GLIN IPA

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Pharmacy Factor

COPD Treatment Guideline and Quality Update

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MDD Overview

Question of the Month

What is the preferred rescue inhaler for patients with COPD?

Per the GOLD 2023 treatment guideline for COPD, a rescue short-acting bronchodilator should be prescribed to all patients for immediate symptom relief as initial management. No preference to which short-acting bronchodilator is referenced within these guidelines.

Although the guideline does not reference preferred rescue inhaler therapy, previous studies indicate Combivent™ (ipratropium bromide and albuterol sulfate) may be more effective than either component alone in COPD. A study by Dr. Sammy Campbell compared safety and efficacy of Combivent to albuterol alone. Over the 29-day trial involving 357 patients it was noted Combivent produced a significantly greater peak and mean improvement in forced expiratory volume in 1 second over the albuterol base alone. Similar changes were also seen with forced vital capacity. The overall incidence of adverse effects were similar among the two treatment groups. Therefore, it was concluded that Combivent was more effective than albuterol in patients with COPD and may be considered the preferred rescue inhaler.

References

Campbell, S. (1999). For COPD a combination of ipratropium bromide and albuterol sulfate is more effective than albuterol base. Archives of Internal Medicine, 159(2), 156. https://doi.org/10.1001/archinte.159.2.156

COPD Treatment Guidelines and Quality Updates

Defining Chronic Obstructive Lung Disease

- A heterogeneous lung condition characterized by symptoms of dyspnea, cough, sputum production, and exacerbations
- Main environmental exposures leading to the development of COPD include tobacco smoke and inhalation of toxic particles
- Host and genetic risk factors include developmental abnormalities, low birthweight, prematurity, and alpha-1 antitrypsin deficiency

Diagnotic Criteria

- Consider diagnosis in any patients with dyspnea, recurrent wheezing, chronic cough, sputum production, history of recurrent lower respiratory tract infections and/or history of exposure to risk factors of the disease
- Presence of non-fully reversible airflow limitation defined by FEV1/FVC < 0.7 post-bronchodilation measured by spirometry

Severity of Airflow Obstruction in COPD Patients

- Consider diagnosis in any patients with dyspnea, recurrent wheezing, chronic cough, sputum production, history of recurrent lower respiratory tract infections and/or history of exposure to risk factors of the disease
- Presence of non-fully reversible airflow limitation defined by FEV1/FVC < 0.7 post-bronchodilation measured by spirometry

Grade	Severity	Spirometry
GOLD 1	Mild	FEV1 > 80% predicted
GOLD 2	Moderate	50% < FEV1< 80% predicted
GOLD 3	Severe	30% < FEV1 <50% predicted

Severity of Airflow Obstruction in COPD Patients (continued)

To assess the magnitude of the patient's symptoms, either the Modified British Medical Research Council (mMRC) Questionnaire or COPD Assessment Tool (CAT) are utilized:

MODIFIED MRC DYSPNEA SCALE[a]

PLEASE TICK IN THE BOX THAT APPLIES TO YOU | ONE BOX ONLY | Grades 0 - 4

mMRC Grade 0.	I only get breathless with strenuous exercise.	☐
mMRC Grade 1.	I get short of breath when hurrying on the level or walking up a slight hill.	☐
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.	☐
mMRC Grade 3.	I stop for breath after walking about 100 meters or after a few minutes on the level.	☐
mMRC Grade 4.	I am too breathless to leave the house or I am breathless when dressing or undressing.	☐

[a] Fletcher CM. BMJ 1960; 2: 1662.

CAT™ ASSESSMENT

For each item below, place a mark (x) in the box that best describes you currently. Be sure to only select one response for each question.

EXAMPLE: I am very happy	0 (X) 2 3 4 5	**I am very sad**	SCORE
I never cough	0 1 2 3 4 5	I cough all the time	
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5	My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	0 1 2 3 4 5	My chest feels very tight	
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	
I am not limited doing any activities at home	0 1 2 3 4 5	I am very limited doing activities at home	
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	
I sleep soundly	0 1 2 3 4 5	I don't sleep soundly because of my lung condition	
I have lots of energy	0 1 2 3 4 5	I have no energy at all	

Reference: Jones et al. ERJ 2009; 34 (3); 648-54.

TOTAL SCORE: ◯

Goals of Treatment of Stable COPD

Reduce Symptons:

- Relieve symptoms
- Improve exercise tolerance
- Improve health status

Reduce Risk:

- Prevent disease progression
- Prevent and treat exacerbations
- Reduce mortality

Management of COPD

Diagnosis
- Symptoms
- Risk Factors
- Spirometry (repeat if borderline)

Initial Assessment
- FEV1 and GOLD1-4
- Symptoms (CAT or mMRC)
- Exacerbation history
- Smoking status
- Alph1-antitrypsin
- Comorbidities

Initial Management
- Smoking cessation
- Vaccination
- Active lifestyle and exercise
- Initial pharmacotherapy
- Self management education
  - Risk factor management
  - Inhaler technique
  - Breathlessness
  - Written action plan
- Manage comorbidities

Review
- Symptoms (CAT or mMRC)
- Exacerbations
- Smoking Status
- Exposure to other risk factors
- Inhaler technique & adherence
- Physical activity and exercise
- Need for pulmonary rehabilitation
- Self management skills
  - Breathlessness
  - Written action plan
- Need for oxygen, lung volume reduction, palliative approaches
- Vaccination
- Management of comorbidities
- Spirometry (at least annually)

Adjust
- Pharmacotherapy
  - Escalate
  - Switch inhaler device or molecules
  - De-escalate
- Non-pharmacological therapy
- Review (see details)

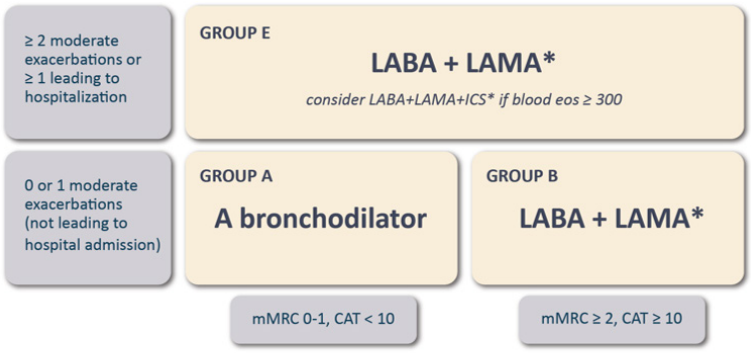
Maintenance Medication in COPD

Drug Name	Inhaler Type	Delivery Options			Duration of Action
		Nebulizer	Oral	Injection	
Beta-2 Agonists					
Short-Acting (SABA)					
Levalbuterol (Xopenex™)	MDI	✓			6-8 hours
Albuterol (Proair™, Proventil™, Ventolin™)	MDI & DPI	✓	Pill, syrup		4-6 hours
Terbutaline			pill	✓	4-6 hours
Long-acting (LABA)					
Arformoterol (Brovana™)		✓			12 hours
Formoterol (Perforomist™)	DPI	✓			12 hours
Olodaterol (Striverdi™)	SMI				24 hours
Salmeterol (Servent™)	DPI				12 hours
Anticholinergics					
Short-acting (SAMA)					
Ipratropium bromide (Atrovent™)	MDI	✓			6-8 hours
Long-acting (LAMA)					
Aclidinium bromide (Tudorza™)	DPI				12 hours
Glycopyrrolate bromide (Lonhala Magnair™)	DPI	✓	solution	✓	12-24 hours
Tiotropium (Spiriva™)	DPI, SMI				24 hours
Umeclidinium (Incruse™)	DPI				24 hours
Revefenacin (Yupelri™)					

Maintenance Medication in COPD (continued)

Drug Name	Inhaler Type	Delivery Options			Duration of Action
		Nebulizer	Oral	Injection	
Combination SABA + SAMA					
albuterol/Ipratropium (Combivent™)	SMI	✓			4-5 hours
Combination LABA + LAMA					
formoterol/aclidinium (Duaklir™)	DPI				12 hours
formoterol/ glycopyrronium (Bevespi™)	MDI				12 hours
vilanterol/umeclidinium (Anoro™)	DPI				24 hours
olodaterol/tiotropium (Stiolto™)	SMI				24 hours
Methylxathines					
Aminophylline			solution	✓	Variable, up to 24 hours
Theophylline (SR) (Theo-24™)			pill	✓	Variable, up to 24 hours
LABA+ ICS					
Formoterol/budesonide (Symbicort™)	MDI				12 hours
Formoterol/mometasone (Dulera™)	MDI				12 hours
Salmeterol/fluticasone propionate (Advair™, AirDuo™, Wixela™)	MDI, DPI				12 hours
Vilanterol/fluticasone furoate (Breo Ellipta™)	MDI				24 hours
Triple Combination (LABA+ LAMA+ ICS					
Fluticasone/umeclidinium/vilanterol (Trelegy™)	DPI				24 hours
Budesonide/formoterol glycopyrrolate (Breztri™)	MDI				12 hours
Phosphodiesterase-4 Inhibitors					
Roflumilast (Daliresp™)			pill		24 hours
Mucolytic Agents					
N-Acetylcysteine (Acetadote™)		✓			

Initial Pharmacological Treatment



*single inhaler therapy may be more convenient and effective than multiple inhalers

The 2023 GOLD guideline proposed further evolution of the "ABCD-combined assessment tool" that recognizes the clinical relevance of exacerbations, independent of the level of symptoms of the patient. The A and B groups are unchanged, but the C and D groups are now merged into a single group termed "E" to highlight the clinical relevance of exacerbations.

Group A: a bronchodilator
Group B: LABA + LAMA*
Group E: LABA + LAMA*
Consider a LABA+LAMA+ICS* if blood eosinophils are ≥ 300 cells/micL

*single inhaler therapy may be more convenient and effective than multiple inhalers

Appropriate Inhalation Device Choice

Availability
Preferred drug in the preferred device type
Cost to patient

Patient Factors
Patients' beliefs, satisfaction with current and previous devices and preference need to be assessed and considered
Size and portability should be considered pending patent lifestyle
Cognition, dexterity and strength must be taken into account
The number of different device types should be minimized; ideally, only one device type should be used if mulitple inhalers are prescribed

Drug
Ability to perform the correct specific inhalation maneuver for the device must be assessed
Dry powder inhalers (DPIs) are appropriate only if the patient can make a forceful and deep inhalation • Check visually that the patient can inhale forcefully through the device • If there is doubt, assess objectively or chose alternative device
Metered dose inhalers (MDIs) and to a lesser extent, soft mist inhalers (SMIs) require coordination between device triggering and inhalation • Patients need to be able to perform a slow and deep inhalation. • Check visually that the patients can inhale slowly and deeply from the device. • If there is doubt, consider adding a spacer/valved holding chamber (VHC) or chose an alternative device
Patients unable to use an MDI with or without a spacer/VHC, a SMI or DPI should be considered

Bronchodilators in Stable COPD

- Inhaled bronchodilators in COPD are central to symptom management and commonly given on regular basis to prevent and reduce symptoms
- Regular and as-needed use of SABA or SAMA improves FEV1 and symptoms
- A combination of SABA and SAMA is superior compared to either medication alone in improving FEV1 and symptoms
- LABAs and LAMAs significantly improve lung function, dyspnea, health status, and reduce exacerbation rates
- LAMAs have a greater effect on exacerbation reduction compared to LABAs and decrease hospitalization
- Combination treatment with LABA and LAMA increases FEV1 and reduces symptoms compared to monotherapy
- Combination treatment with a LABA+LAMA reduces exacerbations compared to monotherapy
- Tiotropium improves the effectiveness of pulmonary rehabilitation in increasing exercise performance
- Theophylline exerts a small bronchodilator effect in stable COPD and is associated with modest symptomatic benefit
- Single inhaler therapy may be more convenient and effective than multiple inhalers
- Patients in hospice or enrolled in palliative care

Anti-Inflammatory Therapy in Stable COPD

Inhaled Corticosteroids

- An ICS combined with a LABA is more effective than the individual components in improving lung function and health status and reducing exacerbations in patients with exacerbations and moderate to very severe COPD
- Regular treatment with ICS increases risk of pneumonia, especially in those with severe disease
- LABA+LAMA+ICS improves lung function, symptoms and health status, and reduces exacerbations compared to LABA+ICS, LABA+LAMA and LAMA monotherapy

Oral Glucocorticoids

- Long-term use of oral glucocorticoids has numerous side effects with no evidence of benefit

PDE4 Inhibitors

- In patients with chronic bronchitis, severe to very severe COPD and history of exacerbations
- Improves lung function and reduces moderate and severe exacerbations
- Improves lung function and decreases exacerbations in patients who are on fixed-dose LABA+ ICS combinations

Antibiotics

- Long-term azithromycin and erythromycin therapy reduces exacerbations over one (1) year
- Treatment with azithromycin is associated with an increased incidence of bacterial resistance and hearing test

Mucoregulators and Antioxidant Agents

- Regular treatment with mucolytics such as NAC reduces the risk of exacerbations in select populations

Other Anti-Inflammatory Agents

- Simvastatin does not prevent exacerbations in COPD patients at increased risk of exacerbations and without indication of statin therapy
- Leukotriene modifiers have not been tested adequately in COPD patients

Best Practices to Improve COPD Treatment

- Counsel patient on differences between long-acting vs. short-acting inhaler therapy to ensure proper utilization
- Counsel patients on inhaler technique to ensure proper utilization
- Use combination inhaler therapy to minimize complexity of regimen for patients
- Instruct patients to use manufacturer coupons on brand name medications to reduce cost of treatment (commercial insurance plans only)
- Use 90 day supplies on generic medications whenever possible to prevent missed monthly refills
- Only available generic therapy for COPD are the ICS/LABAs, even though not preferred to LAMA therapy
- Suggest use of medication reminder applications or alarms to improve adherence
- Send cancellation requests to pharmacy with any changes in medications or dose to ensure outdated script sare not refilled accidentally
- Utilize medication adherence reports from payers to identify non-adherent patients
- Medent Users – Use the “Import RX History” feature to review prescription fill history for your patients during appointments to encourage compliance

With the expansion of the GLIN Pharmacy Team in 2023, our pharmacists will be available to assist in improving these outlined quality metrics. Our pharmacists will provide payer quality reports as done in previous years **AND** provide patient specific messages within your electronic medical record with recommendations **AND** patient follow-up if agreeable by your providers.

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For additional questions, please reach out to your assigned Clinical Transformation Consultant.

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