

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Mepolizumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils ID1237**Final scope****Remit/evaluation objective**

To appraise the clinical and cost effectiveness of mepolizumab within its marketing authorisation for maintenance treatment of chronic obstructive pulmonary disease with raised blood eosinophils (eosinophilic phenotype).

Background

Chronic obstructive pulmonary disease (COPD) is a group of lung conditions that cause breathing difficulties. It includes chronic bronchitis, emphysema, chronic obstructive airways disease and chronic airflow limitation. Smoking is the main cause, but it can also be caused by long-term exposure to harmful fumes or dust. Symptoms include breathlessness, a chronic, productive cough, and difficulty exercising. Lung function usually worsens over time and cannot be fully restored. Type 2 inflammation is associated with higher rates of exacerbations and lower quality of life. It can be identified through raised blood eosinophils and fractional exhaled nitric oxide (FeNO). COPD exacerbations can increase the chance of hospital admission, cardiovascular events, and mortality. They contribute to disease progression and increase the risk of future exacerbations.

There is an estimated 1.2 million people in England with a COPD diagnosis.¹ In 2023 in England, nearly 27,000 people died from it.¹ It is the second most common lung disease in the UK after asthma.² COPD is more common in men and the over 40s, and becomes more common with increasing age.³

Treatment for COPD aims to slow its progression, control symptoms and reduce exacerbations. It includes treatment and support to stop smoking, pneumococcal and influenza vaccinations, pulmonary rehabilitation, a personalised self-management plan, and optimised treatment for comorbidities (see [NICE's guideline on diagnosing and managing COPD in over 16s](#)). If people have stable COPD but are breathless and have limited exercise capacity, they can be offered short-acting beta2 agonists (SABA) or short-acting muscarinic antagonists (SAMA). If they continue to have limiting symptoms or exacerbations, they can have dual therapy with:

- long-acting beta2 agonists (LABA) plus long-acting muscarinic antagonists (LAMA), or
- LABA plus inhaled corticosteroids (ICS).

If people are on dual therapy but continue to have symptoms that adversely affect quality of life, or have 1 severe or 2 moderate exacerbations within a year, the NICE guideline suggests triple inhaled therapy can be trialled. Some recent reports⁴ also suggested that if ICS is indicated, people should be offered LABA plus LAMA plus ICS (triple inhaled therapy) straight away. [NICE also recommends roflumilast for treating chronic COPD](#) (as an add on to bronchodilator therapy) in people who have

had 2 or more exacerbations in the previous 12 months despite triple therapy. Azithromycin can also be considered for frequent exacerbations.

The technology

Mepolizumab (Nucala, GlaxoSmithKline) does not currently have a marketing authorisation in the UK for COPD. It has been compared with placebo, as an add-on therapy to maintenance treatment, for COPD in people aged 40 or older with a history of exacerbation and forced expiratory volume in 1 second (FEV1)/forced vital capacity (FVC) ratio less than 0.70, with or without a high blood eosinophil count at baseline.

Mepolizumab has a marketing authorisation for severe eosinophilic asthma.

Intervention	Mepolizumab as an add-on to maintenance treatment
Population	Adults with uncontrolled COPD with raised blood eosinophils (eosinophilic phenotype)
Subgroups	<p>If the evidence allows, the following subgroups may be considered:</p> <ul style="list-style-type: none"> • levels of eosinophils (at least 500 cells per microlitre) • severity of COPD • frequency of exacerbation within previous 12 months • chronic bronchitis or not • smoking status
Comparators	<ul style="list-style-type: none"> • Standard care without mepolizumab • Dupilumab with double or triple therapy (subject to NICE evaluation)
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • lung function • frequency of moderate or severe exacerbations • frequency of exacerbations resulting in hospital admission or emergency department visit • symptom control • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>

	<p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
Other considerations	<p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
Related NICE recommendations	<p>Related technology appraisals:</p> <p>Roflumilast for treating chronic obstructive pulmonary disease (2017) NICE technology appraisal guidance 461</p> <p>Related technology appraisals in development:</p> <p>Dupilumab for treating moderate to severe chronic obstructive pulmonary disease. NICE technology appraisal guidance [ID6235] Publication date to be confirmed</p> <p>Related NICE guidelines:</p> <p>Chronic obstructive pulmonary disease in over 16s: diagnosis and management (2018, updated 2019) NICE guideline 115</p> <p>Chronic obstructive pulmonary disease (acute exacerbation): antimicrobial prescribing (2018) NICE guideline 114</p> <p>Related interventional procedures:</p> <p>Endobronchial nerve ablation for chronic obstructive pulmonary disease (2021) NICE interventional procedures guidance 714</p> <p>Related quality standards:</p> <p>Chronic obstructive pulmonary disease in adults (2011, updated 2023) NICE quality standard 10</p>

References

1. [COPD: QOF prevalence](#). Fingertips public health profiles from the Department of Health & Social Care [online; accessed March 2025]
2. [COPD in the UK: delayed diagnosis and unequal care](#). Asthma + Lung UK [online; accessed March 2025]
3. [Chronic obstructive pulmonary disease](#). Patient [online; accessed March 2025]
4. [The global strategy for prevention, diagnosis and management of COPD: 2025 report](#). Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2025