NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Dupilumab for treating moderate to severe chronic obstructive pulmonary disease ID6235

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of dupilumab within its marketing authorisation for treating moderate to severe chronic obstructive pulmonary disease (COPD).

Background

Chronic obstructive pulmonary disease (COPD) is the name for a group of lung conditions that cause breathing difficulties. It includes chronic bronchitis, emphysema, chronic obstructive airways disease and chronic airflow limitation. It is characterised by consistent airways obstruction, causing symptoms including persistent and progressive breathlessness, a chronic productive cough and limited exercise capacity. The impairment of lung function is usually progressive and is not fully reversible. COPD is often caused by smoking although it can be caused by long-term exposure to harmful fumes or dust and can also affect people who have never smoked. NICE guideline NG115 defines COPD as forced expiratory volume in 1 second (FEV_1) of less than 80% predicted normal and a forced volume capacity (FEV_1/FVC) ratio less than 0.7. Moderate COPD is defined as FEV_1 less than 79% predicted normal and severe COPD is defined as FEV_1 less than 50% predicted normal.

There is an estimated 1.2 million people with a COPD diagnosis.[1] The prevalence of COPD is increasing, the number of those newly diagnosed increased by 27% in the last 10 years to approximately 2,000 per 100,000.[1] COPD is more common in men and people over the age of 40, it becomes more common with increasing age and is generally higher among smokers.[2]

Treatment for COPD aims to slow its progression and control the symptoms. For people with stable chronic obstructive pulmonary disease who are breathless and have limited exercise capacity, NICE guideline NG115 recommends initial therapy with short-acting $beta_2$ agonist (SABA) or short-acting muscarinic antagonists (SAMA). For people who remain breathless or have exacerbations (that is, people who have severe disease), dual therapy with long-acting beta2 agonists (LABA) and long-acting muscarinic antagonists (LAMA) or inhaled corticosteroids (ICS) is recommended before trial of all these treatments (triple inhaled therapy). NICE guideline NG115 also recommends smoking cessation and pulmonary rehabilitation as part of the management of stable chronic obstructive pulmonary disease.

NICE technology appraisal (TA461) recommends roflumilast for treating severe COPD in people who have had 2 more exacerbations in the previous 12 months despite triple therapy with a long-acting muscarinic antagonist, long-acting beta agonist and an inhaled corticosteroid.

The technology

Dupilumab (Dupixent, Sanofi) does not currently have marketing authorisation in the UK for treating COPD. It is being studied in clinical trials, compared with placebo, as an add-on treatment to triple therapy (long-acting muscarinic antagonists [LAMA], long-acting beta2 agonists [LABA], and inhaled corticosteroids [ICS]) or double therapy (long-acting muscarinic antagonists [LAMA] and long-acting beta2 agonists [LABA] if inhaled corticosteroids is contraindicated), in adults aged 40 to 80 with moderate-to-severe COPD with evidence of type 2 inflammation and high exacerbation risk.

Dupilumab has a marketing authorisation for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO) in children aged 6 and older, adolescents and adults as add-on maintenance treatment.

Intervention(s)	Dupilumab as an add-on to maintenance treatment.
Population(s)	Adults with moderate-to-severe COPD with Type 2 inflammation
Comparators	For people with FEV1/FVC ratio less than 0.7 • Dual inhaled therapy, that is, a long-acting beta-2 agonist in combination with a long-acting muscarinic antagonists • Triple inhaled therapy, that is, a long-acting muscarinic antagonist in combination with a long-acting beta-2 agonist and an inhaled corticosteroid • Roflumilast in combination with a long-acting muscarinic antagonist, a long-acting beta-2 agonist and an inhaled corticosteroid (for people who had 2 or more exacerbations in the previous 12 months despite triple inhaled therapy) • Mepolizumab (subject to NICE evaluation)
Outcomes	The outcome measures to be considered include: • lung function • incidence and severity of acute 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.
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:** Mepolizumab for treating chronic obstructive pulmonary disease. NICE technology appraisal guidance [ID1237] Publication date to be confirmed **Related highly specialised technology appraisals in development:** Human alpha1-proteinase inhibitor for treating emphysema. NICE highly specialised technology guidance [ID856] Publication date to be confirmed. **Related NICE guidelines:** Chronic obstructive pulmonary disease (acute exacerbation): antimicrobial prescribing (2018) NICE guideline NG114. **Related quality standards:** Chronic obstructive pulmonary disease in adults (2011) NICE quality standard 10
Related National Policy	NHS England (2023) Prescribed specialised services manual (version 6) Chapter 4 Adult specialist respiratory services NHS England (2022) Clinical Commissioning Policy: Lung volume reduction by surgery or endobronchial valve for severe emphysema in adults. 200806P [1622]. The NHS Long Term Plan (2019) NHS Long Term Plan

	NHS RightCare (2017) Chronic Obstructive Pulmonary Disease (COPD) Pathway

Questions for consultation

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

Are the comparators listed the only relevant comparators? Would dupilumab be a candidate for managed access?

Do you consider that the use of dupilumab 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.

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 dupilumab 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. British Lung Foundation Chronic obstructive pulmonary disease (COPD) statistics [online; accessed; 21 November 2023]

2. Patient Chronic Obstructive Pulmonary Disease COPD [online; accessed 21 November 2023]