NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Tezepelumab for treating severe chronic rhinosinusitis with nasal polyps ID6379

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of tezepelumab within its marketing authorisation for treating severe chronic rhinosinusitis with nasal polyps.

Background

Chronic rhinosinusitis is a condition in which the lining of the sinuses (air-filled spaces behind the nose, eyes and cheeks) becomes inflamed. It is characterised by symptoms including nasal congestion, discharge, decreased or lost sense of smell, facial pain and headache, which may last many years.[1] Rhinosinusitis is considered chronic when symptoms persist for more than 12 weeks.[2] People with the condition may have nasal polyps, which is also referred to as nasal polyposis. If nasal polyps are also present, the condition is referred to as chronic rhinosinusitis with nasal polyps (CRSwNP). These are growths inside the nasal passages and sinuses, which usually only cause problems if they are large or grow in clusters, causing an obstruction. Additional symptoms of nasal polyps include a blocked nose, snoring and obstructive sleep apnoea (which can disturb sleep).[1]

The cause of CRSwNP is unknown, but multiple factors including allergies and fungal infection, are known to be contributory factors.[1] Chronic rhinosinusitis is a common health condition estimated to affect 5-12% of the general population.[2] Among all people with chronic rhinosinusitis, around 25% to 30% have CRSwNP.[3] It is estimated that there were 476 cases of CRSwNP per 100,000 people in England in 2018, with prevalence highest in men aged 65 to 84 years.[4]

The goal of treatment is to control inflammation and reduce the size of polyps or eliminate them. CRSwNP may present as a distinct entity or alongside comorbidities such as asthma, non-steroidal anti-inflammatory drug-exacerbated respiratory disease and fungal allergy. Each case may have a slightly different treatment pathway but generally treatments can include saline irrigation as well as intranasal, oral or injectable corticosteroids. Surgery is frequently needed, but it does not always provide a permanent solution because polyps tend to recur.[5]

The technology

Tezepelumab (Tezspire, AstraZeneca) does not currently have a marketing authorisation in the UK for the treatment of severe CRSwNP. It has been studied alone and with standard care in clinical trials compared with placebo in adults with CRSwNP.

Intervention(s)	Tezepelumab
Population(s)	People with severe chronic rhinosinusitis with nasal polyps
Subgroups	If the evidence allows, the following subgroups will be considered: • People who have type 2 inflammation co-morbidities (such as asthma and atopic dermatitis) • People who are ineligible for surgery • People who have had previous surgery for chronic rhinosinusitis with nasal polyps • People with aspirin or steroid sensitivity/intolerance
Comparators	• Established clinical management without tezepelumab, including surgery • Dupilumab (subject to NICE evaluation)
Outcomes	The outcome measures to be considered include: • nasal congestion/obstruction • polyp size • sense of smell • sinus opacifications • need for surgery • need for systemic corticosteroids • 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 in development:** Dupilumab for treating severe chronic rhinosinusitis with nasal polyps (review of TA648) [ID6480]. Publication expected October 2025. **Related NICE guidelines:** Sinusitis (acute): antimicrobial prescribing (2017) NICE guideline NG79. **Related interventional procedures:** Cryotherapy for chronic rhinitis (2023) NICE interventional procedures guidance 771 Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis (2016) NICE interventional procedures guidance 551 Combined endoscopic and laparoscopic removal of colonic polyps (2014) NICE interventional procedures guidance 503 Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis (2008) NICE interventional procedures guidance 273 XprESS multi sinus dilation system for treating chronic sinusitis (2016) NICE medical technologies guidance 30 **Related interventional procedures in development:** Corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis. NICE interventional procedures guidance. Publication date to be confirmed.

Questions for consultation

Where do you consider tezepelumab will fit into the existing care pathway for severe chronic rhinosinusitis with nasal polyps?

What treatments are considered established clinical management for severe chronic rhinosinusitis with nasal polyps?

Are the suggested subgroups appropriate? Are there any other subgroups of people in whom tezepelumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?

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

Do you consider that the use of tezepelumab 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 tezepelumab 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. Chaaban M, Walsh E, and Woodworth B (2013). Epidemiology and differential diagnosis of nasal polyps. Am J Rhinol Allergy 27(6): 473–478

2. Fokkens WJ, Lund VJ , Hopkins C et al. (2020) European Position Paper on Rhinosinusitis and Nasal Polyps 2020 Rhinology. Suppl. 29: 1-464

3. Stevens W, Schleimer R, and Kern R (2016). Chronic Rhinosinusitis with Nasal Polyps. J Allergy Clin Immunol Pract. 4(4): 565–572.

4. Benson V, Fu Q, Yang S, et al. (2023) Real-world characterisation of patients with chronic rhinosinusitis with nasal polyps with and without surgery in England. Clinical Otolaryngology 48(4): 680–88.

5. Bachert C, Mannent L, Naclerio RM et al 2016. Effect of subcutaneous dupilumab on nasal polyp burden in patients with chronic sinusitis and nasal polyposis: a randomized clinical trial. Journal of the American Medical Association 315(5): 469-479.