	Clinical Protocol: Chronic Conditions	**SUBDEPARTMENT:** N/A
	POLICY NO.	**ORIGINAL EFFECTIVE DATE:** 12/01/2019
		REVIEWED/REVISED DATE(S): 11/15/2023, 03/6/2024
PREPARED BY: Adriana Martinez, Compliance Manager	**APPROVED BY:** Dan Kahen, DO- Medical Director	
TITLE OF POLICY: Chronic Obstructive Pulmonary Disease		
ATTACHMENTS / REFERENCES: [Attachment #1], [Attachment #2]		
LOB: ☐ Medi-Cal ☐ Medicare ☐ Commercial ☐ D-SNP ☐ Covered California ☒ All ☐ N/A		

PROTOCOL OVERVIEW

In 2012 the American College of Physicians updated the 2007 recommendations for diagnosis and management of stable chronic obstructive pulmonary disease. In addition to these guidelines, it is recommended to follow the multi-component assessment system that has been developed by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) to guide initiation of therapy for COPD

INDICATIONS

Recommendation 1:

Targeted use of spirometry for diagnosis of airflow obstruction is beneficial in patients with respiratory symptoms, particularly dyspnea. However, current evidence does not support the use of spirometry as a screening strategy for airflow obstruction in persons without respiratory symptoms, even in the presence of risk factors

Note: The routine use of spirometry in asymptomatic patients may lead to unnecessary testing, increased costs, unnecessary labeling, and adverse effects from long-term treatment. There is insufficient evidence to support the use of inhaled therapies in asymptomatic patients who have spirometric evidence of airflow obstruction, and there is no difference in the annual rate of FEV1 decline or prevention of symptoms in these patients if they receive treatment. There is no evidence from randomized controlled trials to support treating asymptomatic patients, regardless of their risk factors, if they do not have spirometric evidence of airflow obstruction.

In addition, spirometry does not seem to affect the likelihood that a person would quit smoking or maintain abstinence. In addition, the diagnosis of COPD should be considered and spirometry performed in all patients who report any combination of dyspnea, chronic cough, or chronic sputum production, especially if there is a history of exposure to triggers of COPD (eg, tobacco smoke, occupational dust, indoor biomass smoke), a family history of chronic lung disease, or presence of associated comorbidities.

Recommendation 2:

Inhaled bronchodilators can be used in patients with stable COPD who have respiratory symptoms and an FEV1 between 60 and 80 percent of predicted (weak recommendation; low-quality evidence).

There is limited and conflicting evidence on the benefits of inhaled bronchodilators (anticholinergics or long-acting beta agonists) in symptomatic patients with an FEV1 between 60 and 80 percent of predicted. Individual patients may have improvement in respiratory symptoms, but the duration of 2 maintenance therapy and the frequency of reevaluation are not known. This recommendation does not address the occasional use of short-acting inhaled bronchodilators for relief of acute symptoms.

Recommendation 3:
Inhaled bronchodilators are the treatment of choice in patients with stable COPD who have respiratory symptoms and an FEV1 less than 60 percent of predicted (strong recommendation; moderate-quality evidence).

Patients with respiratory symptoms and airflow obstruction with an FEV1 less than 60 percent of predicted benefit the most from inhaled bronchodilators. This recommendation does not address the occasional use of short-acting inhaled bronchodilators for relief of acute symptoms.

Recommendation 4:
Monotherapy with long-acting inhaled anticholinergics or long-acting inhaled beta agonists should be prescribed for symptomatic patients with COPD and an FEV1 less than 60 percent of predicted (strong recommendation; moderate-quality evidence). The choice of agent should be based on patient preference, cost, and potential adverse effects.

Monotherapy with a long-acting inhaled beta agonist or a long-acting inhaled anticholinergic reduces COPD exacerbations and improves health-related quality of life. Evidence on the effect of inhaled agents on mortality, hospitalizations, and dyspnea is inconclusive. Although inhaled corticosteroids have been proven superior to placebo in reducing exacerbations, their potential adverse effects (e.g., thrush, bone loss, bruising) prevent them from being a preferred monotherapy for patients with stable COPD. Pooled analyses of results from trials of monotherapy do not show any statistically significant differences in outcomes among agents.

Recommendation 5:
A combination of inhaled therapies (long-acting anticholinergics, long-acting beta agonists, or corticosteroids) can be prescribed for symptomatic patients with stable COPD and an FEV1 less than 60 percent of predicted (weak recommendation; moderate-quality evidence).

Symptomatic patients with stable COPD and an FEV1 less than 60 percent of predicted may benefit from combination therapy, but it is not clear when combination therapy should be used instead of monotherapy. In two large clinical trials, the long-term benefit of combination therapy compared with monotherapy was moderate for COPD exacerbations and of borderline statistical significance for mortality. However, these benefits were not consistently found in earlier trials. Some—but not all—trials have found that combination therapy is associated with a moderate increase in the risk of adverse 3 effects. Therefore, there is not sufficient evidence to support a strong recommendation for the broad use of combination therapy, and physicians should weigh the potential benefits and harms of combination therapy on a case-by-case basis.

Recommendation 6:
Pulmonary rehabilitation should be prescribed for symptomatic patients with an FEV1 less than 50 percent predicted (strong recommendation; moderate-quality evidence). It can be considered for symptomatic or exercise-limited patients with an FEV1 greater than 50 percent of predicted (weak recommendation; moderate-quality evidence).

Controlled trials of pulmonary rehabilitation have included patients with a mean FEV1 less than 50 percent of predicted. However, it is not clear if the benefits can be generalized to patients with less severe airflow obstruction. Physicians can consider prescribing pulmonary rehabilitation for patients with an FEV1 greater than 50 percent of predicted if they remain symptomatic or have exercise limitation despite optimal medical therapy.

Recommendation 7:
Continuous oxygen therapy should be prescribed for patients with COPD who have arterial partial pressure of oxygen 55 mm Hg or less, or oxygen saturation 88 percent or less as measured by pulse oximetry (strong recommendation, moderate-quality evidence).

To accurately evaluate oxygen status, the assessment should occur when patients are stable, rather than during or immediately after an exacerbation. Use of supplemental oxygen for at least 15 hours per day can help improve survival in patients with severe resting hypoxemia.

RECOMMENDED RECORDS

- CBC
- CMP and MG Phos
- AAT level
- Spirometry when indicated
- Oxygen saturation
- Chest x ray and Chest C

NOTES

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) defines COPD as follows: "Chronic obstructive pulmonary disease (COPD) is a common, preventable, and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases. The chronic 4 airflow limitation that characterizes COPD is caused by a mixture of small airways disease (eg, obstructive bronchiolitis) and parenchymal destruction (emphysema), the relative contributions of which vary from person to person. Chronic inflammation causes structural changes, small airways narrowing and destruction of lung parenchyma. A loss of small airways may contribute to airflow limitation and mucociliary dysfunction, a characteristic feature of the disease.

Substantial overlap exists between COPD and the other disorders that cause airflow limitation (eg, emphysema, chronic bronchitis, asthma, bronchiectasis, bronchiolitis). Utilizing the GOLD patient categories based on assessment of symptoms and risk of future exacerbations and hospitalizations is highly recommended in clinical practice.

Note: A program of rehabilitative exercise can have significant clinical benefits including reduced hospitalizations, improved dyspnea/breathlessness, fatigue exercise capacity and quality of life.

Background: Chronic Obstructive Pulmonary Disease (COPD) is a slowly progressive lung disease resulting in gradual loss of lung function. It is a preventable and treatable condition characterized by airflow limitation that is not completely reversible. Symptoms range from chronic cough, sputum production and wheezing to more severe symptoms such as dyspnea, poor exercise tolerance and symptoms of right-sided heart failure. COPD affects more than 5% of the U.S. adult population, and in 2008 it surpassed cerebrovascular disease to become the third leading cause of death in the U.S. and the only leading cause that is increasing in prevalence. Although more common among men than among women, more women die of COPD each year; and hospitalization rates for women have increased disproportionately compared to those for men. Women with COPD also tend to report more respiratory symptoms and greater impairment in quality of life.

Cigarette smoking is the major risk factor for development of COPD, although environmental and genetic risk factors such as alpha-1-antitrypsin deficiency also play a role. Air pollution, second-hand smoke, dust, fumes and gases also appear to confer risk.

Diagnosis of COPD is established by spirometry, with obstructive defects identified by a reduction in the FEV1, relative to the FVC. (FEV1/FVC ratio). The FEV1, or forced expiratory volume in one second, is the maximal volume of air exhaled during the initial second of measurement. FVC, or forced vital capacity, is the maximal amount of air exhaled from total lung capacity. COPD is defined as airflow obstruction that is not fully reversible, in contrast to asthma. Thus, to obtain a diagnosis of COPD, spirometry testing must be repeated after a patient inhales a short-acting bronchodilator.

CITATIONS

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