

BREATH OF FRESH AIR: THE LATEST PUFF ON COPD UPDATES

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DISCLOSURES

I have no relevant financial relationships with any entity producing, marketing, re-selling, or distributing health care goods or services, used on, or consumed by, patients to disclose.

OBJECTIVES

Pharmacist

1. Provide an overview on COPD including risk factors associated with COPD exacerbations
2. Discuss recent updates to the GOLD guidelines for the management of COPD
3. Navigate the available safety and efficacy data of emerging therapies for use in COPD
4. Explore the role of the pharmacist in creating a patient care plan to prevent rehospitalization due to frequent COPD exacerbations

Technician

1. Briefly explain what COPD is, including primary causes, symptoms, and progression
2. Discuss medication classes such as LAMAs, LABAs, and combination therapies, and their roles in therapy
3. Identify the current biologic therapy approved for COPD
4. Emphasize the importance of educating patients about COPD management including smoking cessation and proper inhaler use

68-YEAR-OLD WOMAN WITH 50-PACK-YEAR SMOKING HISTORY: WORSENING COPD SYMPTOMS AND CHRONIC COUGH WITH COPIOUS SPUTUM PRODUCTION DESPITE RECEIVING INHALED TRIPLE THERAPY (LABA/LAMA/ICS). SHE EXPERIENCES FREQUENT EXACERBATIONS, REQUIRING ORAL CORTICOSTEROIDS MULTIPLE TIMES IN THE PAST YEAR. HER LUNG FUNCTION TESTS SHOW AN FEV1 OF 53% PREDICTED AND AN FEV1/FVC RATIO OF 0.60 POST-BRONCHODILATOR. A COMPLETE BLOOD COUNT REVEALS A PERSISTENT BLOOD EOSINOPHIL COUNT OF 450 CELLS/ML. SHE DENIES ANY HISTORY OF ASTHMA OR OTHER ALLERGIC DISEASES. WHAT WOULD BE THE BEST STEP TO MANAGE HER COPD?

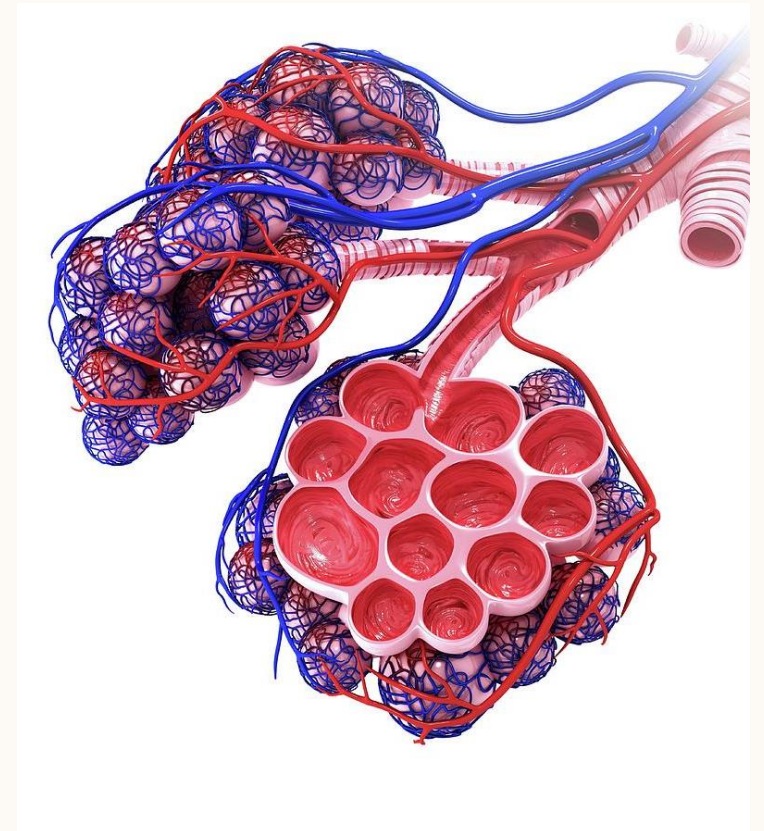
1. Add Azithromycin
2. Add Roflumilast
3. Add Dupilumab
4. Decrease to LABA/LAMA

WHAT IS MOST IMPORTANT TO REDUCE COPD READMISSIONS?

1. Appropriate pharmacotherapy
2. Smoking cessation
3. Vaccinations
4. Medication/inhaler counseling
5. All of the above

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) OVERVIEW

- Chronic respiratory symptoms resulting from airway AND/OR alveoli abnormalities
- Preventable and treatable; one of top 3 causes of death worldwide
- **GETomics** (Gene – Environment interactions over lifetime (T) leading to damage and/or altering normal aging process
 - Environmental: Tobacco smoke, noxious particles/gases from pollution
 - Genetic: SERPINA1 genetic mutations



EPIDEMIOLOGY

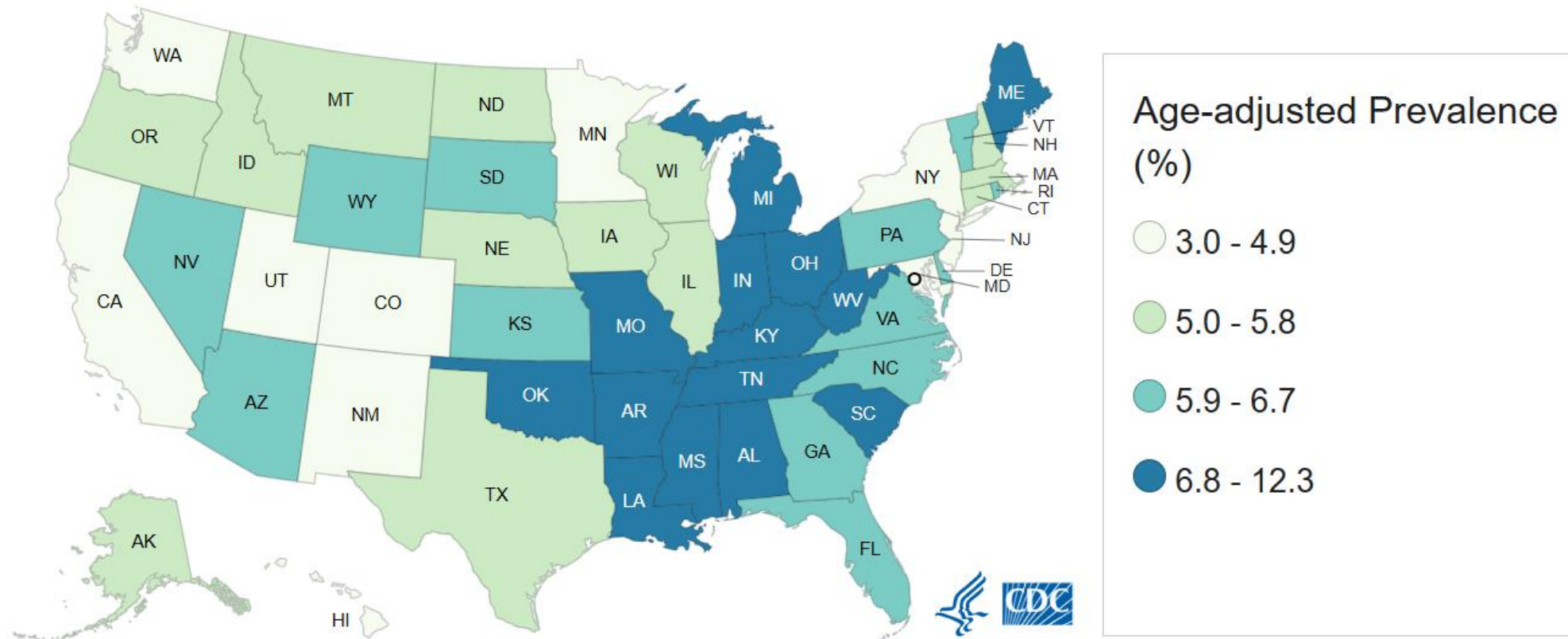
- COPD is one of the top ten causes of death in the US
- 16 million US adults have COPD, with many more unaware
- Nationally
 - Prevalence stable between 2011 and 2022 (slightly higher in women)¹
 - Death rates among 45 and older decreased overall and among men from 1999 to 2021²
 - Differences in death rates between males and females decreased since 1999²
- Globally
 - Prevalence estimated to be 10.6% in 2020³

1. CDC Behavioral Risk Factor Surveillance System (BRFSS), 2011-2022.

2. National Vital Statistics System, 1999-2021. Mortality data at <http://wonder.cdc.gov>.

3. Boers E, Barrett M, Su JG, et al. JAMA Netw Open. 2023;6(12):e2346598.

COPD PREVALENCE 2022



Data Source: CDC Behavioral Risk Factor Surveillance System (BRFSS), 2022. Age-adjusted COPD prevalence based on affirmative response to the question: "Has a doctor, nurse, or other health professional ever told you that you have COPD, emphysema, or chronic bronchitis?"

GOLD 2024 UPDATES

Refine taxonomy

**Treatment impact
on mortality
discussed**

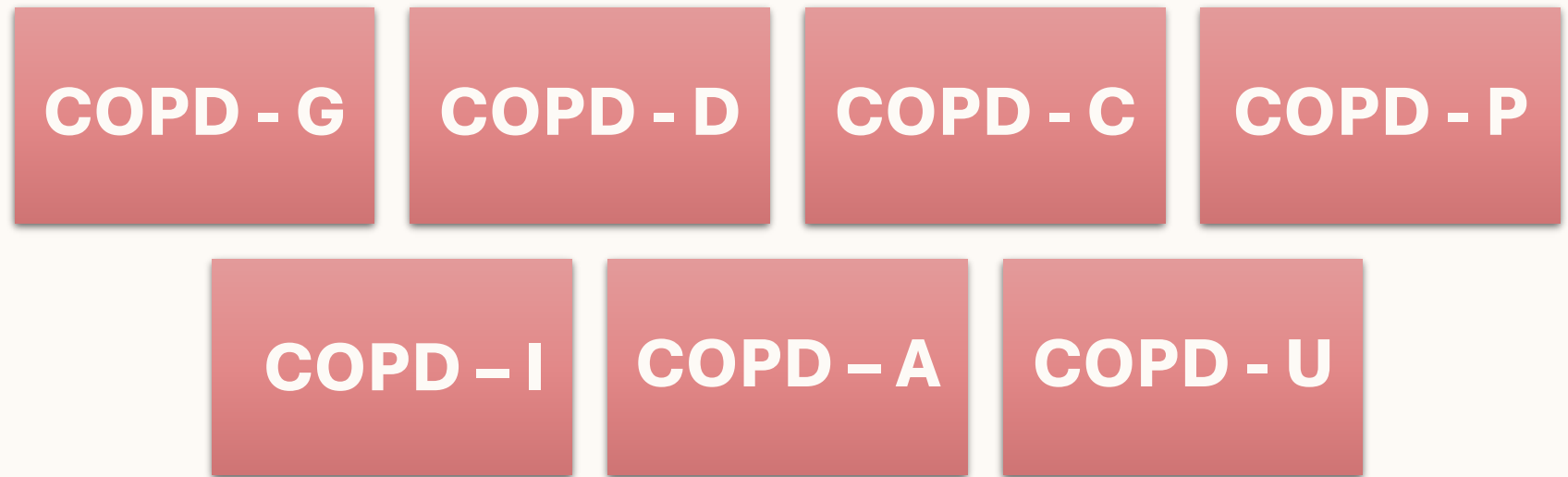
**Adherence
considerations**

**Importance of
inhaler/device
selection**

Role of CT imaging

**Assessment /
management of
exacerbations**

PROPOSED COPD TAXONOMY



COPD TYPES

11

Early COPD

- Discusses "biological" first steps of COPD in experimental setting

Mild COPD

- Use to describe airflow obstruction severity (via spirometry)

Young COPD

- Patients 20 – 50 years old
- Never achieved normal peak lung function and/or shorter plateau and/or early lung function decline

Pre-COPD

- Respiratory symptoms and/or structural/functional abnormality in the absence of airflow obstruction

PRISm

- Preserved ratio impaired spirometry
- Preserved ratio ($FEV1/FVC > 0.7$ after bronchodilation) with impaired spirometry ($FEV1 < 80\%$)

CLINICAL PRESENTATION

- Dyspnea
- Wheezing
- Chest tightness
- Fatigue
- Activity limitation
- Cough with or without sputum production
- Acute exacerbations
- Recurrent LRTIs
- Risk factors

DIAGNOSIS

- Airflow Assessment
- Documented airflow obstruction: FEV1 / FVC <0.7

GOLD 1

Mild: FEV1 \geq 80% predicted

GOLD 2

Moderate: 50% \leq FEV1 < 80%

GOLD 3

Severe: 30% \leq FEV1 < 50%

GOLD 4

Very Severe: FEV1 < 30% predicted

DIAGNOSIS, CONT'D

Modified MRC Dyspnea Scale

Figure 2.8

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

mMRC Grade 0	mMRC Grade 1	mMRC Grade 2	mMRC Grade 3	mMRC Grade 4
I only get breathless with strenuous exercise	I get short of breath when hurrying on the level or walking up a slight hill	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	I stop for breath after walking about 100 meters or after a few minutes on the level	I am too breathless to leave the house or I am breathless when dressing or undressing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Reference: ATS (1982) Am Rev Respir Dis. Nov;126(5):952-6.

mMRC: Modified Medical Research Council dyspnea scale

Figure 2.9

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 <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	I am very sad	Score
I never cough	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	I cough all the time	
I have no phlegm (mucus) in my chest at all	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 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 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	I am not at all confident leaving my home because of my lung condition	
I sleep soundly	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	I don't sleep soundly because of my lung condition	
I have lots of energy	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	I have no energy at all	

CAT: COPD Assessment Test assessing health in COPD

COPD ABE ASSESSMENT TOOL

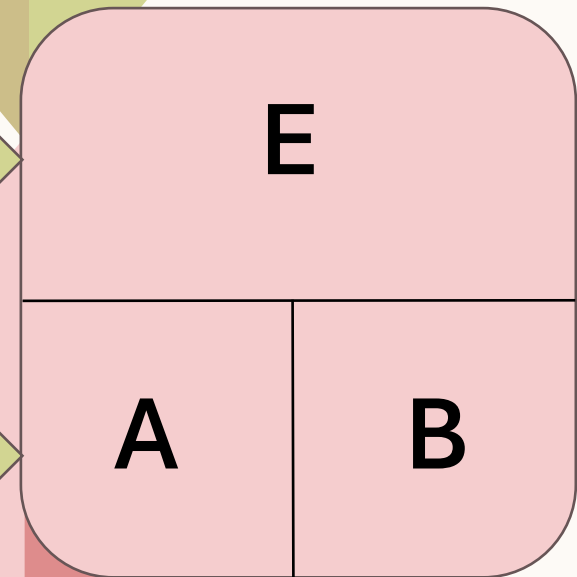
Spirometric diagnosis → Airflow obstruction assessment → Symptom/exacerbation risk assessment

Post bronchodilator
FEV1/FVC
< 0.7

FEV1 GOLD
Category

≥2 moderate exacerbations
OR
≥ 1 leading to hospitalization

0 or 1 moderate exacerbation
(no hospitalization)



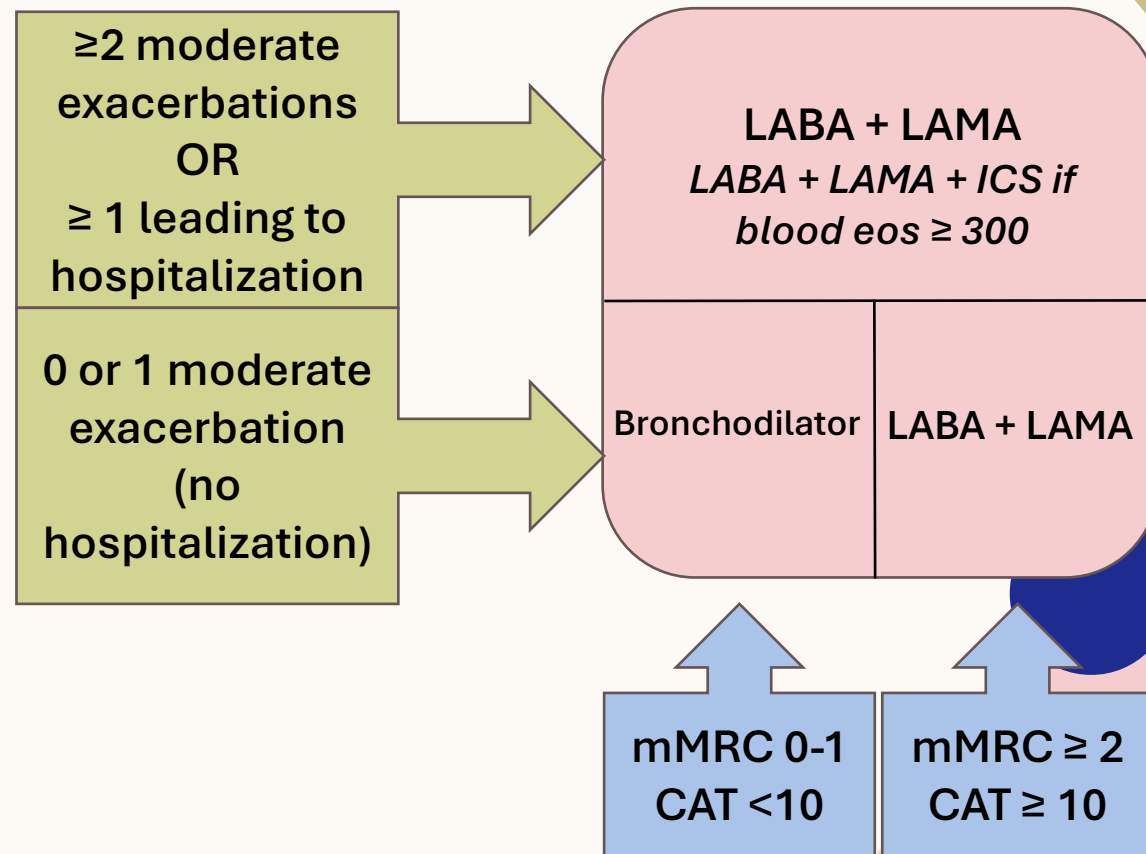
mMRC 0-1
CAT < 10

mMRC ≥ 2
CAT ≥ 10

ADDITIONAL ASSESSMENT

- **Smoking status**
 - Recommend cessation
- **Vaccinations**
 - Ensure appropriate vaccinations up to date
- **Blood eosinophil count**
 - Predictor of ICS benefit; may direct therapeutic choices
 - ≥ 300 cells/ μL
- **Comorbidities**
 - Impact mortality and hospitalization independent of airflow obstruction

INITIAL THERAPEUTIC MANAGEMENT



Single combination inhaler may be more convenient and effective by improving adherence to therapy

BRONCHODILATORS

Short – Acting (SABA)s		
Agent	Brand Names	Delivery Method
Albuterol	ProAir, Proventil, Ventolin	MDI, DPI
Levalbuterol	Xopenex	MDI
Long – Acting (LABA)s		
Arformoterol	Brovana	Nebulizer
Formoterol	Perforomist	DPI
Olodaterol	Striverdi	DPI
Salmeterol	Serevent	DPI

ANTICHOLINERGICS

Short – Acting (SAMA)s		
Agent	Brand Names	Delivery Method
Ipratropium	Atrovent	MDI
Long – Acting (LAMA)s		
Acclidinium	Tudorza Pressair	DPI
Tiotropium	Spiriva	DPI, SMI, MDI
Umeclidium	Incruse	DPI
Revefenacin	Yupelri	Nebulizer

COMBINATION BRONCHODILATOR & ANTICHOLINERGIC

SABA & SAMA		
Agent	Brand Names	Delivery Method
Albuterol/ipratropium	Combivent	MDI, SMI
LABA & LAMA		
Formoterol/aclidinium	Duaklir Pressair	DPI
Vilanterol/umeclidinium	Anoro Ellipta	DPI
Olodaterol/tiotropium	Stiolto Respimat	SMI

COMBINATION INHALERS WITH CORTICOSTEROIDS (ICS)

LABA & ICS		
Agent	Brand Names	Delivery Method
Formoterol/budesonide	Symbicort, Breyna	MDI, DPI
Formoterol/mometasone	Dulera	MDI
Salmeterol/fluticasone	Advair, Airduo, Wixela	MDI, DPI
Vilanterol/fluticasone	Breo Ellipta	DPI
LABA & LAMA & ICS		
Fluticasone/umeclidinium/ vilanterol	Trelegy Ellipta	DPI
Budesonide/glycopyrrolate/ formoterol	Breztri Aerosphere	MDI

WHEN TO CONSIDER ICS IN COPD

Strongly Favors Use

History of hospitalizations for exacerbations
≥2 moderate exacerbations per year
Blood eosinophils ≥300 cells/μL
History of, or concomitant asthma

Favors Use

1 moderate COPD exacerbation per year
Blood eosinophils 100 to <300 cells/μL

Against Use

Repeated pneumonia events
Blood eosinophils <100 cells/μL
History of mycobacterial infection

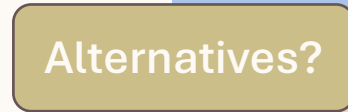
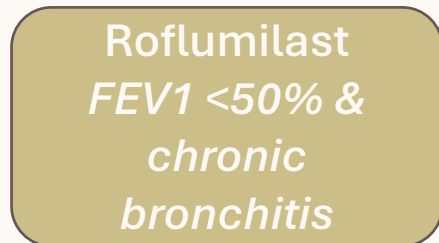
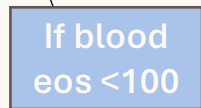
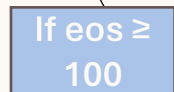
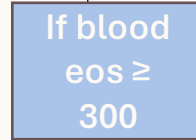
FOLLOW – UP THERAPY MANAGEMENT

Dyspnea



Consider switching inhaler device or molecules; Implement/escalate non-pharm treatment; Investigate/treat other causes of dyspnea

Exacerbations



ROFLUMILAST

- Phosphodiesterase-4 inhibitor
- Once daily oral medication
- Consider in patients not controlled on LABA/LAMA or triple therapy with low eos and chronic bronchitis
- Calverley et. al demonstrated:
 - Reduced moderate/severe exacerbations (requiring systemic corticosteroids) in
 - Patients with chronic bronchitis
 - Severe/very severe COPD
 - Exacerbation history

ANTIBIOTICS

- Previous studies showed no effect of continuous prophylactic macrolides on exacerbation frequency
- Azithromycin (250 mg daily/500 mg three times weekly) or erythromycin (250 mg twice daily) for one year reduced exacerbation risk compared to usual care
 - Reduced benefit in active smokers
 - Bacterial resistance risk, QTc prolongation, impaired hearing tests
- Fluoroquinolones (Moxifloxacin) and tetracyclines (doxycycline) have shown no benefit in studies

ALTERNATIVE OPTIONS FOR COPD MANAGEMENT?

- Type 2 inflammation present in 20 to 40% of patients with COPD
 - Associated with increased risk of exacerbations
 - More common elevations in interleukin-5, interleukin-4, interleukin-13, type 2 innate lymphoid cells and type 2 helper T cells
 - Increased levels of these can lead to elevated eosinophil counts in sputum, bronchial tissue and blood; also increases elevated levels of fractional exhaled nitric oxide (FeNO)
- Those with type 2 inflammation may respond better to glucocorticoids
- IL-5 pathway drives eosinophil maturation and survival
- IL-4 and IL-13 pathways increase FeNO level and promote eosinophil and type 2 inflammatory cell infiltrates into lung

INFLIXIMAB

- Assessed in patients with moderate to severe COPD from 2003 to 2004
- 1:1:1 placebo (n=77):infliximab 3mg/kg(n=78): infliximab 5mg/kg (n=79) at weeks 0, 2, 6, 12, 18 and 24
- Primary endpoint: Chronic Respiratory Questionnaire improvement
 - Medication generally well tolerated but no treatment benefits shown
- No change in prebronchodilator FEV1, 6-minute walking distance, or moderate-to-severe exacerbations
- Possible increase in malignancy (9/157 in infliximab group vs. 1/77 in placebo group)

MEPOLIZUMAB

Anti IL-5 monoclonal antibody (subcutaneous injection) studied for eosinophilic COPD

METREX and METREO trials

- Studied in COPD with history of moderate/severe exacerbations while on triple therapy with eos ≥ 150 cells/ μ L and ≥ 300 cells/ μ L
- Inconsistent results
 - METREX: Eosinophilic COPD mean annual rate of exacerbation compared to placebo (1.4 vs 1.71, rate ratio 0.82; 95% CI 0.68 – 0.98, P=0.04); non-eosinophilic COPD not statistically significant
 - METREO: Statistically non-significant decrease in rate ratio for both 100 mg and 300 mg vs. placebo
- Greater effect seen on annual rate of exacerbation reduction in those with higher blood eos at screen

Currently Phase III MATINEE Trial ongoing

- ≥ 40 y/o with one or more moderate/severe exacerbations in previous 12 months optimized on ICS+LABA+LAMA (≥ 3 months) and eos ≥ 300 cells/ μ L and ≥ 150 cells/ μ L at visit 0 and historically

BENRALIZUMAB

- Anti-IL5R monoclonal antibody (subcutaneous injection) studied for use in prevention of exacerbations in moderate to severe COPD
- GALATHEA and TERRANOVA trials assessed utilization as add-on therapy COPD with frequent exacerbations and eos either ≥ 220 cells/ μL or < 220 cells/ μL
- Inconsistent results

GALATHEA

Primary endpoint:
Estimated mean annual rate of exacerbation with 100 mg dose compared to placebo (1.03 vs 1.24, rate ratio 0.83; 95% CI 0.90 – 1.19, P=0.05) and 30 mg dose (statistically non-significant)

TERRANOVA

Primary endpoint:
Estimated mean annual rate of exacerbation with 10 mg, 30 mg, 100mg vs. placebo

Statistically non-significant decrease in rate ratio for 10 mg, 30 mg, and 100 mg at 56 week

Eosinophil depletion with use

RESOLUTE

Phase III ongoing
40 – 85 y/o with moderate/severe COPD and ≥ 2 exacerbations in the prior year on triple therapy (≥ 3 months) with blood eos ≥ 300 cells/ μL at screening and ≥ 150 cells/ μL historically

DUPIILUMAB

- Anti-IL4R/IL13 monoclonal antibody
- Current indications: Atopic dermatitis, moderate-to-severe OCS dependent asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), eosinophilic esophagitis, prurigo nodularis, chronic spontaneous urticaria
- Approved for COPD September 27, 2024
- First biologic approved for use in eosinophilic phenotype COPD

BOREAS TRIAL

- Inclusion criteria:

- 40 – 80 years old with diagnosed COPD > 12 months before randomization
- Current or former smokers (minimum 10 pack years)
- Post bronchodilator FEV1 30 – 70% predicted normal value
- Dyspnea score of 2 or greater on mMRC
- On triple therapy for ≥ 3 months prior to randomization, with 1-month stable dose
- Chronic bronchitis symptoms for ≥ 3 months during year prior to screening
- Blood eos ≥ 300 cells/ μ L
- High exacerbation risk

- Exclusion Criteria

- Current diagnosis or history of asthma
- Exacerbations during screening
- Active tuberculosis, latent untreated TB
- Inhaler noncompliance
- Received live, attenuated vaccines within 4 weeks prior to visit 1
- Macrolide use (unless stable >12 months)

BOREAS TRIAL

- Mean (\pm SD) age was 65.1 \pm 8.1 years; predominantly male; non-Hispanic or non-Latino and White
- Randomized 1:1 to receive Dupilumab 300 mg subcutaneously every other week or placebo
- Primary end point: Annualized rate of moderate or severe COPD exacerbations over 52 weeks
- Secondary end points: Change in prebronchodilator FEV1, St. George's Respiratory Questionnaire (SGRQ) and Evaluating Respiratory Symptoms in COPD (E-RS-COPD)
- Intention to treat; estimated 462 individuals needed in each group to reach 90% power; 2-sided alpha level 0.049
- 939 patients underwent randomization: 468 in dupilumab group; 471 in placebo group

RESULTS

- Primary End Point: Annual rate of moderate or severe exacerbations with dupilumab 0.78 (95% CI 0.64 – 0.93) vs. 1.1 (95% CI 0.93 – 1.3) with the placebo [rate ratio: 0.7 (95% CI 0.58 – 0.86), P<0.001]

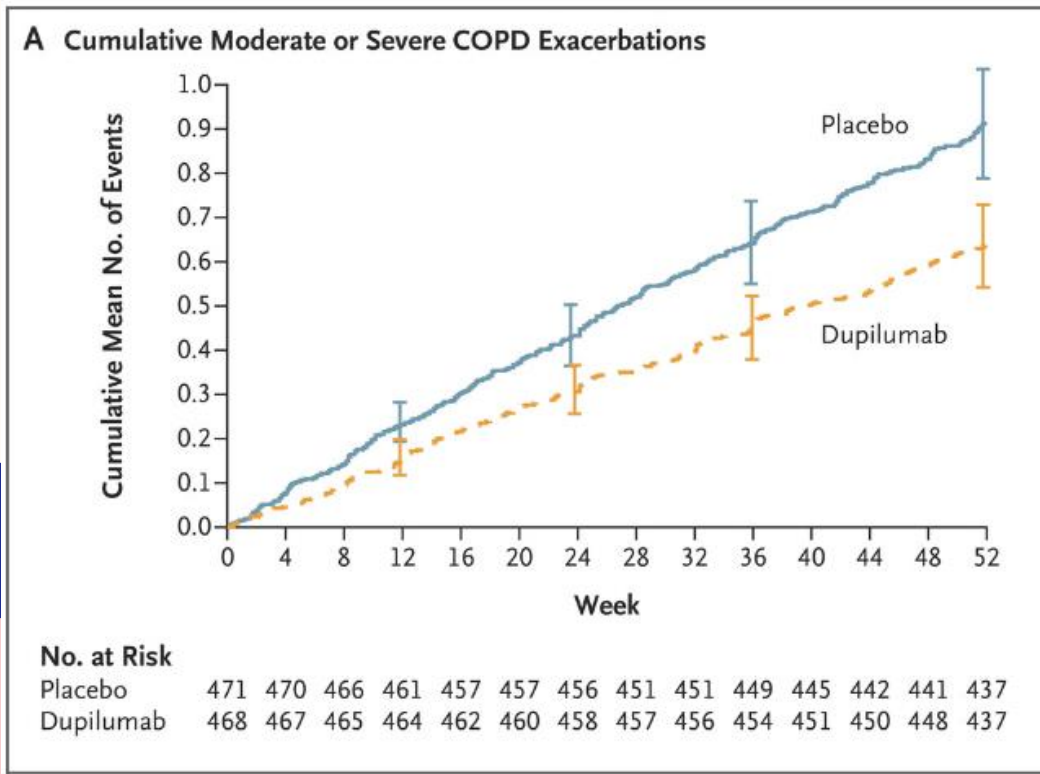
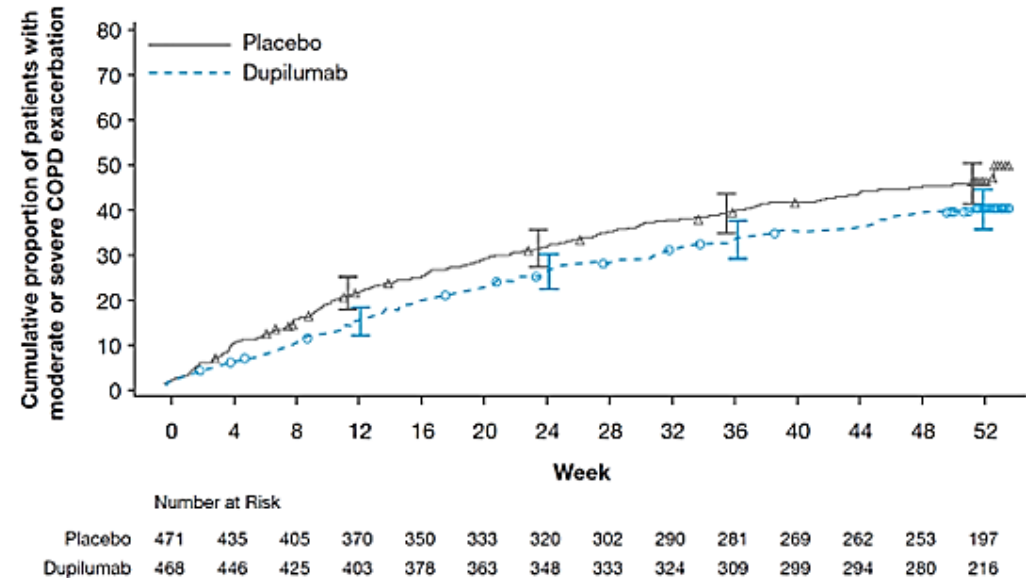
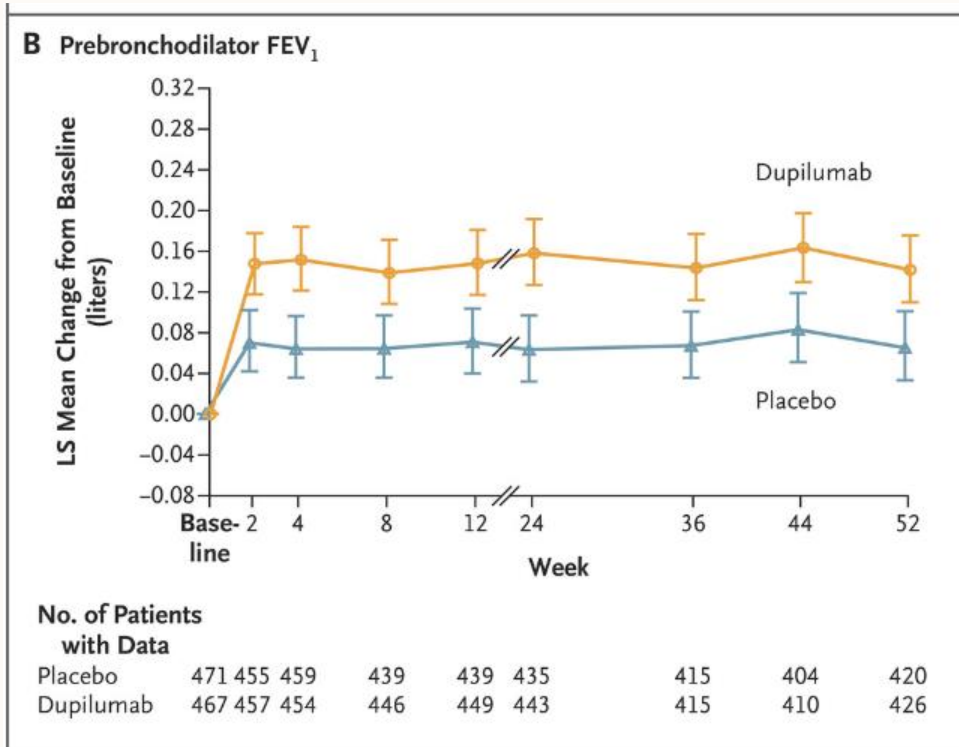


FIGURE S4. TIME-TO-FIRST MODERATE OR SEVERE COPD EXACERBATION DURING THE 52-WEEK TREATMENT PERIOD



RESULTS

Secondary outcomes:
Prebronchodilator FEV1



At week 12:
 Dupilumab: 160 mL (95% CI 126 to 195)
 Placebo: 77 mL (95% CI 42 to 112)
 Least squares mean difference: 83 mL (95% CI 42 to 125, P<0.001)

Improvement observed within 2 weeks of initiating dupilumab and sustained through week 52
 Dupilumab: 153 mL (95% CI 116 to 189)
 Placebo: 70 mL (95% CI 33 to 107)
 Least squares mean difference: 83 mL, 95% CI 38 to 128, P<0.001

RESULTS

Secondary End Point	Least Squares Difference vs. Placebo	P - value
Change in SGRQ from baseline at week 52	-3.4 (95% CI -5.5 to -1.3)	P = 0.002
Change in E-RS-COPD from baseline at week 52	-1.1 (95% CI -1.8 to -0.4)	P = 0.001

Safety End Point	Dupilumab (n%)	Placebo (n%)
Any adverse event	363 (77.4%)	357 (76%)
Any serious adverse event	64 (13.6%)	73 (15.5%)

NOTUS TRIAL

36

- **Inclusion criteria:**
 - 40 – 85 years old with diagnosed COPD > 12 months before randomization
 - Blood eos \geq 300 cells/ μ L
 - Current or former smokers (minimum 10 pack years)
 - Post bronchodilator FEV1 30 – 70% predicted normal value
 - Dyspnea score of 2 or greater on mMRC
 - On triple therapy for \geq 3 months prior to randomization, with 1-month stable dose
 - Chronic bronchitis symptoms for \geq 3 months during year prior to screening
 - High exacerbation risk
- **Exclusion Criteria**
 - Current diagnosis or history of asthma
 - Exacerbations during screening
 - Active tuberculosis, latent untreated TB
 - Inhaler noncompliance
 - Received live, attenuated vaccines within 4 weeks prior to visit 1
 - Macrolide use (unless stable >12 months)
 - Omalizumab use within 130 days
 - Exposure to investigative drugs within 6 months
 - Numerous cardiac exclusions
 - Active or history of malignancy
 - Active autoimmune diseases
 - Active infectious (viral, bacterial, helminth, etc.)
 - Hepatic disorder

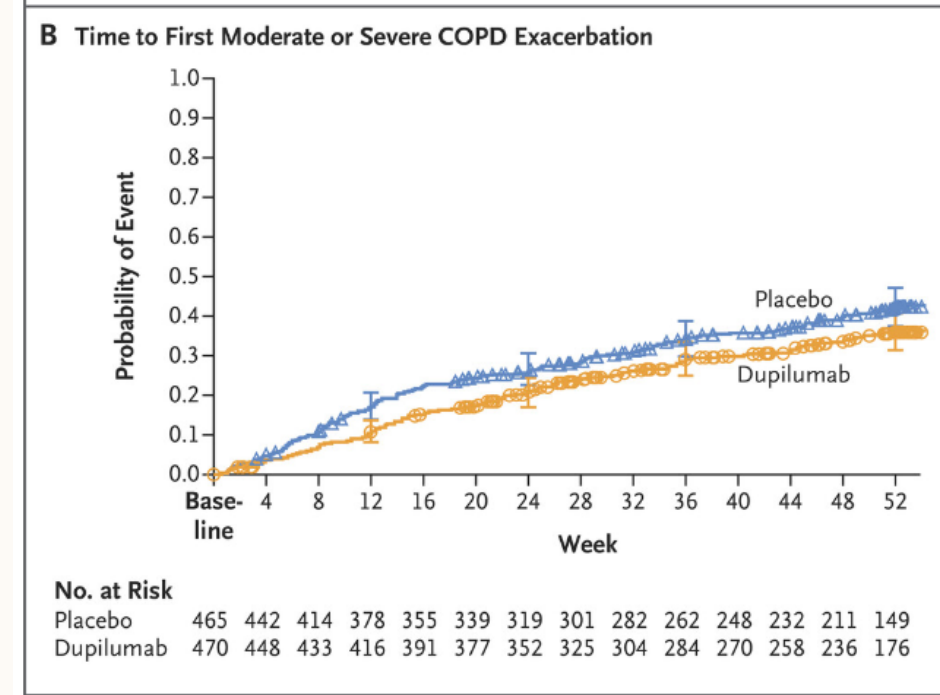
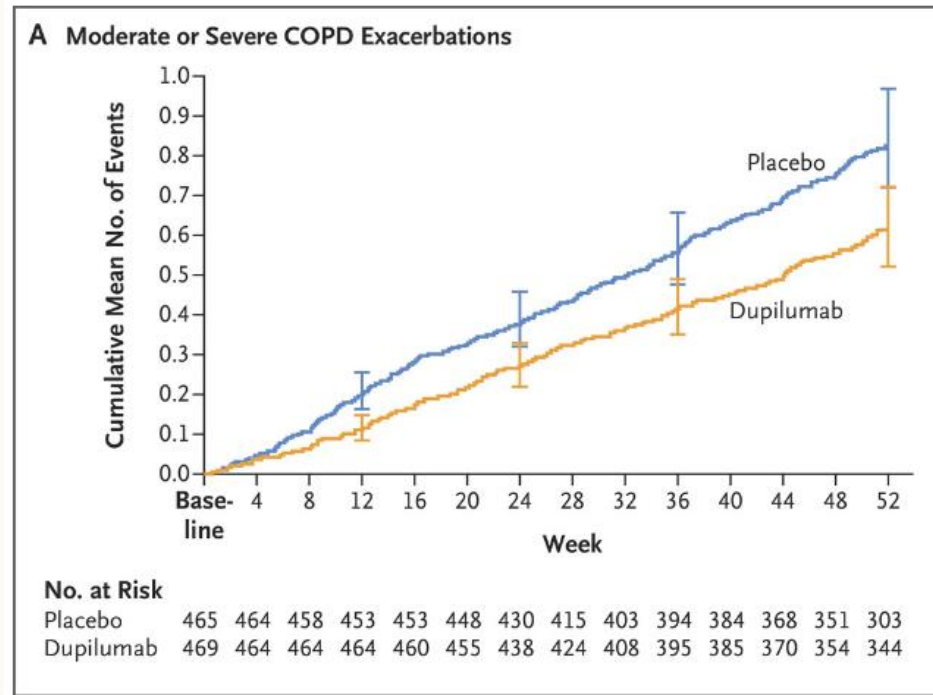
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- Intention to treat; estimated 462 individuals needed in each group to reach 90% power; 2-sided alpha level 0.05
- 935 patients underwent randomization: 470 in dupilumab group; 465 in placebo group

RESULTS

Primary End Point:

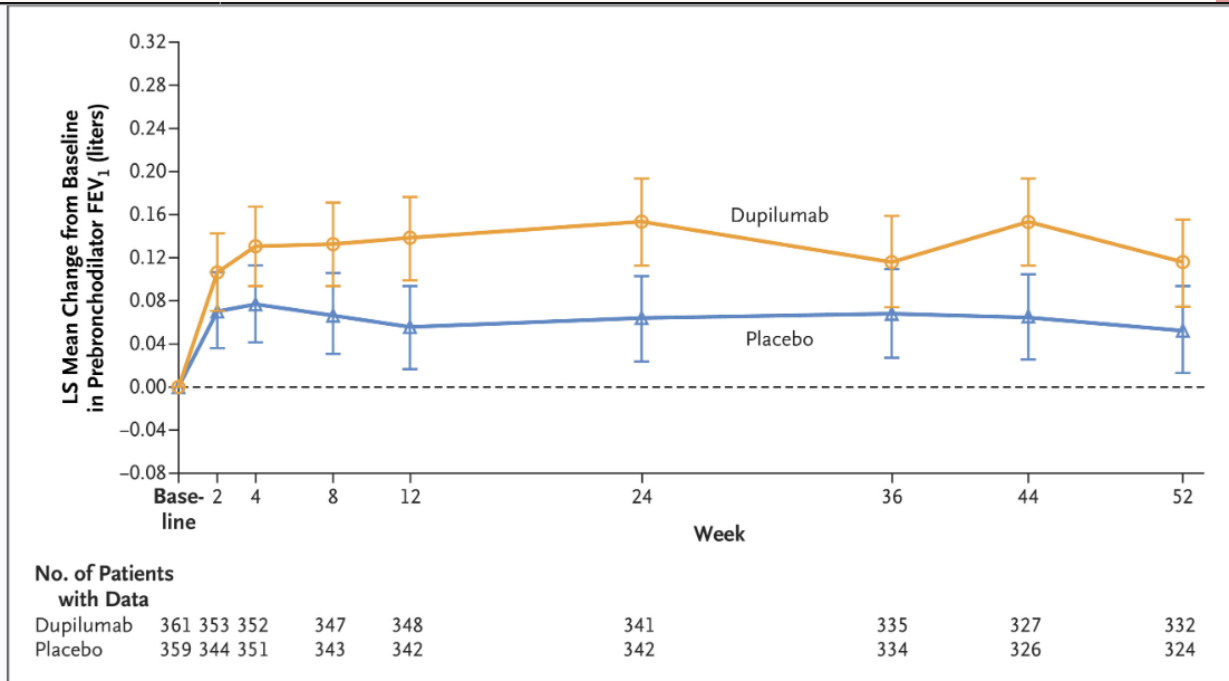
Annual rate of moderate or severe exacerbations with dupilumab 0.86 (95% CI 0.7 – 1.06) vs. 1.3 (95% CI 1.05 – 1.6) with the placebo [rate ratio: 0.66 (95% CI 0.54 – 0.82), $P < 0.001$]



RESULTS

Secondary outcomes:
Prebronchodilator FEV₁

At week 12:
 Dupilumab: 139 mL (95% CI 105 to 173)
 Placebo: 57 mL (95% CI 23 to 91)
 Least squares mean difference: 82 mL (95% CI 40 to 124, P<0.001)



Improvement sustained through week 52
 Dupilumab: 115 mL (95% CI 75 to 156)
 Placebo: 54 mL (95% CI 14 to 93)
 Least squares mean difference: 62 mL, 95% CI 11 to 113, P=0.02

RESULTS

Secondary End Point	Least Squares Difference vs. Placebo
Change in SGRQ from baseline at week 52	-3.4 (95% CI -5.8 to -0.9)
Change in E-RS-COPD from baseline at week 52	-0.6 (95% CI -1.4 to -0.2)

Safety End Point	Dupilumab (n%)	Placebo (n%)
Any adverse event	313 (66.7%)	306 (65.9%)
Any serious adverse event	61 (13%)	74 (15.9%)

Study Conclusion: “Our trial confirmed that add-on dupilumab treatment reduced the rate of exacerbations and increased lung function in patients with COPD with type 2 inflammation as indicated by blood eosinophil counts.”

ENSIFENTRINE

Novel phosphodiesterase 3 (PDE3) and phosphodiesterase 4 (PDE4) inhibitor approved June 2024 via standard jet nebulizer twice daily

ENHANCE trials

- Studied in symptomatic moderate-to-severe COPD between 40 and 80 years with postbronchodilator FEV1 between 30 and 70% and minimal 10 pack smoking history
- No long-acting maintenance therapy or on LABA (with or without ICS) or LAMA (with or without ICS)
- ENHANCE-1: 763 patients, average FEV1 area under the curve at 0 – 12 hours vs placebo (87 mL, 95% CI 0.55 – 119, P<0.001); reduced rate of moderate/severe exacerbations over 24 weeks (0.64, 95%CI 0.4 – 1, P=0.05)
- ENHANCE-2: 789 patients, average FEV1 area under the curve at 0 – 12 hours vs placebo (94 mL, 95% CI 65 – 124, P<0.001); reduced rate of moderate/severe exacerbations over 24 weeks (0.57, 95%CI 0.38 – 0.87, P=0.009)

Limitations

- Administered to <3000 people globally
- Not in GOLD algorithm yet; exact population unclear
- Cost and insurance

TEZEPelumAB

- May 2024 - Phase IIa COURSE Trial
- Currently FDA approved for severe asthma
- Tezepelumab studied in moderate-to-severe COPD with a broad range of eosinophils (BEC) irrespective of emphysema, chronic bronchitis and smoking status
- Blocks thymic stromal lymphoprotein, epithelial cytokine that plays a role in chronic airway inflammation
- Subcutaneous injection every 4 weeks vs. placebo
 - On triple inhaled maintenance therapy with ≥ 2 exacerbations in the past 12 months

Endpoints:

Reduced annualized rate of moderate or severe exacerbations vs placebo:

17% (90%CI -6-36, P=0.1042)

Greater reductions in patients with higher BECs

Also improved least-squares mean change in pre-bronchodilator FEV1 from baseline to week 52:

55mL (95% CI 14 – 96 mL)

ONGOING TRIALS

- **Tozorakimab**
 - Anti-IL-33 in COPD patients with history of exacerbations
 - OBERON, PROSPERO, TITANIA, MIRANDA
 - Late 2026 completion projections
- **Itepekimab**
 - Anti-IL-33 in moderate-to-severe COPD patients that are former smokers
 - AERIFY-1, AERIFY-2
 - Late 2025 completion projection

MANAGING COPD AS A PHARMACIST

- Pharmacotherapy is key but more to it
 - Device selection/adherence
 - Access/healthcare disparities
 - Transitions of care
 - Comorbid care

DEVICE SELECTION

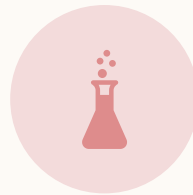


- 22 different inhaler devices available
 - Nebulizers
 - Metered-dose inhalers (MDIs) [with or without valved holding chamber (VHC)/spacers]
 - Breath-actuated MDIs (BAIs)
 - Soft mist inhalers (SMIs)
 - Dry powder inhalers (DPIs)
- Technique verification ideally at each visit

CONSIDERATIONS FOR DEVICE SELECTION



What class of medication is indicated for the GOLD class?



What formulations/devices are available?



Can the patient access the device (financial/insurance/etc.)?



Can the patient handle the device? (Physical maneuvers)



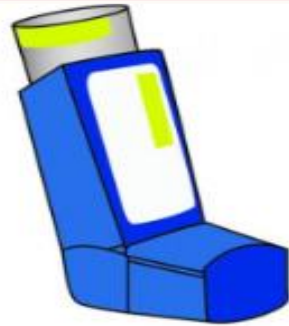
Can the patient perform correct inhalation technique?



If DPI – does the patient have a sufficient peak inspiratory flow?

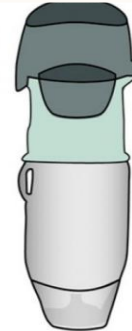
DEVICE ERRORS

- More than 67% of patients make at least one error when using an inhalation device



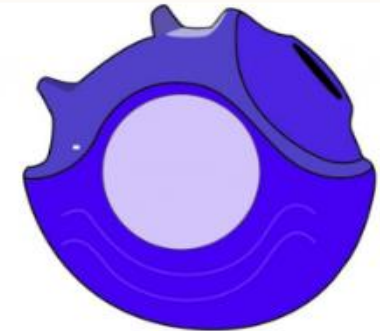
MDI

Coordination
Speed/depth of inhalation
No post-breath hold



SMI

Device preparation
No full exhale before inhaling
No post-breath hold
Inhalation maneuver



DPI

Device preparation
No full exhale before inhaling
No post-breath hold

Mahler DA, Halpin D. *Ann Am Thorac Soc.* 2023;20:1389.

Sanchis J, Gich I, Pedersen S. *Chest.* 2016;150(2):394-406.

Sulaiman I, Cushen B, Greene G, et al. *Am J Respir Crit Care Med.* 2017;195:1333

Images: <https://www.lungsask.ca/lungs/programs-support/inhaler-resources>

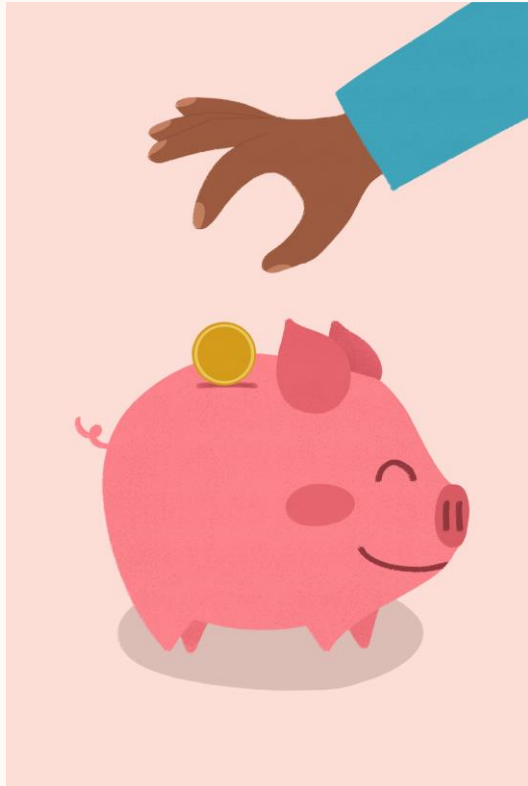
DEVICE SELECTION CONSEQUENCES



In-check DIAL: Handheld inspiratory flow measurement device used to assess peak inspiratory flow (PIF) by simulating resistance for DPIs and MDIs

- Suboptimal Inspiratory Flow Rates Are Associated with Chronic Obstructive Pulmonary Disease and All-Cause Readmissions (Loh, et al)
- Assessed patients in North Carolina from May 2014 – Dec 2015 admitted for acute exacerbations of COPD (AECOPD)
- AECOPD patients are commonly discharged on DPIs (due to fewer steps than MDIs)
- Peak inspiratory flow (PIF) ≤ 60 L/min defined as suboptimal (sPIF)
- 123 patients reviewed; 64 (52%) had sPIF with greater CAT scores ($P=0.0073$), rates of 90-day COPD readmission ($P=0.048$), all-cause readmissions ($P=0.009$)
- sPIF patients had significantly lower all-cause and COPD 30- and 90-day readmission rates when discharged on nebulizer versus DPI

MEDICATION ACCESS



Inhalers/inhaled therapies are expensive

Patients may need financial assistance to improve adherence

Free trials

Patient assistance programs

- Manufacturer access programs
- Rxassist.org
- Rxhope.com

\$35 inhaler cap

- Participating: GSK, AstraZeneca, Boehringer Ingelheim

Dispensary of Hope

Needy meds.org

GoodRx

Rxoutreach.org

MEDICATION ACCESS

- **Biologics require additional considerations**
 - Immune status (helminth infections)
 - Live vaccines
 - Pregnancy or breastfeeding
 - Eye issues
 - Hypersensitivity
 - Needle/injection phobia



TRANSITIONS OF CARE

Inpatient

- Medication reconciliation
 - Med name, formulation, dose/route/frequency, when last taken
- Continue home meds/devices when able to
 - Change to similar device if necessary
- Discharge counseling
- Encourage patient/family engagement
- Continuity of care (post acute follow up appointments scheduled, referrals)

Outpatient

- Medication reconciliation
 - Med name, formulation, dose/route/frequency, when last taken
- Assess/reinforce inhaler technique
- Assist with financial barriers
- Encourage patient/family engagement
- Smoking cessation
- Assess COPD triggers/comorbid conditions
- Continuity of care (follow ups, telehealth)

SMOKING CESSATION

Ask

Advise

Assess

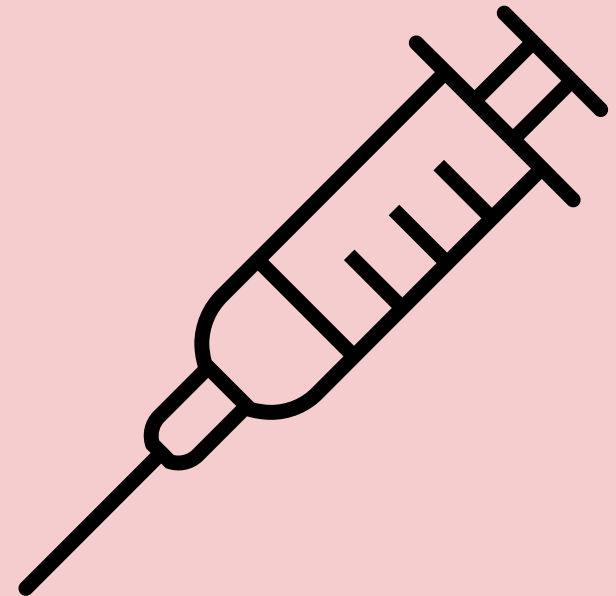
Assist

Arrange

VACCINATIONS

Ensure vaccinations up to date

- Influenza vaccine annually
- Pneumococcal conjugate (PCV21 or PCV20)
- COVID vaccine
- RSV Vaccine
 - Bivalent prefusion F protein-based vaccine or prefusion F protein vaccine
- Tdap vaccine
- Zoster vaccine



68-YEAR-OLD WOMAN WITH 50-PACK-YEAR SMOKING HISTORY: WORSENING COPD SYMPTOMS AND CHRONIC COUGH WITH COPIOUS SPUTUM PRODUCTION DESPITE RECEIVING INHALED TRIPLE THERAPY (LABA/LAMA/ICS). SHE EXPERIENCES FREQUENT EXACERBATIONS, REQUIRING ORAL CORTICOSTEROIDS MULTIPLE TIMES IN THE PAST YEAR. HER LUNG FUNCTION TESTS SHOW AN FEV1 OF 53% PREDICTED AND AN FEV1/FVC RATIO OF 0.60 POST-BRONCHODILATOR. A COMPLETE BLOOD COUNT REVEALS A PERSISTENT BLOOD EOSINOPHIL COUNT OF 450 CELLS/ML. SHE DENIES ANY HISTORY OF ASTHMA OR OTHER ALLERGIC DISEASES. WHAT WOULD BE THE BEST STEP TO MANAGE HER COPD?

1. Add Azithromycin
2. Add Roflumilast
3. Add Dupilumab
4. Decrease to LABA/LAMA

WHAT IS MOST IMPORTANT TO REDUCE COPD READMISSIONS?

1. Appropriate pharmacotherapy
2. Smoking cessation
3. Vaccinations
4. Medication/inhaler counseling
5. All of the above

**BREATH OF FRESH AIR:
THE LATEST PUFF ON COPD
UPDATES**

**THANK YOU!
QUESTIONS?**

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