

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Tezepelumab for treating severe asthma

Final scope

Final remit/appraisal objective

To appraise the clinical and cost effectiveness of tezepelumab within its marketing authorisation for treating severe asthma.

Background

Asthma is a chronic inflammatory disease associated with variable airflow obstruction and airway hyperresponsiveness. It is characterised by exacerbations associated with symptoms such as breathlessness, chest tightness, wheezing, sputum production and cough. Asthma is classified as severe when it does not improve with standard therapy.¹ Eosinophils are thought to play a major role in airway inflammation in asthma. Asthma can also have an allergic component, resulting in over-production of human immunoglobulin E (IgE).

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. There were 1,484 deaths from asthma in the UK in 2017.² Around 4.8 million people in England and Wales currently have treatment for asthma.²

NICE guideline [\[NG80\]](#) on asthma: diagnosis, monitoring and chronic asthma management, and guidelines from the Global Initiative for Asthma (GINA)³ recommend a stepwise approach for treating asthma. Control is maintained by stepping up treatment as necessary using combinations of inhaled corticosteroids (ICS), leukotriene receptor antagonists (LTRAs) and long-acting beta-2 agonists (LABAs), and stepping down when control is good. People whose asthma is inadequately controlled by medium-dose ICS plus a LABA with or without an LTRA should be stepped up to have high-dose ICS or offered a trial of an additional drug (for example, a long-acting muscarinic receptor agonist or theophylline).

[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.

[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 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.

The technology

Tezepelumab (brand name unknown, AstraZeneca) is a monoclonal antibody against thymic stromal lymphopoietin (TSLP). Blocking TSLP may prevent the release of pro-inflammatory cytokines by immune cells, preventing asthma exacerbations and improving disease control. Tezepelumab is administered subcutaneously in addition to best standard asthma care.

Tezepelumab does not currently have a marketing authorisation in the UK for treating severe asthma. It has been studied in clinical trials compared with placebo in people with severe asthma that is inadequately controlled by medium- or high-dose ICS plus at least 1 other maintenance treatment.

Intervention(s)	Tezepelumab as an add-on to standard therapy
Population(s)	People aged 12 years or older with severe asthma that is inadequately controlled by standard therapy
Comparators	<p>For people for whom biologics are indicated or suitable according to NICE guidance, in addition to standard therapy:</p> <ul style="list-style-type: none"> • Reslizumab • Benralizumab • Mepolizumab • Omalizumab • Dupilumab (subject to ongoing NICE appraisal) <p>For people for whom currently available biologics are not indicated or suitable:</p> <ul style="list-style-type: none"> • Optimised standard therapy without biologics
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • asthma control • incidence of clinically significant exacerbations, including those which require unscheduled contact with healthcare professionals or hospitalisation • use of oral corticosteroids

	<ul style="list-style-type: none"> • patient and clinician evaluation of response • lung function • mortality • time to discontinuation • 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>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.</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>
Other considerations	<p>If the evidence allows, the following subgroups will be considered:</p> <ul style="list-style-type: none"> • baseline eosinophil levels • baseline fractional exhaled nitric oxide levels • people who require maintenance oral corticosteroid treatment • people who require frequent oral corticosteroid treatment. <p>The availability and cost of biosimilar and generic products should be taken into account.</p> <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 and NICE Pathways	<p>Related Technology Appraisals:</p> <p>‘Mepolizumab for treating severe eosinophilic asthma’ (2021). NICE Technology Appraisal 671. Review date 2024</p>

	<p>‘Benralizumab for treating severe eosinophilic asthma’ (2019). NICE Technology Appraisal 565. Review date 2022</p> <p>‘Reslizumab for treating severe eosinophilic asthma’ (2017). NICE Technology Appraisal 479. Review date 2020</p> <p>‘Omalizumab for treating severe persistent allergic asthma’ (2013). NICE Technology Appraisal 278. Guidance on static list</p> <p>‘Inhaled corticosteroids for the treatment of chronic asthma in adults and in children aged 12 years and over’ (2008). NICE Technology Appraisal 138. Guidance on static list</p> <p>‘Inhaler devices for routine treatment of chronic asthma in older children (aged 5–15 years)’ (2002). NICE Technology Appraisal 38. Guidance on static list</p> <p>Appraisals in development (including suspended appraisals):</p> <p>‘Dupilumab for treating severe asthma’ NICE technology appraisals guidance [ID1213]. Publication date to be confirmed.</p> <p>Related Guidelines:</p> <p>‘Asthma: diagnosis, monitoring and chronic asthma management’ (2017, updated 2020). NICE guideline 80</p> <p>‘COVID-19 rapid guideline: severe asthma’ (2020). NICE guideline 166</p> <p>Related Interventional Procedures:</p> <p>‘Bronchial thermoplasty for severe asthma’ (2018). NICE interventional procedures guidance 635.</p> <p>Related Quality Standards:</p> <p>‘Asthma’ (2013, updated 2018). NICE quality standard 25</p> <p>Related NICE Pathways:</p> <p>Asthma (2020) NICE pathway</p>
<p>Related National Policy</p>	<p>The NHS Long Term Plan, 2019. NHS Long Term Plan</p> <p>NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019)</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 1, 2 and 3. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</p> <p>NHS England (2019) PSS8 Severe Asthma Specialised Care Review PSS CQUIN Indicator</p> <p>NHS England (2019) Specialised Respiratory Services (adult) – Severe Asthma. Reference 170002/S</p>

References

1. Asthma UK. [What is severe asthma?](#) Accessed February 2021
2. Asthma UK. [Asthma facts and statistics.](#) Accessed February 2021
3. Global Initiative for Asthma (2019) [Global strategy for asthma management and prevention.](#) Accessed February 2021