

FDA OKs Nucala for Hard-to-Treat COPD

May 23, 2025 -- The FDA has approved the asthma drug Nucala for adults with chronic obstructive pulmonary disease (COPD). It is the second biologic therapy approved for the condition, following the approval of Dupixent for COPD in September.

The approval is the fifth time the drug has been cleared for use and allows it to be used as an add-on treatment for eosinophilic COPD. This form of the disease involves inflammation and higher levels of certain white blood cells (eosinophils) and tends to lead to more frequent flare-ups and hospitalizations.

COPD is a chronic lung condition that gets worse over time, making breathing difficult as inflammation narrows the airways. It affects more than 390 million people and is the third leading cause of death worldwide.

With eosinophilic COPD, even a moderate blood eosinophil count of 150 cells/ μ L — or 150 eosinophils per microliter of blood — is enough to raise the risk of flare-ups, often leading to hospital visits and permanent lung damage. About 70% of COPD patients struggle with flare-ups despite using inhalers, especially when eosinophil levels exceed this threshold. Nucala (generic name mepolizumab) works alongside inhalers.

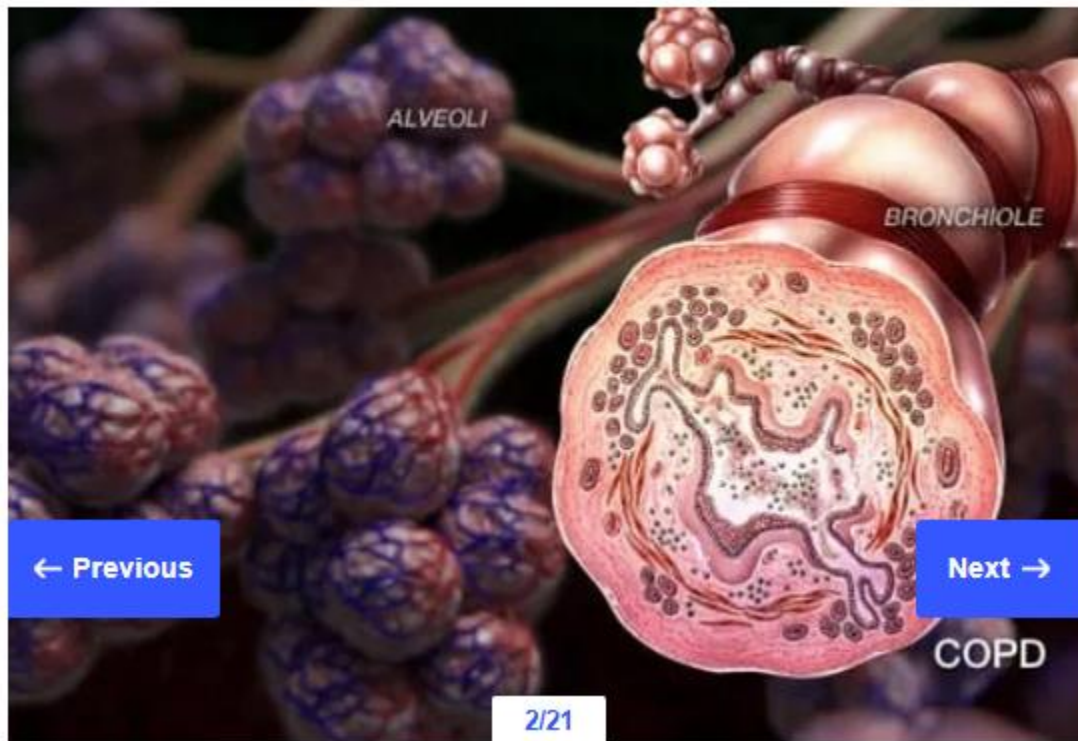
A Visual Guide to COPD



What is COPD?

COPD, or **chronic obstructive pulmonary disease**, is a lung disorder that makes it hard to breathe. The first symptoms can be so mild that people mistakenly chalk them up to "getting old." People with COPD may develop chronic bronchitis, **emphysema**, or both. COPD tends to get worse over time, but catching it early, along with good care, can help many people stay active and may slow the disease.

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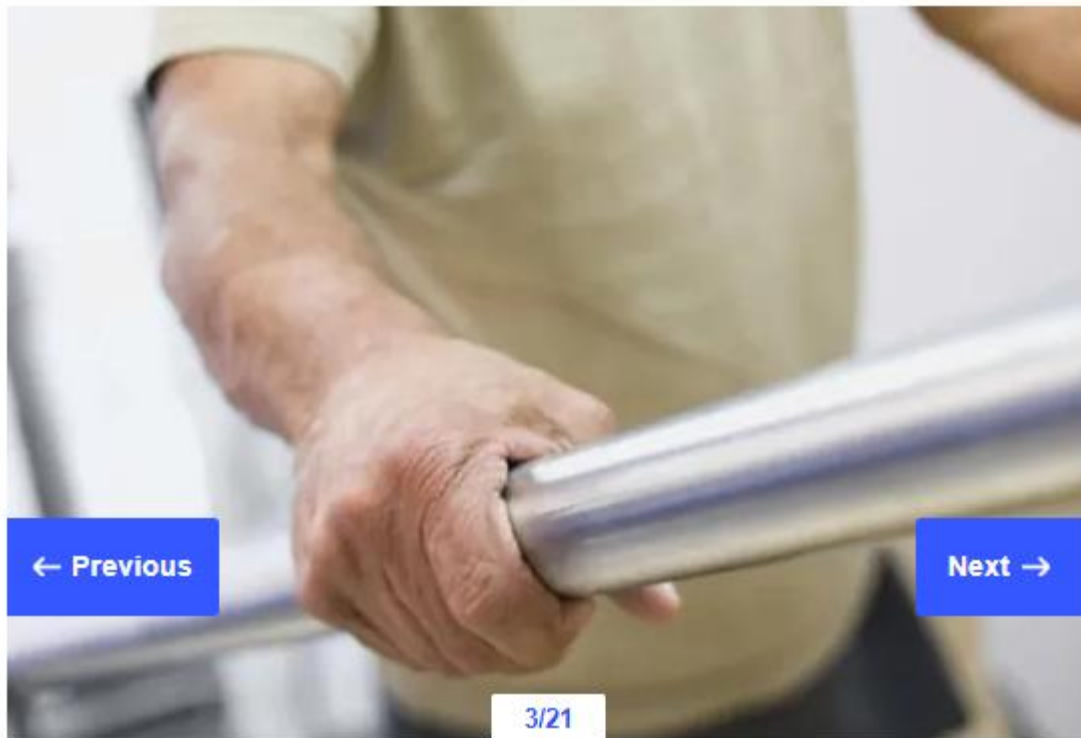


Symptoms of COPD

Inside the lungs, COPD can clog the airways and damage the tiny, balloon-like sacs (alveoli) that absorb oxygen. These changes can cause the following symptoms:

- Shortness of breath in everyday activities
- Wheezing
- Chest tightness
- Constant coughing
- Producing a lot of mucus (sputum)
- Feeling tired
- Frequent colds or [flu](#)

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Advanced Symptoms of COPD

Severe COPD can make it difficult to walk, cook, clean house, or even bathe. Coughing up excess mucus and feeling short of breath may worsen. Advanced illness can also cause:

- Swollen legs or **feet** from fluid buildup
- Weight loss
- Less muscle strength and endurance
- A **headache** in the morning
- Blue or grey lips or fingernails (due to low oxygen levels)

“COPD isn’t just a disease, it’s a relentless cycle,” said Jean Wright, MD, chief executive officer of the COPD Foundation, in a news release. “For individuals living with COPD, managing exacerbations is an ongoing challenge, even with inhaled maintenance therapy. Biologics like mepolizumab are providing renewed optimism for those affected by COPD.”

According to the release — issued by GSK, the drug's maker — the approval was based on two clinical trials involving more than 1,600 patients. In the trials, Nucala significantly reduced the number of flare-ups in patients whose COPD wasn't well controlled with inhalers. Those who received Nucala injections every four weeks had 18% to 21% fewer episodes of moderate to severe exacerbations than those given a placebo.

First approved in 2015, Nucala is a monoclonal antibody, meaning it recruits your body's immune system to fight disease. It helps reduce inflammation by targeting a protein called interleukin-5 (IL5), a major contributor to COPD-related lung inflammation. The drug is given as an injection by a health care provider and is already approved in the U.S. to treat four other conditions related to IL-5. The most common side effects include back pain, diarrhea, and cough, according to GSK.

News Source:

<https://www.webmd.com/lung/copd/news/20250523/fda-oks-nucala-hard-treat-copd>