Clinical Practice Guidelines
Chronic Obstructive Pulmonary Disease

Objective
The purpose is to guide the appropriate diagnosis and management of Chronic Obstructive Pulmonary Disease (COPD).

Guideline
These are only guidelines, and are based on the best available information at the time. These may not be “all inclusive” as new medications and treatments are ever-evolving. These guidelines are updated by MDwise at least biannually as national guidelines are updated.

Consistent with the National Institutes of Health’s (NIH) National Heart, Lung, and Blood Institute (NHLBI) and the World Health Organization (WHO), MDwise references the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines when administering its COPD programs.

GOLD - the Global Initiative for Chronic Obstructive Lung Disease 2017

Assessment & Diagnosis

CRITERIA FOR COPD DIAGNOSIS
Diagnosis of COPD (spirometry is required to establish a diagnosis of COPD) should be considered if any of the following patient-specific factors are present in an individual > 40 year of age:

• Dyspnea: progressive, persistent, worsens with exercise, and described by the patient as an “increased effort to breath”, “heaviness”, or “gasping”.
• Chronic cough: possibly intermittent or unproductive
• Chronic sputum production
• History of exposure to risk factors: tobacco smoke, occupational dusts and chemicals, and smoke from home cooking and heating fuels.
• Post-bronchodilation FEV1/FVC < 0.7 confirms presence of persistent airflow limitation

DIFFERENTIAL DIAGNOSIS OF COPD VS ASTHMA
• COPD
  o Midlife onset: usually > 40 years
  o Smoking history: usually > 10 years
  o Sputum production: common
  o Allergies: uncommon
  o Slow, progressive symptom development
• Asthma
  o Early onset: usually < 40 years
  o Smoking history: uncommon
  o Sputum production: infrequent
  o Allergies, rhinitis, and/or eczema common
  o Symptoms intermittent and variable, nighttime/early morning symptoms prevalent
  o Family history of asthma
Gold Classification System for COPD

| Classification of airflow limitation severity in COPD in patients with FEV1/FVC < 0.7 |
|---------------------------------|---------------------------------|
| 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            |

GROUPS OF COPD

- **Patient Group A** – Low Risk, Less Symptoms: GOLD 1 or 2; and/or 0-1 exacerbation per year and no hospitalization for exacerbation and CAT score < 10 or mMRC grade 0-1.
- **Patient Group B** – Low Risk, More Symptoms: GOLD 1 or 2; and/or 0-1 exacerbations per year and no hospitalization for exacerbation and CAT score ≥ 10 or mMRC grade ≥ 2.
- **Patient Group C** – High Risk, Less Symptoms: GOLD 3 or 4; and/or ≥ 2 exacerbation per year or ≥ 1 with hospitalization for exacerbation and CAT score < 10 or mMRC grade 0-1.
- **Patient Group D** – High Risk, More Symptoms: GOLD 3 or 4; and/or ≥ 2 exacerbations per year or ≥ 1 with hospitalization for exacerbation and CAT score ≥ 10 or mMRC grade ≥ 2.

NON-PHARMACOLOGIC THERAPY

- Smoking cessation is the only management strategy proven to slow the progression of COPD
- Vaccinations – reduce risk of hospitalizations due to serious respiratory illness
  - Annual influenza vaccine
  - Pneumococcal vaccination
    - The 23-valent pneumococcal polysaccharide vaccine (PPSV23) has been shown to reduce the incidence of community-acquired pneumonia in COPD patients < 65 years of age with a FEV1 < 40% predicted and in those with comorbidities.
    - Adults ≥ 65 years should receive the 13-valent conjugated pneumococcal vaccine (PCV13) followed by PPSV23 at least 1 year after PCV13, and at least 5 years after the most recent dose of PPSV23.
- Rehabilitation/oxygen therapy
  - All COPD patients, regardless of their disease stage, achieve improvements in exercise tolerance and symptoms of dyspnea and fatigue following completion of at least a 6-week exercise rehabilitation program.
  - Long-term oxygen therapy should be considered in Stage IV COPD patients with severe resting hypoxemia (PaO2 < 55 mmHg or SaO2 < 88%).

PHARMACOLOGIC THERAPY

- Bronchodilators
  - Short-acting bronchodilators are prescribed on an as-needed or on a regular basis to prevent or reduce symptoms
    - Short-acting beta agonists (SABAs)
      - Albuterol (ProAir HFA®, ProAir RespiClick®, Proventil HFA®, Ventolin HFA®)
      - Levalbuterol (Xopenex®, Xopenex HFA®)
    - Short-acting muscarinic antagonist (SAMA)
      - Ipratropium bromide (Atrovent®)
Long-acting bronchodilators are more effective at producing maintained symptom relief than short-acting bronchodilators

- Long-acting beta agonists (LABAs)
  - Formoterol (Foradil Aerolizer®, Perforomist®)
  - Salmeterol (Serevent Diskus®)
- Long-acting muscarinic antagonist (LAMA)
  - Tiotropium (Spiriva HandiHaler®, Spiriva Respimat®)

Long-acting bronchodilators are preferred over short-acting agents except for patients with only occasional dyspnea.
- Inhaled therapy is preferred over oral.
- Combination products of different pharmacologic classes may improve efficacy and decrease risk of side effects compared to increasing the dose of a single agent.

- Corticosteroids
  - Long-term treatment with inhaled corticosteroids (ICS) may be considered in combination with LABAs for patients with a history of exacerbations despite appropriate treatment with long-acting bronchodilators.
    - Budesonide/formoterol (Symbicort®)
    - Fluticasone/salmeterol (Advair Diskus®, AirDuo RespiClick®)
    - Mometasone/formoterol (Dulera®)
    - Fluticasone/vilanterol (Breo Ellipta®)
  - Inhaled therapy is preferred over oral.
  - Monotherapy with ICS not recommended.
  - Prolonged treatment with oral corticosteroids not recommended.
  - Regular treatment with inhaled corticosteroids improves symptoms, lung function, and quality of life by reducing the frequency of exacerbations in COPD patients with FEV1 < 60% predicted.

- Phosphodiesterase-4 inhibitors
  - May be considered in patients with exacerbations despite LABA/ICS or LABA/LAMA/ICS and/or have chronic bronchitis and severe to very severe airflow obstruction.
  - Roflumilast has been shown to improve FEV1 in patients treated with salmeterol or tiotropium, and reduces moderate and severe exacerbations treated with corticosteroids by 15-20% in patients with chronic bronchitis, severe to very severe COPD, and a history of exacerbations.
  - Must always be used in combination with at least one long-acting bronchodilator.

*Treatment Algorithm*

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>Recommended Treatment</th>
<th>Escalation of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>LABA or LAMA, SABA/SAMA* prn</td>
<td>Try a different class of bronchodilator as monotherapy</td>
</tr>
<tr>
<td>B</td>
<td>LAMA or LABA</td>
<td>LAMA + LABA</td>
</tr>
<tr>
<td>C</td>
<td>LAMA**</td>
<td>LAMA + LABA OR LABA + ICS</td>
</tr>
<tr>
<td>D</td>
<td>LAMA + LABA QR LABA + ICS</td>
<td>LAMA + LABA + ICS</td>
</tr>
</tbody>
</table>

*combination products show greater improvement in FEV1 and symptoms compared to either agent alone

**LAMAs are preferred over LABAs in Group C patients as they have shown to have a greater impact on exacerbation rates

*Newer combination products are available with the likelihood of improved adherence that also reduces the risk of confusion with inhaler technique

**Coverage of these newer agents may be subject to step therapy requirements and a higher copay for the patient. Please refer to the MDwise Formulary for further guidance.
References

GOLD - the Global Initiative for Chronic Obstructive Lung Disease 2017

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