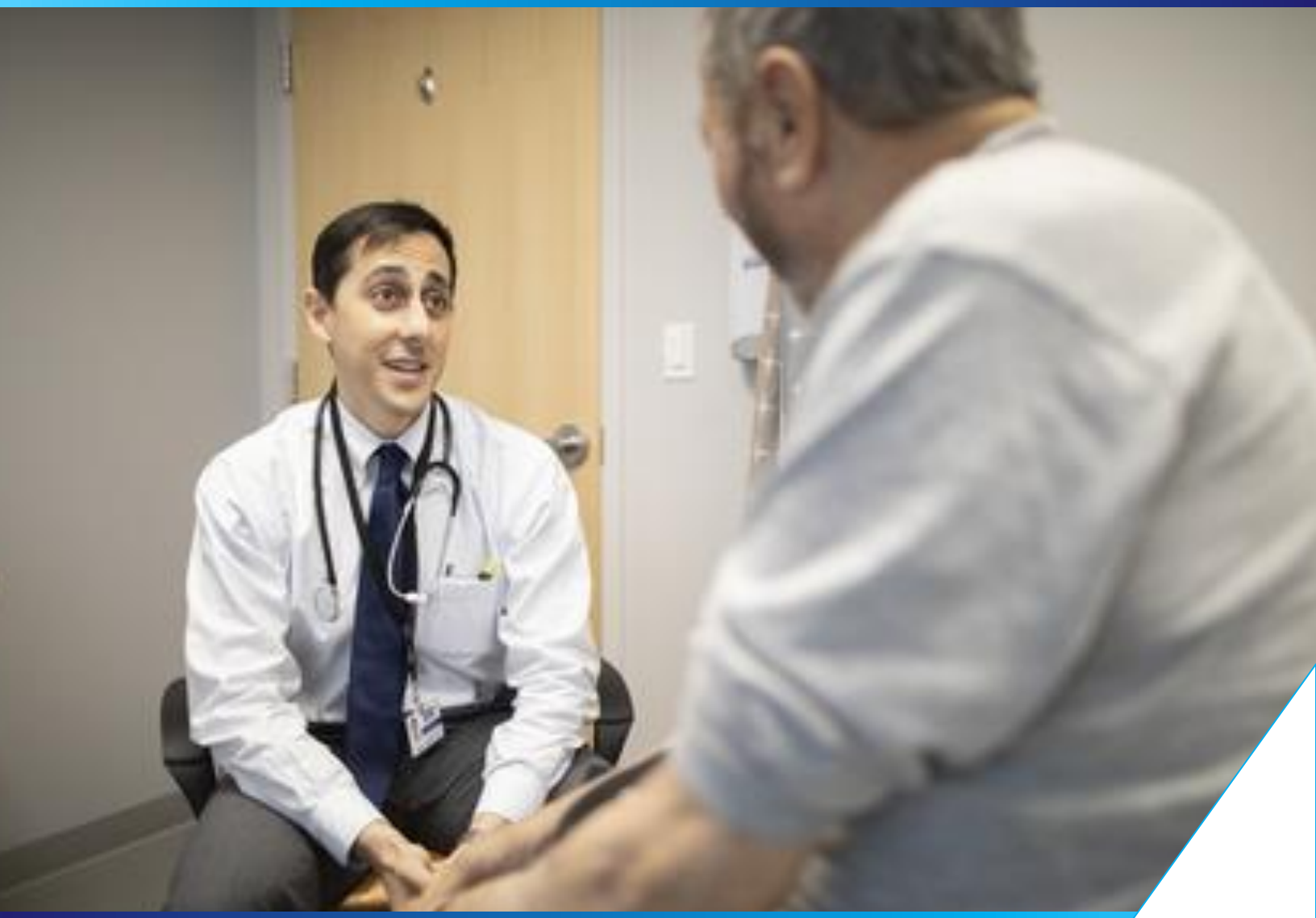

COPD

Ambulatory Care Pathway

Mount Sinai Health Partners

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Background

- Ensure the patient has COPD based on Spirometry/PFTs.
- The management strategy for stable COPD should be predominantly based on the individualized assessment of symptoms and future risk of exacerbations.
- **The main treatment goals are reduction of symptoms and future risk of exacerbations.**
- Management strategies are not limited to pharmacological treatments, and should be complemented by appropriate non-pharmacological interventions.
- **Primary care has a vital role** in providing holistic, person-centered care from first symptoms to end of life.
- This document is intended to provide **guidance to support primary care providers and the collaborative team on COPD diagnosis and management.**
- **Classify by GOLD Criteria** using Modified Medical Research Council (MMRC), Dyspnea Scale COPD Assessment Test (CAT), and # of exacerbations and hospitalizations.
- Patients must see a COPD care provider (PCP or pulmonoligist) four times (4x) per year for COPD management.

Table of Contents

This 2021 MSHS COPD Ambulatory Pathway is organized into the following sections:

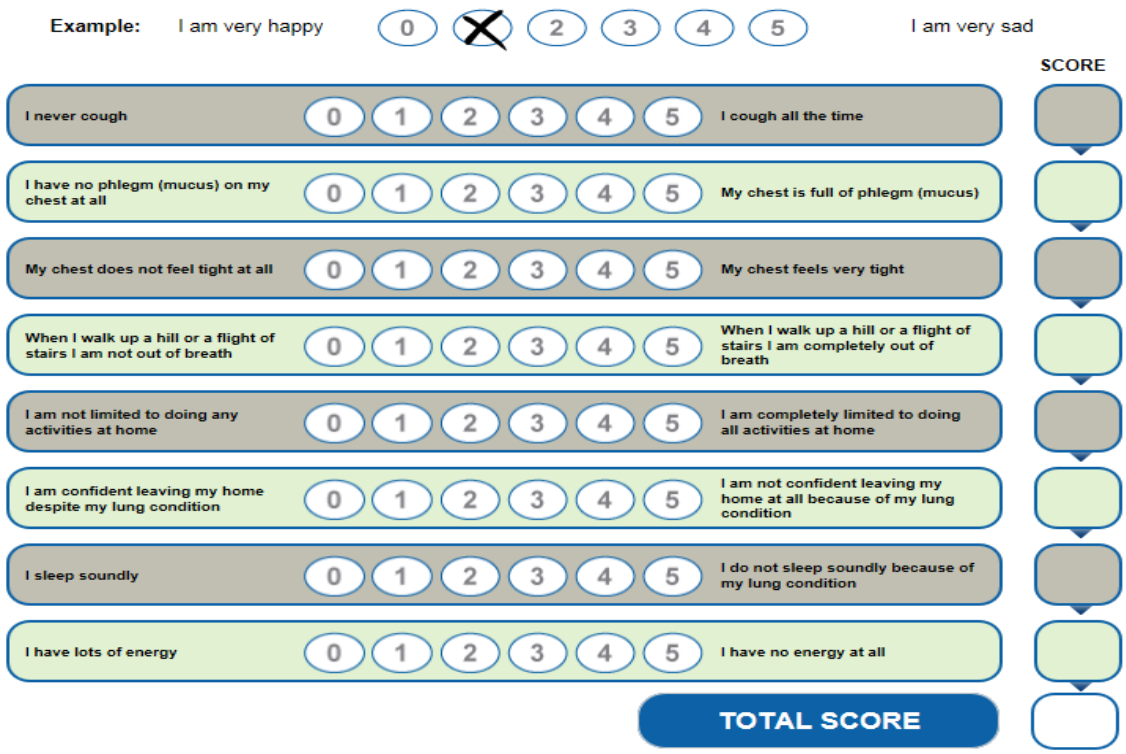
GOLD Criteria Classification

- Classify by GOLD Criteria using Modified Medical Research Council (MMRC) Dyspnea Scale, COPD Assessment Test (CAT), and # of exacerbations and hospitalizations.
- Patients must see a pulmonary care provider (PCP or pulmonoligist) four times (4x) per year for COPD management.

The Modified Medical Research Council (MMRC) Dyspnoea Scale

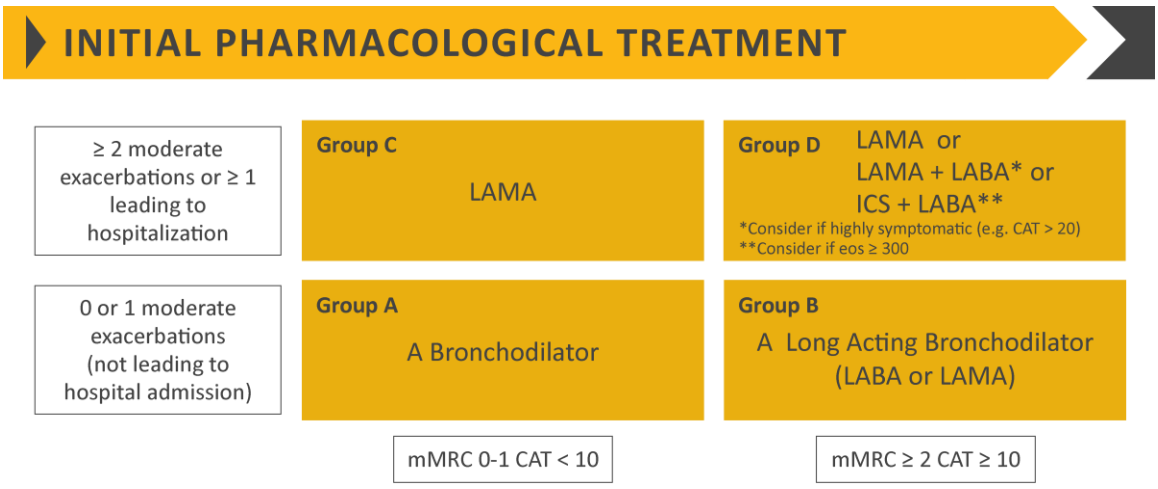
Grade of dyspnoea	Description
0	Not troubled by breathlessness except on strenuous exercise
1	Shortness of breath when hurrying on the level *or* walking up a slight hill
2	Walks slower than people of the same age on the level because of breathlessness *or* has to stop for breath when walking at own pace on the level
3	Stops for breath after walking about 100 m *or* after a few minutes on the level
4	Too breathless to leave the house *or* breathless when dressing or undressing

COPD ASSESSMENT TEST (CAT)



Medication & Pharmacological Treatment

Medication Guidelines based on GOLD Classification



Group A

- All Group A patients should be offered bronchodilator treatment based on its effect on breathlessness. This can be either a short- or a long-acting bronchodilator.
- This should be continued if symptomatic benefit is documented.

Group B

- Initial therapy should consist of a long acting bronchodilator. **Long-acting inhaled bronchodilators are superior to short-acting bronchodilators (taken prn) and are therefore recommended.**
- There is no evidence to recommend one class of long-acting bronchodilators over another for initial relief of symptoms in this group of patients.
- For patients with persistent breathlessness on monotherapy the use of two bronchodilators is recommended.
- For patients with severe breathlessness on initial therapy, treatment with two bronchodilators may be considered.
- If the addition of a second bronchodilator does not improve symptoms, we suggest the treatment could be stepped down again to a single bronchodilator.
- Group B patients are likely to have comorbidities that may add to their symptomatology and impact their prognosis, and these possibilities should be investigated.

Group C

- Initial therapy should consist of a single long acting bronchodilator. In two head-to-head comparisons the tested LAMA was superior to the LABA regarding exacerbation prevention, therefore **we recommend starting therapy with a LAMA in this group**.
- Patients with persistent exacerbations may benefit from adding a second long acting bronchodilator (LABA/LAMA) or using a combination of a long acting beta2-agonist and an inhaled corticosteroid (LABA/ICS). As ICS increases the risk for developing pneumonia in some patients, our primary choice is LABA/LAMA.

Group D

We recommend starting therapy with a LABA/LAMA combination because:

- In studies with patient reported outcomes as the primary endpoint LABA/LAMA combinations showed superior results compared to the single substances. If a single bronchodilator is chosen as initial treatment, a LAMA is preferred for exacerbation prevention based on comparison to LABAs.
- A LABA/LAMA combination was superior to a LABA/ICS combination in preventing exacerbations and other patient reported outcomes in Group D patients.
- **Group D patients are at higher risk of developing pneumonia when receiving treatment with ICS.**
- In some patients initial therapy with LABA/ICS may be the first choice. These patients may have a history and/or findings suggestive of asthma-COPD overlap. High blood eosinophil counts **(>300** cells/µL) may also be considered as a parameter to support the use of ICS.
- In patients who develop further exacerbations on LABA/LAMA therapy suggest two alternative pathways:
    - Escalation to LABA/LAMA/ICS (consider if eosinophil count >100 cells/µL)
    - Addition of roflumilast or azithromycin (consider if eosinophil count <100 cells/µL) (see below)

If patients treated with LABA/LAMA/ICS (or LAMA/LABA without eosinophilia) still have exacerbations the following options may be considered:

- Add roflumilast. This may be considered in patients with an FEV1 < 50% predicted and chronic bronchitis, particularly if they have experienced at least one hospitalization for an exacerbation in the previous year.

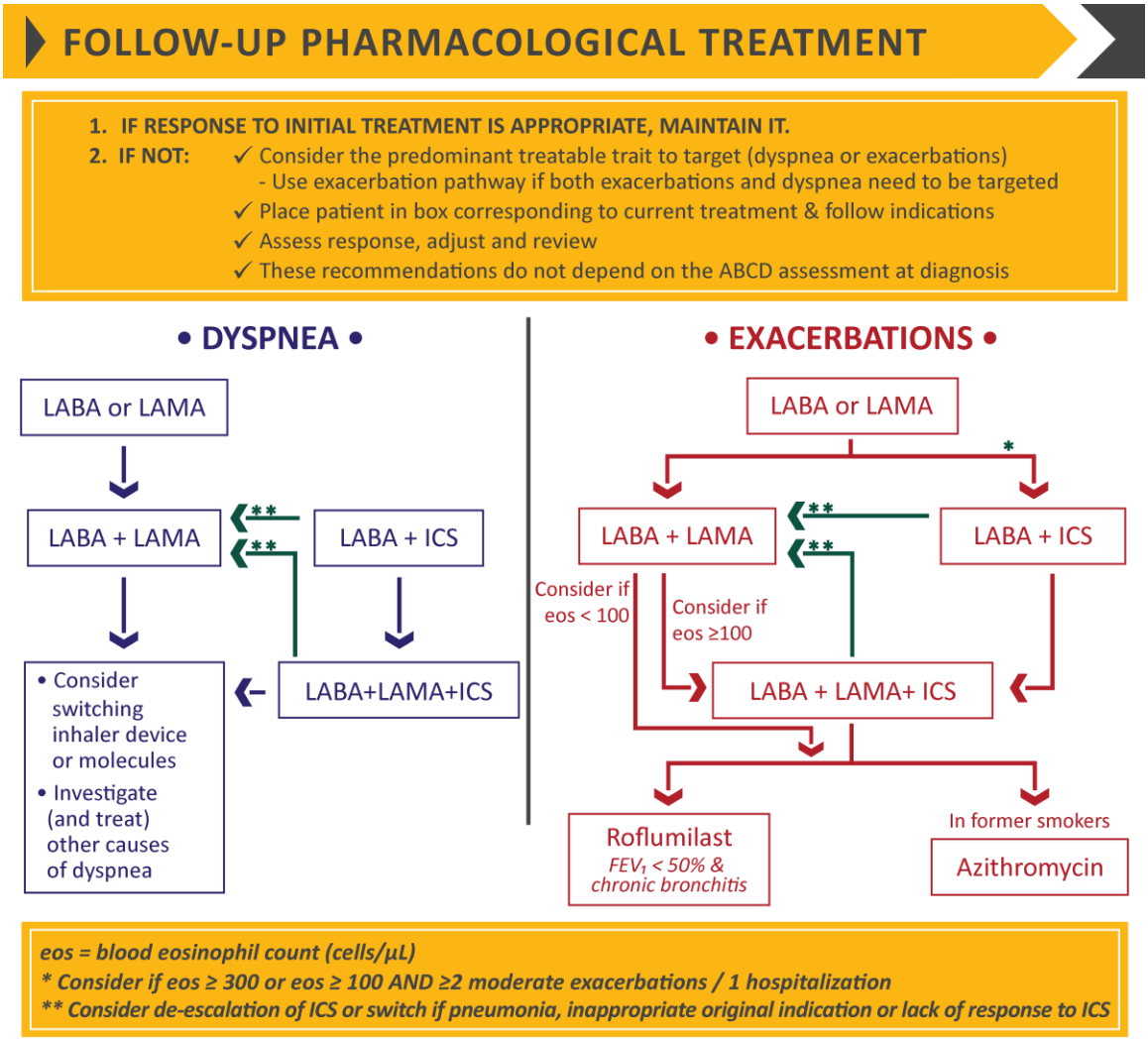
- Add a macrolide. The best available evidence exists for the use of azithromycin. Consideration to the development of resistant organisms should be factored into decision making.

Stopping ICS. A reported lack of efficacy, an elevated risk of adverse effects (including pneumonia) and evidence showing no significant harm from withdrawal supports this recommendation.

Commonly Used Maintenance Medication in COPD[1]					
Types of Delivery Options					
Generic Drug Name	**Inhaler Type**	**Nebulizer**	**Oral**	**Injection**	**Duration of Action**
$Beta_2$-Agonists					
Short-Acting (SABA)					
Levalbuterol	MDI	Yes			6-8 hours
Albuterol	MDI & DPI	Yes	Pill, syrup, ext. release tablet	Yes	4-6 hours 12 hours (ext. release)
Terbutaline	DPI		Pill	Yes	4-6 hours
Long-Acting (LABA)					
Formoterol	DPI	Yes			12 hours
Indacterol	DPI				24 hours
Olodaterol	SMI				24 hours
Salmeterol	MDI & DPI				12 hours
Anticholinergics					
Short-Acting (SAMA)					
Ipratroplum bromide	MDI	Yes			6-8 hours
Long-Acting (LAMA)					
Aclidinium bromide	DPI, MDI				12 hours
Glycopyrronium bromide	DPI		Solution	Yes	12-24 hours
Tiotropium	DPI, SMI				24 hours
Umeclidium	DPI				24 hours
Combination Long-Acting-$Beta_2$-Agonist Plus Anticholinergic in One Device (LABA/LAMA)					
Formoterol/aclidium	DPI				12 hours
Formoterol/glycopyrronium	MDI				12 hours
Indacaterol/glycopyrronium	DPI				12-24 hours
Vilanterol/umeclidium	DPI				24 hours
Olodaterol/tiotropium	SMI				24 hours
Methylxanthines					
Theophyline (SR)			Pill	Yes	Variable, up to 24 hrs
Combination of Long-Acting $Beta_2$-Agonist Plus Corticosteroids in One Device (LABA/ICS)					
Formoterol/budesonide	MDI, DPI				
Formoterol/mometasone	MDI				
Salmeterol/fluticasone	MDI, DPI				
Vilanterol/fluticasone furoate	DPI				
Triple Combination in One Device (LABA/LAMA/ICS)					
Fluticasone/umeclidium/vilanterol	DPI				
Phosphodieterase-4 Inhibitors					
Roflumilast			Pill		

[1] Medication recommendations adapted from the 2019 Global Institute for Chronic Obstructive Lung Institute's "Management of Stable COPD" (https://goldcopd.org/wp-content/uploads/2017/11/GOLD-2018-v6.0-FINAL-revised-20-Nov_WMS.pdf)

Pharmacological treatment algorithms by GOLD Grade (Green boxes and arrows indicate preferred treatment pathways)



Key Points for Inhalation of Drugs

- The choice of inhaler device has to be individually tailored and will depend on access, cost, prescriber, and most importantly, patient's ability and preference.
- It is essential to provide instructions and to demonstrate the proper inhalation technique when prescribing a device, to ensure that inhaler technique is adequate and re-check at each visit that patients continue to use their inhaler correctly.
- **Inhaler technique (and adherence to therapy) should be assessed before concluding that the current therapy requires modification.**

Key Points for Use of Bronchodilators

- LABAs and LAMAs are preferred over short-acting agents except for patients with only occasional dyspnea.

- Patients may be started on single long-acting bronchodilator therapy or dual long-acting bronchodilator therapy. In patients with persistent dyspnea on one bronchodilator treatment should be escalated to two.
- Inhaled bronchodilators are recommended over oral bronchodilators.
- Theophylline is not recommended unless other long-term treatment bronchodilators are unavailable or unaffordable.

Key Points for Use of Anti-Inflammatory Agents

- **Long-term monotherapy with ICS is not recommended**.
- Long-term treatment with ICS may be considered in association with LABAs for patients with a history of exacerbations despite appropriate treatment with long-acting bronchodilators.
- **Long-term therapy with oral corticosteroids is not recommended**
- In patients with exacerbations despite LABA/ICS or LABA/LAMA/ICS, chronic bronchitis and severe to very severe airflow obstruction, the addition of a PDE4 inhibitor can be considered.
- In former smokers with exacerbations despite appropriate therapy, macrolides can be considered.
- Statin therapy is not recommended for the prevention of exacerbations.
- Antioxidant mucolytics are recommended only in selected patients.

Key Points for Use of Other Pharmacological Treatments

- **Anitussives cannot be recommended.**
- **Drugs approved for primary pulmonary hypertension are not recommended for patients with pulmonary hypertension secondary to COPD.**
- Patients with severe hereditary alpha-1 antitrypsin deficiency and established emphysema may be candidates for alpha-1 antitrypsin augmentation therapy.
- Low-dose long acting oral, parenteral opioids may be considered tor treating dyspnea in COPD patients with severe disease.
- Review understanding of treatment regimen.

Advanced COPD Treatments

When to Refer to a Pulmonary Specialist

- History of severe obstruction (FEV1<50% predicted) or requiring supplemental home oxygen.
- Mild to moderate COPD (FEV1≥50% predicted) with high symptom burden (CAT≥20) despite appropriate dual inhaler therapy and physical rehabilitation.
- Any patient requiring hospitalization in the past year.

When to Refer to a Pulmonary Rehab

- All patients in Gold Group B-D.
- Patients with a hospitalization for COPD should begin a rehabilitation program within 4 weeks of discharge.[2]
- Unfortunately, limited availability in New Yok City area.

[2] Information provided by MSHS Department of Pulmonology

Non-Pharmacological Treatments

Non-Pharmacological Management of COPD			
Patient Group	**Essential**	**Recommended**	**Depending on National Guidelines**
A	Smoking cessation (can include pharmacological treatment)	Physical activity	Flu vaccine Pneumococcal vaccination
B-D	Smoking cessation (can include pharmacological treatment) Pulmonary rehabilitation	Physical activity	Flu vaccine Pneumococcal vaccination

Key Points for the Use of Non-Pharmacological Treatments

Education, Self-Management, and Pulmonary Rehabilitation

- Education is needed to change patient's knowledge but there is no evidence that used alone it will change patient behavior.
- ***Education and self-management with the support of a case manager with or without the use of a written action plan is recommended for the prevention of exacerbation complications such as hospital admissions.***
- Pulmonary Rehabilitation: consider referral for 1. Symptomatic patients with FEV1 <50%, 2. Persistent symptoms significantly limiting activity and FEV1 >50, GOLD Classification B-D.
- ***Physical activity is a strong predictor of mortality***. Patients should be encouraged to increase the level of physical activity.
- Consider pursed lip breathing (i.e. longer exhale than inhale).

Vaccinations

- Influenza vaccination is recommended for all patients with COPD.
- Pneumococcal vaccination with PPSV23 are recommended for all patients with COPD.
- Administration of PCV13 should be considered for COPD patients >65 years old.

Nutrition

- Nutritional supplementation and/or nutritionist referral should be considered in malnourished patients with COPD.

End of Life and Palliative Care

- All clinicians managing patients with COPD should be aware of the effectiveness of palliative approaches to symptom control and use these in their practice.

- End-of-life care should include discussions with patients and their families about their views on resuscitation, advance directives and place of death preferences.

Treatment of Hypoxemia

- **In patients with severed resting hypoxemia long-term oxygen therapy is indicated.**
- In patients with stable COPD and resting or exercise-induced moderate desaturation, long term oxygen treatment should not be routinely prescribed. However, individual patient factors may be considered when evaluating the patient's needs for supplemental oxygen.
- *Resting oxygenation at sea level does not exclude the development of severe hypoxemia when travelling by air.*

Prescription of Supplemental Oxygen to COPD Patients:

Arterial hypoxemia defined as: PaO_2 < 55 mmHg (8 kPa) or SaO_2 < 88% or PaO_2 > 55 but 60 mmHg (> 8 but < 8.5 kPa with right heart failure or erythrocytosis	Prescribe supplemental oxygen and titrate to keep SaO_2 ≥ 90%	Recheck in 60 to 90 days to assess: • If oxygen is still indicated • If prescribed supplemental oxygen is effective

Treatment of Hypercapnia

- In patients with severe chronic hypercapnia and a history of hospitalization for acute respiratory failure, long term non-invasive ventilation may be considered.

Interventional Bronchoscopic and Surgical Treatments for Advanced Treatment for COPD:

- Bronchoscopic lung volume reduction (BLVR)
- Endobronchial valve (EBV)
- Lung volume reduction surgery (LVRS)
- Lunch volume reduction coil (LVRC)
- Bullectomy
- Lung transplant

Key Outcomes & Care Team Members

Key Outcome Metrics

- Spirometry obtained at least once
- Annual flu vaccination
- Pneumococcal vaccination with PPSV23. Administration of PCV13 should be considered for COPD patients 65 and over.
- Assessed annually for tobacco use, advised to quit, counseled on cessation strategies, and provided a prescription of smoking cessation medication.

Identify and Reduce Risk Factor Exposure

- Smoking cessation interventions should be actively persued in all COPD patients.
- Efficient ventilation, non-polluting cooking stoves, and similar interventions should be recommended.
- Clinicians should advise patient to avoid continued exposures to potential pulmonary irritants, if possible.

Possible Care Team Members

A wide-variety of team members can be involved in the diagnosis and care of COPD. Below of some examples of care delivery steps and possible team members.

Care Delivery Step	Possible Team Member(s)
Diagnosis and Severity Classification	Primary Care Provider (PCP), Specialist, Advanced Practice Nurse (APN)
Initial Treatment (Medication, Nutrition, Vaccines)	PCP, Specialist, APN, Pharmacy
Maintenance Treatment (Medication Adjust/Adherence, Nutrition, Vaccines)	PCP, Specialist, APN, Pharmacy
Self-Management (Weight monitoring/Symptom Response, Motivational Interviewing)	Pharmacy, Care Management (RN), RD-CDE
Coordinate Specialty Treatment or Testing/ Advanced Care	Care Management (SW, RN)
Behavioral Health- Screen and Refer/Initiate Treatment	PCP, APP, Pharmacy, LCSW (if available)
Ambulatory Care Management/Home Care Services	Care Managers (RN, SW), Home Health Aide, Community Paramedicine
Telemonitoring/Home Care Services	Specialist, Care Management (RN), Home Health Aide
Palliative Care Screening	PCP, Specialist (cardiologist, pulmonogist, or palliative care), APN, Pharmacy, Care Management (RN)

Team Member Acronym Legend

Acronym	Full Name
PCP	Primary Care Provider
APN	Advanced Practice Nurse
RN	Registered Nurse
LCSW	Licensed Clinical Social Worker
RD-CDE	Registered Dietician, Certified Diabetes Educator
SW	Social Worker

MSHS Disease Management Services

Clinical Pharmacy

- Pharmacists are a **key part of the care team for chronic disease management** including including COPD, heart failure, and diabetes.
- The team of pharmacists is rapidly expanding in primary and specialty care.
- They are credentialed providers that can prescribe and adjust medications through the Collaborative Drug Treatment Model.[3]

Referrals to Pharmacists

  - Uncontrolled chronic diseases, such as: Hypertension, diabetes, heart failure, asthma, COPD, depression, behavioral health
  - Post-discharge
  - High utilizers
  - Polypharmacy, Medication Reconciliation and Medication Adherence

Home Health

- Referrals for Home Health Care should be handled through the **designated Home Health nurse coordinator**, a member of the care management team.
- The Home Health nurse coordinator will **assess the patient's needs** and determine appropriateness of Home Health.
- **Telephonic education and reinforcement** can be also be delivered by the Nurse Clinical Coordinator. (The home health RN will not provide patient interventions, they will refer to nurse care coordinator if needed.)
- Providing Home Health nursing and therapy **can promote recovery** in vulnerable COPD patients with post-hospital syndrome and potentially reduce readmissions.[4]
- Nursing interventions can include various educational components including recognition of COPD symptoms with an action plan, dietary guidelines, medication management, and weight monitoring.

Care Coordination in COPD at MSHS[5]

- The medical complexity inherent in most patients with COPD generally requires the involvement of multiple clinicians across many care settings.
- Interdisciplinary, team-based care may be the most effective approach to complex COPD care.
- Mount Sinai Health Partners Care Management social workers and nurses partner with patients, family caregivers, and providers to identify and address known risk factors that can impact patients' health.
- Care Management intervention includes:
  - A comprehensive assessment of the patient's understanding of and ability to manage their illness and the psychosocial.
  - Development of a comprehensive care plan to set goals to optimize health and quality of life.

[3] https://www.amcp.org/sites/default/files/2019-03/Practice%20Advisory%20on%20CDTM%202.2012_0.pdf

Referral Criteria may include those with:

- Multiple no-shows
- Unexplained non-adherence to medications, testing or treatment
- Demonstrated difficulty managing symptoms and/or disease processes (including those newly diagnosed)
- Frequent admissions or ED visits that may be preventable with additional support
- Complex family dynamics that deplete the provider
- Difficulty accessing needed community-based care
- A high "worry score" (patients you as the provider are most worried about from visit to visit)

How to refer to MSHP Care Management:

- **Use the MSHP Care Management Referral in Epic (order #391414).**
- **Email mshpcmreferral@mountsinai.org or call 212-241-7228.**
    - Providers who refer patients can expect:
        - Prompt and efficient processing of your referral.
        - Communication about referral processing and assignment through the Epic Inbasket.
        - Follow up from clinical staff within one week of assignment.

Behavioral Health[6]

Patients should be screened for depression using the PHQ-2/PHQ-9 and referred to psychiatric services through their current care pathway depending on their clinic.

- Individuals with COPD are 2-5 times more likely to have anxiety and depressive disorders compared with the general population.[7]
- Patients with chronic medical illness and a co-morbid psychiatric diagnosis have poorer quality of life, increased functional disability, and increased mortality to name a few.
- Increased recognition of treatment of these comorbid conditions is essential.

Community Paramedicine

Community Paramedicine offers **rapid evaluation and in-home treatment** for patients with acute symptoms, with less than a 60 min response time, available 24/7 in Manhattan, Queens, Brooklyn, Staten Island, and Long Island.

Who can access it:

- **Any clinician can trigger service** for their patient who needs urgent evaluation and treatment at home, with the goal of stabilizing the patient at home and preventing an ED visit.

How to use the service:

- **Clinicians need to be signed-up in order to use CP**.
- Contact Ari.Breslauer@mountsinai.org to sign up.
- Once signed up, just call 1-800-TO-SINAI (option 3) to activate Community Paramedicine for your patient

[7] Ratcliff, Chelsea & Fletcher, Terri & Petersen, Nancy & Sansgiry, Shubhada & Kauth, Michael & Kunik, Mark & Stanley, Melinda & Cully, Jeffrey. (2017). Recognition of anxiety, depression, and PTSD in patients with COPD and CHF: Who gets missed?. General Hospital Psychiatry. 47. 10.1016/j.genhosppsych.2017.05.004.

Background[8]

- Palliative care is **beneficial at any stage** of a serious illness.[9]
- Palliative care, and the medical sub-specialty of palliative medicine, is specialized medical care for people living with serious illness.
- It focuses on providing **relief from the symptoms and stress** of a serious illness.
- The goal is to improve quality of life for both the patient and the family.

Palliative Care Referral Criteria And Options[10]

- Consider a specialty-level palliative care referral for patients who meet any of these criteria despite optimal therapy:
    - **Severe symptoms**
    - Frequent COPD readmissions;
    - **Anxiety or depression** adversely affecting patient's quality of life or their ability to manage their illness; AND/OR
    - Assistance with **decision-making** regarding advanced therapies.

- Patients with COPD may be referred to one of two practices. The services provided at each location are identical; please choose the location that is most convenient to your patient.
    - Mount Sinai Health System Palliative Care Practices:
        - To make a referral to the Martha Stewart Center for Living at 1440 Madison Avenue, please call: 212-241-1446
        - To make a referral to the Martha Stewart Center for Living Downtown at Union Square, please call: 212-844-1712

Hospice Care Referral Criteria

- Severely symptomatic, end-stage COPD patients with life expectancy ≤ 6 months

Additional Medication Information

Drug Class	Generic Name	Brand Name Examples
Beta Agonists		
Short-Acting (SABA)	Levalbuterol	
	Albuterol	Xopenex, Xopenex HFA
	Terbutaline	Ventolin HFA, Proventil HFA, ProAir HFA, ProAir RespiClick
Long-Acting (LABA)	Formoterol	None
	Indacterol	Arcapta Neohaler
	Olodaterol	Striverdi Respimat

[8] Information developed and provided by the Mount Sinai Brookdale Department of Geriatrics and Palliative Medicine

[9] Center to Advance Palliative Care; Serious Illness Quality Alignment HUB: State Palliative Care Definitions and Standards. Available at: *https://www.capc.org/documents/133/).*

[10] Information developed and provided by the Mount Sinai Brookdale Department of Geriatrics and Palliative Medicine

	Salmeterol	Serevent Diskus
Anticholinergics		
Short Acting (SABA)	Ipratroplum bromide	Atrovent HFA
Long-Acting (LAMA)	Aclidinium bromide	Tudorza Pressair
	Glycopyrrolate	Lonhala Magnair, Seebri Neohaler
	Tiotropium	Spiriva HandiHaler, Spiriva Respimat
	Umeclidium	Incruse Ellipta
Combination Long-Acting-Beta$_2$-Agonist Plus Anticholinergic in One Device (LABA/LAMA)		
	Formoterol/aclidium	Duaklir Pressir
	Formoterol/glycopyrrolate	Bevespi Aerosphere
	Indacaterol/ glycopyrrolate	Utibron Neohaler
	Vilanterol /umeclidium	Anoro Ellipta
	Olodaterol/tiotropium	Stiolto Respimat
Methylxanthines		
	Theophyline (SR)	Theo-24, Uniphyl
Combination of Long-Acting Beta$_2$-Agonist Plus Corticosteroids in One Device (LABA/ICS)		
	Formoterol/budesonide	Symbicort
	Formoterol/mometasone	Dulera
	Salmeterol/fluticasone	Advair Diskus, Advair HFA, Wixela Inhub, AirDuo RespiClick
	Vilanterol/fluticasone furoate	Breo Ellipta
Triple Combination in One Device (LABA/LAMA/ICS)		
	Fluticasone/umeclidium/vilanterol	Trelegy Ellipta
Phosphodieterase-4 Inhibitors		
	Roflumilast	Daliresp