NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Tozorakimab for treating exacerbations of chronic obstructive pulmonary disease after optimised inhaled dual or triple therapy ID6711

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of tozorakimab within its marketing authorisation for treating exacerbations of chronic obstructive pulmonary disease after optimised inhaled dual or triple therapy.

Background

Chronic obstructive pulmonary disease (COPD) is a group of progressive lung conditions that cause breathing difficulties. It includes chronic bronchitis, emphysema, chronic obstructive airways disease and chronic airflow limitation. Smoking is the main cause, although COPD can also result from long-term exposure to harmful fumes or dust. Symptoms include breathlessness, a chronic productive cough and reduced exercise tolerance. Lung function typically worsens over time and cannot be fully restored. Type 2 inflammation is associated with higher rates of exacerbations and poorer quality of life. It may be indicated by raised blood eosinophil counts and, in some people, elevated fractional exhaled nitric oxide (FeNO).

In England in 2024, nearly 1.2 million people were diagnosed with COPD.[1] Around 30,000 people die from the disease each year. COPD is the second most common lung disease in the UK after asthma.[2] It is more common in men and in people aged over 40 years, and its prevalence increases with age.[3]

Treatment for COPD aims to slow disease progression, control symptoms and reduce exacerbations. It includes smoking cessation support, pneumococcal and influenza vaccination, pulmonary rehabilitation, personalised self-management plans, and optimisation of treatment for comorbidities (see NICE guideline on diagnosing and managing COPD in over 16s). People with stable COPD who are breathless and have limited exercise capacity may be offered short-acting $beta_2$ agonists (SABAs) or short-acting muscarinic antagonists (SAMAs). If symptoms or exacerbations persist, dual therapy with a long-acting $beta_2$ agonist (LABA) plus a long-acting muscarinic antagonist (LAMA), or a LABA plus an inhaled corticosteroid (ICS), may be offered. People whose symptoms continue to adversely affect quality of life, or who have had 1 severe or 2 moderate exacerbations within a year, may be offered triple inhaled therapy (LABA, LAMA and ICS).

NICE also recommends:

- roflumilast as an add-on to bronchodilator therapy for people who have had 2 or more exacerbations in the previous 12 months despite triple therapy (NICE technology appraisal guidance 461).
- dupilumab as an add-on maintenance treatment option for uncontrolled COPD with raised blood eosinophils in adults if they are having triple therapy including an ICS, a LABA and a LAMA, or double therapy including a LABA

and a LAMA if ICS are not appropriate (NICE technology appraisal guidance 1142).

- mepolizumab as an add-on maintenance treatment option for uncontrolled COPD with raised blood eosinophils in adults, if they are having triple therapy including an ICS, a LABA and a LAMA (NICE technology appraisal guidance 1166).

Azithromycin may also be considered for people with frequent exacerbations.

The technology

Tozorakimab (brand name unknown, AstraZeneca) does not currently have a marketing authorisation in the UK for treating exacerbations of chronic obstructive pulmonary disease after optimised inhaled dual or triple therapy. It has been studied in clinical trials in which tozorakimab regimens were compared with placebo in adults with symptomatic COPD and a history of exacerbations despite optimised inhaled maintenance therapy.

Intervention(s)	Tozorakimab
Population(s)	People with moderate or severe COPD
Subgroups	If the evidence allows, the following subgroups of people may be considered • Severity of COPD • Frequency of exacerbations within previous 12 months • Eosinophil count • FeNO levels • Chronic bronchitis status • Smoking status
Comparators	• Standard care without tozorakimab • Dupilumab • Mepolizumab • Roflumilast • Azithromycin

Outcomes	The outcome measures to be considered include: • 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	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out. 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:** Mepolizumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils (2026) NICE technology appraisal guidance 1166. Dupilumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils (2026) NICE technology appraisal guidance 1142.

	Roflumilast for treating chronic obstructive pulmonary disease (2017) NICE technology appraisal guidance 461. **Related technology appraisals in development:** Itepekimab as add-on maintenance treatment for moderate to severe chronic obstructive pulmonary disease. NICE technology appraisal guidance [ID6547] Publication date to be confirmed. **Related NICE guidelines:** Chronic obstructive pulmonary disease in over 16s: diagnosis and management (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 (2023) NICE quality standard 10.

Questions for consultation

Where do you consider tozorakimab will fit into the existing care pathway for treating COPD exacerbations after optimised inhaled dual or triple therapy?

Please select from the following, will tozorakimab 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 tozorakimab be a candidate for managed access?

Do you consider that the use of tozorakimab 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 tozorakimab 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. Office for Health Improvement and Disparities. 2026 Public health profiles. COPD:QOF prevalence (accessed June 2026).
2. Asthma and Lung UK 2022 COPD in the UK: Delayed diagnosis and unequal care (accessed June 2026).
3. Patient 2023 Chronic obstructive pulmonary disease (accessed June 2026).