NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Depemokimab for treating severe eosinophilic asthma in people 12 years and over ID6447

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of depemokimab within its marketing authorisation for severe eosinophilic asthma in people 12 years and over.

Background

Asthma is a chronic inflammatory disease associated with variable airflow obstruction and airway hyperresponsiveness. It is characterised by exacerbations where people may experience breathlessness, chest tightness, wheezing, sputum production and cough. Eosinophils, which are a type of white blood cell, are thought to play a major role in airway inflammation in asthma. Severe eosinophilic asthma is a subset of the condition that is associated with high levels of eosinophils and recurrent exacerbations. Eosinophilic nasal polyps may also be present.

People with severe asthma often have a severely impaired quality of life which can lead to fatigue, absence from school or work and psychological problems including stress, anxiety and depression. Exacerbations may result in hospitalisation and can be life-threatening. In the UK, 5.4 million people have asthma, with around 200,000 people with severe asthma.[1] In England in 2023, there were 1,195 recorded deaths from asthma.[2]

NICE guideline NG245 and guidelines from the Global Initiative for Asthma (GINA) recommend a stepwise approach for treating asthma. Control is maintained by stepping up treatment as necessary and stepping down when control is good. The recommendations are summarised as follows:

- Offer a low-dose inhaled corticosteroid (ICS)/formoterol combination inhaler to be taken as needed for symptom relief to people with newly diagnosed asthma. If control is inadequate, people will then be offered daily maintenance treatment with MART (maintenance and reliever therapy) in addition to using it as a reliever therapy when needed.

- If control is inadequate on moderate-dose MART, but neither Fractional Exhaled Nitric Oxide nor eosinophil count is raised, people may take either a leukotriene receptor antagonist (LTRA) or a long-acting muscarinic receptor antagonist (LAMA) in addition to moderate-dose MART.

Some people take steroid tablets as maintenance therapy where symptoms are not well controlled despite other treatments.

People may be offered the following biological treatments if they meet the eligibility criteria:

NICE TA880 recommends tezepelumab as an add-on maintenance treatment for severe asthma when treatment with high-dose inhaled corticosteroids plus another maintenance treatment has not worked well enough. It is recommended only if people:

- have had 3 or more exacerbations in the previous year, or
- are having maintenance oral corticosteroids.

NICE TA751 recommends dupilumab as an add-on maintenance therapy for treating severe asthma with type 2 inflammation that is inadequately controlled, despite maintenance therapy with high-dose inhaled corticosteroids and another maintenance treatment, only if:

- the person has a blood eosinophil count of 150 cells per microlitre or more and fractional exhaled nitric oxide of 25 parts per billion or more, and has had at least 4 or more exacerbations in the previous 12 months
- the person is not eligible for mepolizumab, reslizumab or benralizumab, or has asthma that has not responded adequately to these biological therapies

NICE TA565 and NICE TA671 recommend benralizumab and mepolizumab in adults as add-ons for treating severe refractory eosinophilic asthma, only if:

- the blood eosinophil count has been recorded as 300 cells per microlitre or more with 4 or more exacerbations needing systemic corticosteroids in the previous 12 months, or the person has had continuous oral corticosteroids of at least the equivalent of prednisolone 5 mg per day over the previous 6 months, or
- the blood eosinophil count has been recorded as 400 cells per microlitre or more with 3 or more exacerbations needing systemic corticosteroids in the past 12 months.

NICE TA479 recommends reslizumab as an add-on for treating severe eosinophilic asthma that is inadequately controlled in adults despite maintenance therapy with high-dose ICS plus another drug, only if the blood eosinophil count has been recorded as 400 cells per microlitre or more with 3 or more severe asthma exacerbations needing systemic corticosteroids in the past 12 months.

NICE TA278 recommends omalizumab for treating severe persistent confirmed allergic IgE-mediated asthma as an add-on to optimised standard therapy in people aged 6 and older who need continuous or frequent treatment with oral corticosteroids (4 or more courses in the previous year). Optimised standard therapy is defined as a full trial of and, if tolerated, documented compliance with high-dose ICS, LABAs, LTRAs, theophyllines, oral corticosteroids, and smoking cessation if clinically appropriate.

The technology

Depemokimab (brand name unknown, GlaxoSmithKlein UK Ltd) does not currently have a marketing authorisation in the UK for treating severe eosinophilic asthma. It is being studied in phase 3 clinical trials as add add-on treatment for people 12 years and older with eosinophilic asthma. It is compared with placebo, mepolizumab and benralizumab.

Intervention(s)	Depemokimab
Population(s)	People 12 years and over with severe eosinophilic asthma
Subgroups	If the evidence allows, the following subgroups will be considered: • baseline eosinophil levels • baseline fractional exhaled nitric oxide levels • people who require maintenance oral corticosteroid treatment • people who require frequent oral corticosteroid treatment
Comparators	For people for whom biologics are indicated or suitable according to NICE guidance, in addition to standard therapy: • Tezepelumab • Reslizumab • Benralizumab • Mepolizumab • Dupilumab • Omalizumab For people for whom currently available biologics are not indicated or suitable: • Optimised standard therapy without biologics
Outcomes	The outcome measures to be considered include: • asthma control • incidence of clinically significant exacerbations, including those which require unscheduled contact with healthcare professionals or hospitalisation • use of oral corticosteroids • patient and clinician evaluation of response • lung function (objective measures such as forced expiratory volume, FEV_1; peak expiratory flow, PEF). • immunogenicity • mortality • time to discontinuation • 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	The availability and cost of biosimilar and generic products should be taken into account. 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:** Tezepelumab for treating severe asthma (2023) NICE technology appraisal guidance 880 Dupilumab for treating severe asthma with type 2 inflammation (2021) NICE technology appraisal guidance 751 Mepolizumab for treating severe eosinophilic asthma (2021) NICE technology appraisal guidance 671 Benralizumab for treating severe eosinophilic asthma (2019) NICE technology appraisal guidance 565 Reslizumab for treating severe eosinophilic asthma (2017) NICE technology appraisal guidance 479 Omalizumab for treating severe persistent allergic asthma (2013) NICE technology appraisal guidance 278 **Related technology appraisals in development:** Depemokimab for treating chronic rhinosinusitis with nasal polyps. NICE technology appraisal guidance (ID6449) Publication date to be confirmed. **Related NICE guidelines:**

	Asthma: diagnosis, monitoring and chronic asthma management (BTS, NICE, SIGN) (2024) NICE guideline 245 Asthma pathway (BTS, NICE, SIGN) (2024) NICE guideline 244 **Related interventional procedures:** Smart Peak Flow for monitoring asthma (2022) NICE MedTech innovation briefing 282 OxyMask for delivering oxygen therapy (2018) NICE MedTech innovation briefing 160 Smartinhaler for asthma (2017) NICE MedTech innovation briefing 90 Alair bronchial thermoplasty system for adults with severe difficult to control asthma (2016) NICE MedTech innovation briefing 71 **Related quality standards:** Asthma (2013) NICE quality standard 25

Questions for consultation

Will the intervention be used to treat the same population as the comparator(s)?

Which treatments are the most relevant comparators for depemokimab? Are there any other relevant comparators that have not been included in the scope?

Which comparators are used in the same place in the treatment pathway as depemokimab? Have there been any major changes to the treatment pathway recently? If so, please describe.

Which treatments are the most relevant comparators for people aged 12-17?

Where do you consider depemokimab will fit into the existing care pathway for severe eosinophilic asthma?

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

Do you consider that the use of depemokimab 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 depemokimab 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 O. Umerah, Asthma in adults (2004) *BMJ Best practice*. Available: https://bestpractice.bmj.com/topics/en-gb/44, Accessed: January 2025

2 Deaths registered in England and Wales: 2023, (2024) *Office for National Statistics*. Available: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsregistrationsummarytables/2023 , Accessed: 04/02/2025