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BREATHE EASY: GOLD 2025 GUIDELINES AT A GLANCE

The 2025 report from the Global Initiative for Chronic Obstructive Lung Disease (GOLD) marks a pivotal moment in the global approach to the diagnosis, management, and prevention of Chronic Obstructive Pulmonary Disease (COPD). Drawing from the latest evidence, the updated guidelines aim to improve patient outcomes by highlighting the importance of comorbidities, environmental risk factors, novel therapies, and refined diagnostic strategies.

1. Emphasis on Comorbidities and Cardiovascular Risk

For the first time, GOLD 2025 places strong emphasis on structured follow-up post-COPD exacerbations, recognizing the significantly increased cardiovascular risk during this time. New guidance recommends patient evaluations at 1–4 weeks and again at 12–16 weeks post-exacerbation to assess treatment response, detect comorbid conditions, and review medication adherence and inhaler technique.

Additionally, guidance has been introduced for managing Pul includes a treatable traits apmonary Hypertension in COPD (PH-COPD) patients. This proach to tailor therapies based on individual risk profiles and underlying causes.

2. Recognition of Climate and Environmental Risk

GOLD 2025 acknowledges the growing role of environmental risks, particularly climate change, in COPD exacerbations. Patients exposed to high air pollution, temperature extremes, and wildfire smoke are at increased risk for symptom worsening and hospitalizations. Clinicians are encouraged to integrate environmental exposure history into COPD risk assessments.

3. Improved Spirometry Interpretation

While the post-bronchodilator FEV?/FVC < 0.70 ratio remains the diagnostic benchmark, the updated report cautions against overreliance on this fixed value. It may result in overdiagnosis in older individuals and underdiagnosis in younger populations. GOLD 2025 promotes the complementary use of Lower Limit of Normal (LLN) and z-scores for a more accurate interpretation of lung function tests.

4. Introduction of New Therapeutic Options

The 2025 report integrates two new medications into the COPD treatment landscape: Ensifentrine and Dupilumab. Ensifentrine, a dual PDE3/4 inhibitor, is noted for its bronchodilatory and anti-inflammatory effects. Dupilumab, previously used in asthma, shows promise in reducing exacerbations in eosinophilic COPD.

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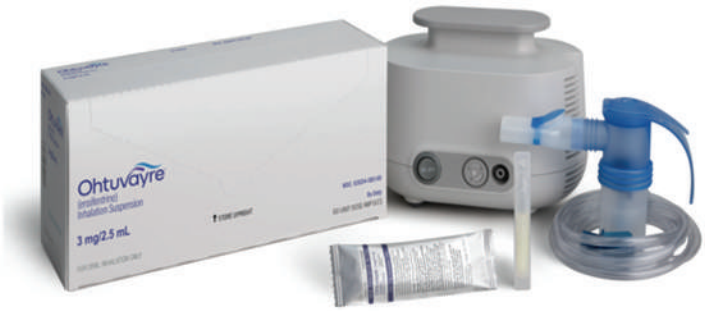
5. Updated Immunization Guidance and COVID-19 Integration

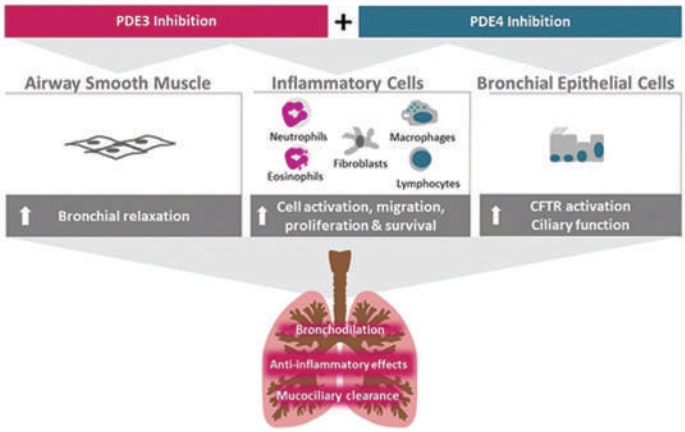
Vaccination remains a key component of COPD care. The GOLD 2025 recommendations align with current CDC guidance, emphasizing influenza, pneumococcal, COVID-19, and RSV vaccines. Notably, the previously separate COVID-19 chapter has been removed, with relevant content now integrated throughout the report.

ENSIFENTRINE: A BREAKTHROUGH IN COPD TREATMENT

In 2024, the U.S. FDA approved Ensifentrine, an innovative inhaled medication for the treatment of Chronic Obstructive Pulmonary Disease (COPD). Ensifentrine represents the first novel class of bronchodilator in over two decades, offering both bronchodilatory and anti-inflammatory effects. Its approval brings a significant advancement in the management of moderate to severe COPD, especially for patients inadequately controlled with current therapies.



Mechanism of Action



Clinical Trials and Efficacy

The FDA approval was based on the results of the ENHANCE-1 and ENHANCE-2 Phase 3 trials. These randomized, double-blind, placebo-controlled studies evaluated the efficacy and safety of ensifentrine in over 1,500 patients with moderate to severe COPD.

Key findings from the trials include:

- Significant improvement in lung function (increase in FEV?) over 12 hours post-dose.
- Approximately 40% reduction in the rate of moderate and severe COPD exacerbations.
- Improved quality of life as measured by patient-reported outcomes and symptom scores.
- Consistent efficacy in both monotherapy and add-on therapy to existing maintenance treatments.

Administration and Dosage

Ensifentrine is supplied as a 3 mg/2.5 mL unit-dose solution for inhalation. It is administered via a standard jet nebulizer with a mouthpiece. The recommended dose is 3 mg inhaled twice daily. It is not indicated for acute symptom relief or as a rescue medication. Patients must be trained properly on nebulizer use for optimal drug delivery.

Safety and Side Effects

Ensifentrine has demonstrated a favorable safety profile. Common adverse reactions reported during clinical trials include:

- Back pain (1.8%)
- Hypertension (1.7%)
- Urinary tract infection (1.3%)
- Diarrhea (1.0%)

Rare but serious side effects include paradoxical bronchospasm, hypersensitivity reactions, and psychiatric symptoms such as anxiety and depression. Physicians are advised to monitor patients for any new or worsening symptoms after initiation of therapy.

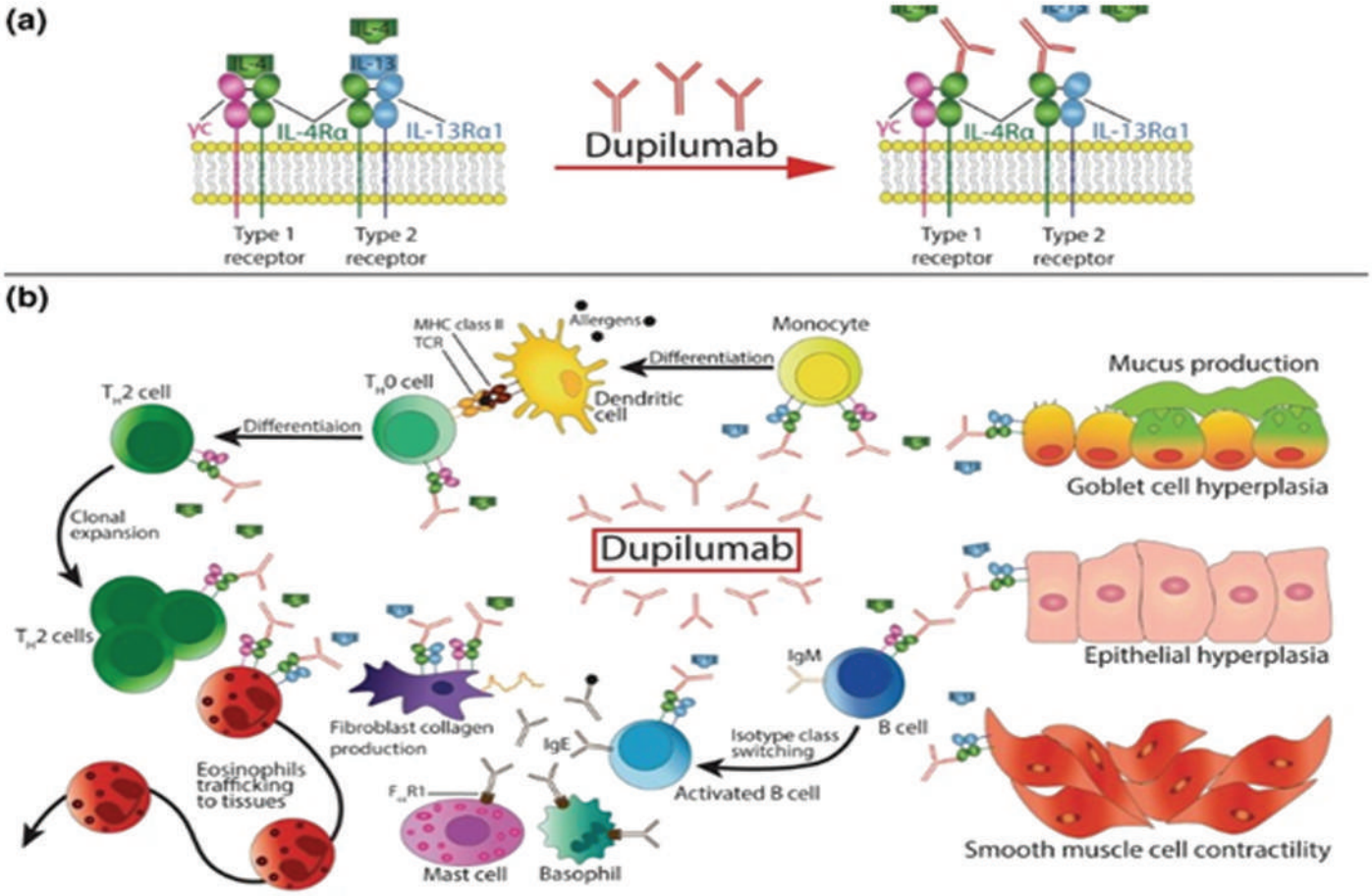
Patient Selection

Ensifentrine is best suited for COPD patients who remain symptomatic despite existing maintenance therapies. It is also a valuable option for patients who have difficulty using handheld inhalers, as nebulized delivery may offer improved adherence. Clinical judgment should guide its use, especially in individuals with cardiovascular comorbidities or psychiatric history.

DUPILUMAB: A NEW ERA IN COPD TREATMENT

In September 2024, the U.S. Food and Drug Administration (FDA) approved Dupixent (dupilumab) as the first biologic therapy for adults with uncontrolled COPD characterized by an eosinophilic phenotype. This approval marks a significant advancement in the management of COPD, offering a novel treatment option for patients inadequately controlled with standard inhaled therapies.

Mechanism of Action



Clinical Trial Highlights

The FDA approval was based on two pivotal Phase 3 trials, BOREAS and NOTUS, which evaluated Dupixent in adults with moderate-to-severe COPD and elevated blood eosinophil counts (≥300 cells/μL).

Key Findings

• Reduction in Exacerbations: Dupixent demonstrated a 30% and 34% reduction in the annualized rate of moderate or severe COPD exacerbations in the BOREAS and NOTUS trials, respectively.

• Improved Lung Function: Patients treated with Dupixent showed significant improvements in pre-bronchodilator FEV? at 12 weeks, with increases of 160 mL in BOREAS and 139 mL in NOTUS, compared to 77 mL and 57 mL in the placebo groups.

• Enhanced Quality of Life: Dupixent-treated patients reported improvements in health-related quality of life, as measured by the St. George's Respiratory Questionnaire (SGRQ).

Patient Eligibility

Dupixent is indicated as an add-on maintenance treatment for adults with uncontrolled COPD and an eosinophilic phenotype, defined by blood eosinophil counts ≥300 cells/μL. It is intended for patients who continue to experience exacerbations despite being on maximal standard-of-care inhaled therapies.

Administration and Dosage

Dupixent is administered via subcutaneous injection at a dose of 300 mg every two weeks. It is supplied in pre-filled syringes or pens for self-administration, following proper training by a healthcare provider.

Safety Profile

The safety profile of Dupixent in COPD patients is consistent with its known safety in other approved indications. Common adverse events observed in clinical trials included nasopharyngitis, headache, back pain, and injection site reactions. Serious adverse events were rare and occurred at similar rates in the Dupixent and placebo groups.

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19th Annual Day Celebrations

World Earth Day

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