV₁&gt;80% predicted</td>
<td>Cough ±sputum</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimal or no dyspnea</td>
</tr>
<tr>
<td>Moderate GOLD 2</td>
<td>FEV₁ ≤50%, &lt; 80%</td>
<td>Cough ±sputum</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reduction in breath sounds</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dyspnea ± wheezing on exertion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Possible hypoxemia</td>
</tr>
<tr>
<td>Severe GOLD 3</td>
<td>FEV₁ between 30% and 49%</td>
<td>Dyspnea at rest or with any exertion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prominent cough and wheezing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lung hyperinflation</td>
</tr>
<tr>
<td>Very Severe GOLD 4</td>
<td>FEV₁ &lt; 30%</td>
<td>Above plus:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cyanosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peripheral edema</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hypoxemia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hypercapnea</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Polycythemia</td>
</tr>
</tbody>
</table>

### TABLE 3  Smoking Cessation

<table>
<thead>
<tr>
<th>ASK</th>
<th>Has the patient thought about quitting?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Does the patient think he/she will quit within the next 6 months?</td>
</tr>
<tr>
<td>ADVISE</td>
<td>Advise the patient to quit smoking.</td>
</tr>
<tr>
<td>ASSESS</td>
<td>Assess user’s willingness to make a quit attempt</td>
</tr>
<tr>
<td>ASSIST</td>
<td>Provide the patient with literature.</td>
</tr>
<tr>
<td></td>
<td>Provide the patient with information about available programs and methods to quit.</td>
</tr>
<tr>
<td></td>
<td>Refer to tobacco cessation program.</td>
</tr>
<tr>
<td></td>
<td>Utilize nicotine replacement therapy and/or Zyban or Chantix per GHP Formulary</td>
</tr>
<tr>
<td>ARRANGE</td>
<td>Facilitate referral of the patient to the appropriate smoking cessation services.</td>
</tr>
</tbody>
</table>
### TABLE 4 Pharmacologic Management

Note: Pharmaceutical coverage is dependent upon individual pharmacy benefit design and certain drugs may require prior authorization. Providers are encouraged to review the GHP formulary at http://www.thehealthplan.com, or contact the GHP Pharmacy Department at 1-800-988-4861.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1 – Mild</td>
<td>Intermittent chronic cough and sputum production. (FEV1 80% or higher of predicted).</td>
</tr>
<tr>
<td></td>
<td>Short-acting bronchodilators</td>
</tr>
<tr>
<td></td>
<td>• Beta-agonists (albuterol, levabuterol)</td>
</tr>
<tr>
<td></td>
<td>• Anticholinergics (Ipratropium)</td>
</tr>
<tr>
<td>Stage 2 – Moderate</td>
<td>Shortness of breath on exertion. Increased cough and sputum production (FEV1 50–79.9% of predicted).</td>
</tr>
<tr>
<td></td>
<td>Daily long acting bronchodilators</td>
</tr>
<tr>
<td></td>
<td>• Anticholinergics (tiotroium, aclidinium)</td>
</tr>
<tr>
<td></td>
<td>• Long-acting beta-agonists (arformoterol, formotorol, salmeterol)</td>
</tr>
<tr>
<td></td>
<td>Inhaled corticosteroids if frequent exacerbations</td>
</tr>
<tr>
<td></td>
<td>Consider adding PDE4 inhibitor (roflumilast)</td>
</tr>
<tr>
<td>Stage 3 – Severe</td>
<td>Increased shortness of breath. Reduced exercise capacity. Fatigue. Repeated exacerbation and sputum production (FEV1 30–49.9% of predicted)</td>
</tr>
<tr>
<td></td>
<td>Daily long-acting bronchodilators plus inhaled corticosteroids</td>
</tr>
<tr>
<td></td>
<td>Oral steroid bursts for exacerbations</td>
</tr>
<tr>
<td>Stage 4 – Very severe</td>
<td>Complications of chronic respiratory failure: PaO2 lower than 60 mm Hg, PaCO2 higher than 50 mm Hg, right-sided heart failure (FEV1 lower than 30%, or FEV1 lower than 50% with chronic respiratory failure).</td>
</tr>
<tr>
<td></td>
<td>Combination therapy</td>
</tr>
<tr>
<td></td>
<td>Oral steroids as needed</td>
</tr>
</tbody>
</table>

### TABLE 5 Non-Pharmacologic Interventions

**Oxygen Therapy**  
Supplemental oxygen therapy is recommended for patients with hypoxemia, defined as any of the following:
- PaO2 55 mm Hg or lower and/or SaO2 88% or lower.
- PaO2 56–59 mm Hg and/or SaO2 89% or lower, and signs of tissue hypoxia (hematocrit higher than 55%, pulmonary hypertension, or cor pulmonale).
- SaO2 88% or lower on exertion.

**Pulmonary Rehabilitation**

**Surgical Interventions:**
- Lung Volume Reduction Surgery
- Bullectomy
- Lung Transplant
### TABLE 6 Ongoing Management

**Repeat spirometry** is recommended for those patients with a change in symptoms or to assess response to a new treatment.

**For patients on medications, monitor:**
- Symptoms at each visit.
- Pulmonary function using peak flow and/or other tests.
- FEV1 at least annually

Patients being treated with short-acting beta2-agonist Albuterol
- Blood pressure
- Heart rate
- Tremor

Patients being treated with long-acting beta2-agonist Salmeterol
- Blood pressure
- Heart rate
- Tremor

Patients being treated with short-acting anticholinergic Ipratropium bromide
- Heart rate

Patients being treated with long-acting anticholinergic Tiotropium
- Heart rate

**Immunizations**
- Annual influenza vaccination.
- Pneumococcal vaccination. Patients who received a vaccination before age 65 need one revaccination after age 65, with at least 5 years between doses.

**Comorbidities**
- Cardiovascular disease.
- Skeletal muscle dysfunction.
- Diabetes.
- Metabolic syndrome.
- Osteoporosis.
- Lung cancer.
- Depression

**Referral To Pulmonologist (referral for opinion may be beneficial at any stage of disease)**
- When lung function is not consistent with symptoms
- When patient has been hospitalized for COPD
- When patient has hypoxic or hypercapnic COPD.
- When patient has pulmonary hypertension.
- When patient has a rapid decline of FEV1
- When patient has two or more exacerbations per year.
- When patient is considered for lung volume reduction surgery.
- When patient is considered for lung transplantation.
- When patient is appropriate for alpha1-antitrypsin augmentation
TABLE 7 Treatment of COPD Exacerbation

<table>
<thead>
<tr>
<th>Pharmacologic</th>
<th>Short-acting bronchodilator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Short acting beta2-agonists with or without short-acting anticholinergics are usually the preferred bronchodilators.</td>
</tr>
<tr>
<td>Corticosteroid</td>
<td>Systemic corticosteroids (30–40 mg prednisone/day for 10–14 days) may shorten recovery time; improve FEV₁ and arterial hypoxemia; and reduce risk of early relapse, treatment failure, and length of hospital stay.</td>
</tr>
<tr>
<td>Antibiotic</td>
<td>Use for patients whose exacerbation includes purulent sputum. Duration of antibiotic use should not exceed 10 days</td>
</tr>
<tr>
<td>Adjunct therapies</td>
<td>Appropriate fluid balance, diuretics, anticoagulants, and treatment of other comorbidities as needed</td>
</tr>
<tr>
<td>Respiratory support</td>
<td>Oxygen therapy, ventilatory support</td>
</tr>
</tbody>
</table>

TABLE 8 Admission to Hospital

The following may be indications to consider hospital admission for an acute exacerbation of COPD:

• Marked increase in intensity of symptoms, such as sudden development of resting dyspnea
• History of severe COPD, especially if mechanical ventilation was required
• Onset of new physical signs (e.g., cyanosis, peripheral edema)
• Failure of exacerbation to respond to initial outpatient medical management
• High-risk comorbidities, pulmonary (e.g., pneumonia requiring hospitalization) or cardiac symptoms
• Increasing hypoxemia despite supplemental oxygen
• New or worsening carbon dioxide (CO2) retention or pH less than 7.32
• Marked decrease in ability to ambulate, eat or sleep due to dyspnea
• History of prolonged, progressive symptoms
• Newly occurring arrhythmias
• Diagnostic uncertainty
• Older age
• Insufficient home support
• Decrease in alertness
• Pulmonary embolism

MEASURES
• Percent of members on anticholinergic and beta agonist
  
• Percent of members with PFT
  
• Percent of members that quit tobacco at one year
  
  • Admits/1000
  
  • Inpatient days/1000
  
  • ER days/1000

• Percent of members with acute exacerbation and bronchodilator start within 30 days

• Percent of members with acute exacerbation and oral corticosteroid start within 14 days

SEED GUIDELINE(S)


GOALS

Minimize the morbidity and mortality of members with COPD while achieving the highest possible quality of life. This is accomplished through:

1. Incorporation of COPD clinical guideline into a comprehensive disease management approach.
2. The promotion of a Tobacco Cessation Program for members identified with COPD who smoke; and
3. The encouragement of member’s self-improvement in their own chronic disease management.

FAST FACTS

Chronic Obstructive Pulmonary Disease (COPD), includes emphysema and chronic bronchitis – diseases that are characterized by obstruction to airflow.

Approximately 16.4 million Americans suffer from COPD, which is the fourth leading cause of death, claiming the lives of 122,283 Americans in 2003.
Approximately 80 to 90 percent of COPD cases are caused by smoking. Female smokers are nearly 13 times as likely to die from COPD as women who have never smoked. Male smokers are nearly 12 times as likely to die from COPD as men who have never smoked.

Diagnosis of COPD is made by pulmonary function tests, along with the patient’s history, examination and other tests.

Depending on the severity of the disease, treatments include bronchodilators, which open up air passages in the lungs, antibiotics, exercise to strengthen muscles, oxygen therapy, and systematic glucocorticosteroids.

Pulmonary rehabilitation is a preventive health care program provided by a team of health professionals to help people cope physically, psychologically and socially with COPD.

**BIBLIOGRAPHY**

American Lung Association Fact Sheet on Chronic Obstructive Pulmonary Disease (COPD), American Lung Association web site at http://www.lungusa.org.

