NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Mepolizumab for reducing eosinophilic exacerbations of chronic obstructive pulmonary disease ID1237

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of mepolizumab within its marketing authorisation for reducing eosinophilic exacerbations of chronic obstructive pulmonary disease.

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).

In England in 2024, nearly 1.2 million people were diagnosed with COPD.[1] Every year around 30,000 people die from it. 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 they continue to have symptoms that adversely affect quality of life or have 1 severe or 2 moderate exacerbations within a year, all 3 treatments can be trialled (triple inhaled therapy). 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 COPD
Subgroups	If the evidence allows, the following subgroups of people may be considered: • high levels of eosinophils (at least 500 cells per microlitre) • severity of COPD • frequency of exacerbation within previous 12 months.
Comparators	• Standard care without mepolizumab (triple inhaled therapy or dual therapy when ICS is not appropriate) • Roflumilast with triple inhaled therapy • Azithromycin • Dupilumab with double or triple therapy (subject to NICE evaluation)
Outcomes	The outcome measures to be considered include: • lung function • frequency of moderate/severe exacerbations • symptom control • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. 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. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.
Other considerations	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.
Related NICE recommendations	**Related technology appraisals:** Roflumilast for treating chronic obstructive pulmonary disease (2017) NICE technology appraisal guidance 461 **Related technology appraisals in development:** Dupilumab for treating moderate to severe chronic obstructive pulmonary disease. NICE technology appraisal guidance [ID6235] Publication date to be confirmed **Related NICE guidelines:** Chronic obstructive pulmonary disease in over 16s: diagnosis and management (2018, updated 2019) NICE guideline 115 Chronic obstructive pulmonary disease (acute exacerbation): antimicrobial prescribing (2018) NICE guideline 114 **Related interventional procedures:** Endobronchial nerve ablation for chronic obstructive pulmonary disease (2021) NICE interventional procedures guidance 714 **Related quality standards:** Chronic obstructive pulmonary disease in adults (2011, updated 2023) NICE quality standard 10

Questions for consultation

Is the population in the draft scope appropriate?

Is the intervention in the draft scope defined properly?

Are the comparators listed appropriate? Is anything missing?

Where do you consider mepolizumab will fit into the existing care pathway for COPD?

Are the outcomes listed appropriate?

Are there any other relevant outcomes to consider?

Are there any subgroups of people in whom mepolizumab is expected to provide greater clinical benefits or more value for money, or other groups that should be examined separately?

Please select from the following, will mepolizumab be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would mepolizumab be a candidate for managed access?

Do you consider that the use of mepolizumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which mepolizumab will be licensed
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

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]