National Institute for Health and Care Excellence

Health Technology Evaluation

Tezepelumab for treating severe chronic rhinosinusitis with nasal polyps [ID6379]
Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Association of Respiratory Nurses	Yes it is appropriate as a consideration for add on therapy.	Thank you for your comment.
	AstraZeneca	AstraZeneca consider the proposed evaluation route to be appropriate.	Thank you for your comment.
	Sanofi	Appropriate	Thank you for your comment.
Wording	Association of Respiratory Nurses	No comment.	Thank you for your comment.
	AstraZeneca	The wording of the remit should align with the anticipated marketing authorisation wording. The anticipated market authorisation wording is [redacted]	Thank you for your comment. The wording has been updated in the remit and population of

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		[redacted]. AstraZeneca, therefore, kindly request the wording to be updated to “to appraise the clinical and cost-effectiveness of tezepelumab as an add-on treatment for adult patients with severe CRSwNP for whom therapy with SCS, and/or surgery do not provide adequate disease control”.	the scope to reflect the positive CHMP opinion.
	Sanofi	Yes	Thank you for your comment.
Timing Issues	Association of Respiratory Nurses	I would not suggest that an urgent evaluation is needed as some patients are already receiving this if they have co-existing severe asthma. There are already conventional prescribable treatments available on the NHS.	Thank you for your comment. No action required.
	AstraZeneca	Patients with severe CRSwNP experience significant and debilitating symptoms, such as loss of smell and taste, sinonasal obstruction, chronic infections, and facial pain.[1] These persistent symptoms have a substantial adverse impact on health-related quality of life (HRQoL), affecting sleep, mood, and daily activities.[2,3,4] Delays in diagnosis and access to specialist care are common, with most patients waiting over 12 months for treatment. The long waiting lists within the National Health Service (NHS) further increase disease burden, as symptoms progress and HRQoL deteriorates.[5] The established clinical management (ECM) for severe CRSwNP includes maintenance therapy with intranasal corticosteroids (INCS), saline rinses, intermittent short-term courses of systemic corticosteroids (SCS) for exacerbations, and endoscopic sinonasal surgery (ESS).[6] However, current ECM has notable limitations. Surgery often fails to address the underlying type 2 inflammation, resulting in high recurrence rates and necessitating revision surgeries in approximately 15% to 30% of patients within five	Thank you for your comment. No action required.

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		years.[7,8] Each additional surgery shortens the interval until revision is needed, emphasising the temporary nature of surgical benefits and limited HRQoL gains when surgery is not effective.[2, 9] Moreover, while short courses of SCS can be effective, repeated or prolonged use carries significant risks, including infections, cardiovascular events, diabetes, osteoporosis, ocular complications, and psychological effects.[6,10,11] The European Academy of Allergy and Clinical Immunology (EAACI) strongly recommends limiting SCS exposure, with consensus from key experts and patients that minimising SCS use is a key treatment goal.[12] There is a clear unmet need for a therapy providing sustained disease control by targeting the underlying pathology, type 2 inflammation. Currently, no reimbursed therapies achieve this. Tezepelumab, a biologic that directly targets type 2 inflammation, offers the potential to address all these outlined challenges: improving disease control, reducing the need for SCS and surgery, enhancing HRQoL, and supporting NHS resource optimisation. Finally, NHS waiting times for ESS can be as long as three years, with half of these surgeries being revisions.[5] This delay prolongs uncontrolled symptoms, increases the risk of complications, further impairing HRQoL. Introducing an effective therapy like tezepelumab would not only improve individual patient outcomes but also lessen the overall burden on the NHS by reducing surgical demand and waiting times. In summary, a timely appraisal and evaluation of tezepelumab is of acute urgency to the NHS. It addresses a high unmet clinical need for patients inadequately controlled by current ECM, provides long-term disease control, minimises SCS use, and contributes to alleviating NHS waiting lists and associated resource challenges.	

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	Sanofi	There is a high burden of illness for people with CRSwNP which is currently underserved.	Thank you for your comment. No action required.
Additional comments on the draft remit	Association of Respiratory Nurses	No comment.	Thank you for your comment.
	AstraZeneca	N/A	Thank you for your comment.
	Sanofi	No	Thank you for your comment.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Association of Respiratory Nurses	The background information explains the current condition clearly and the effects it can have on patients. However, some of the data is limited and outdated as per the quoted references.	Thank you for your comment.
	AstraZeneca	The background information provided is broadly accurate; however, AstraZeneca kindly requests a few amendments to ensure the brief summary fully reflects current medical understanding and accuracy. **Paragraph 1**	Thank you for your comment. The background section has been updated to include your suggested

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		Nasal polyps are growths inside the nasal passage, but it is important to note that they are benign. Therefore, AstraZeneca kindly request the wording to be updated to reflect this: “These are **benign** growths **which occur** inside the nasal passages and sinuses…”. Additionally, the wording that polyps “**usually only** cause problems if they are large or grow in clusters” can be interpreted as downplaying and minimising the extent of the potential issues from nasal polyps. Therefore, AstraZeneca kindly request the wording be updated to: “which **can** cause problem if they are large or grow in clusters”. **Paragraph 3** AstraZeneca notes that endoscopic sinonasal surgery (ESS) not only removes nasal polyps but also excises some of the surrounding inflamed tissue. This distinction is important, as consultations with clinical experts confirm that polypectomies are no longer performed, and ESS represents the sole surgical intervention currently utilised in UK clinical practice. Additionally, it is essential to specify both the underlying cause and the frequency of polyp recurrence, as these facets provide important context. Accordingly, AstraZeneca requests that the wording of the final sentence in the third background paragraph be amended to accurately reflect the nature of ESS, the primary drivers of disease recurrence, and the frequency with which revision surgeries are required: “**Endoscopic sinonasal surgery (ESS) is frequently needed to remove polyps and some of the inflamed tissue. However,** it does not always provide a permanent solution because **ESS does not directly address the underlying type 2 inflammation therefore** polyps **and inflammation** tend to recur. As such rate of revision surgery can range from 15% to 30% over a 5-year period.[7, 8]	wording: “These are benign growths which occur inside the nasal passages and sinuses…”, “which can cause problem if they are large or grow in clusters” and ““Surgery is frequently needed to remove polyps and some of the inflamed tissue…”.

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	Sanofi	The background information is generally complete and accurate, however established clinical management rarely includes injectable corticosteroids.	Thank you for your comment. The scope background section is intended to give a brief overview of the condition, including potentially relevant comparators. It is anticipated that what represents current clinical practice in the NHS will be explored in the evaluation. No action needed.
Population	Association of Respiratory Nurses	Yes	Thank you for your comment.
	AstraZeneca	There are currently no UK-specific clinical guidelines for the management of CRSwNP. In the absence of national recommendations, clinical decision-making in the UK can reasonably be informed by established European guidelines. Both the European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA) and the 2020 European Position Paper (EPOS2020) on CRSwNP advise considering biologics for patients who remain uncontrolled despite appropriate medical therapy and ESS. Given the significant involvement of prominent UK key external experts (KEEs) in the development of these guidelines, they can be viewed as representative and applicable to clinical practice within the UK context.[3]	Thank you for your comment. The population in the scope is intended to be broad to cover the final marketing authorisation. The company can present a narrower population in its submission for the

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		Feedback from UK KEEs supports surgery as the initial treatment for CRSwNP, as it often provides symptom control. However, patients with more aggressive disease frequently experience recurrence, and revision surgeries offer limited long-term benefit. For these individuals, biologic therapies such as tezepelumab are recommended when symptoms remain uncontrolled after ESS. In summary, in line with both European guidelines and UK expert consensus, AstraZeneca proposes the appropriate population to be appraised as "Adult patients with severe CRSwNP following one or more surgeries." This population is a subgroup of the [redacted] and WAYPOINT trial population. Therefore, AstraZeneca kindly request that the submission population is updated accordingly.	committee to consider. No action needed.
	Sanofi	We suggest the population should be: People with severe *uncontrolled* CRSwNP	Thank you for your comment. NICE will evaluate the technology within its marketing authorisation. No action needed.
Subgroups	Association of Respiratory Nurses	Patients at the severe end of disease who are uncontrolled, and it is affecting their quality of life and have a significant symptom burden it would be more effective for than the general population. It would be extremely expensive to give to the general population also.	Thank you for your comment. The population has been updated to reflect the positive CHMP opinion. This includes people with severe disease that has inadequate disease control with systemic

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			corticosteroids, and/or surgery. No action needed.
	AstraZeneca	Given the appraisal population will be adult patients with severe CRSwNP following one or more surgeries, the subgroup of patients who have had previous surgery for CRSwNP is addressed implicitly. AstraZeneca do not believe that atopic dermatitis (AD) is an appropriate subgroup, as this is not a common comorbidity. EU5 data from an observational real-world study showed 9% of CRSwNP patients have comorbid AD and 4% of AD patients have comorbid CRSwNP, compared with 47% and 29% respectively for asthma.[13] Data for patients who are ineligible for surgery, and people with aspirin or steroid sensitivity/intolerance are not recorded in the WAYPOINT trial; consequently, AstraZeneca request these subgroups be removed from the draft scope. In summary, AstraZeneca kindly request that the following subgroup is included in the final scope: **Patients with comorbid asthma**	Thank you for your comment. The subgroups in the scope are intended to be comprehensive and will be explored further in the evaluation. No action needed. People with comorbid asthma is expected to be captured by the subgroup of people who have type 2 inflammation co-morbidities (such as asthma and atopic dermatitis). No action needed.
	Sanofi	It is more relevant to consider the subgroup of people with asthma only than the broader type 2 population with other inflammatory co-morbidities.	Thank you for your comment. The subgroups in the scope are intended to be comprehensive and will be explored further in the evaluation. If evidence allows the

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			company can present subgroups in their submission for the committee to consider.
Comparators	Association of Respiratory Nurses	There is Dupilumab which is not licenced and has a single technology appraisal for consideration. There are various biologics on the market and some others that also can help with nasal problems which patients who have for a diagnosis of severe asthma and alongside they can help with symptoms. There are other standard options such as nasal corticosteroids, oral corticosteroids and ENT interventions as an option already.	Thank you for your comment. The appraisal committee will discuss the most appropriate comparator(s), including the definition of established clinical management without tezepelumab, during the development of this appraisal. No action needed.
	AstraZeneca	AstraZeneca considers the comparison to ECM including surgery and dupilumab (subject to NICE evaluation) to be appropriate.	Thank you for your comment.
	Sanofi	Yes	Thank you for your comment.
Outcomes	Association of Respiratory Nurses	Yes, I think the outcomes are appropriate, however I would also like to see included, alongside exacerbation rate and additional medication such as antibiotics and oral corticosteroids. Also, use of questionnaires such as the total nasal symptom score or Sino-nasal outcome test-22 (SNOTT-22) to measure pre and post treatment outcomes.	Thank you for your comment. Frequency of exacerbations and need for antibiotics have been added to the scope. Need for

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			systemic corticosteroids is already included. The outcomes do not specify any particular scales or instruments. This is to avoid the exclusion of potential evidence that uses measurement scales/instruments not specified in the scope.
	AstraZeneca	AstraZeneca considers the outcomes in the draft scope to be appropriate.	Thank you for your comment.
	Sanofi	Yes	Thank you for your comment.
Equality	Association of Respiratory Nurses	It would depend on where the treatment would sit in the current pathway of treatment. As with other biological therapies access can be difficult if patients do not meet the requirements for treatment and geographical areas of residence can also be a barrier when treatments are delivered via specialist centres.	Thank you for your comment. This has been noted in the accompanying equality impact assessment (EIA) form. The committee will consider equalities issues where evidence is presented.

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			No change to scope required.
	AstraZeneca	N/A	Thank you for your comment.
	Sanofi	No comment	Thank you for your comment.
Other considerations	Association of Respiratory Nurses	It could be considered at the end of the treatment pathway if patients are still very symptomatic and uncontrolled with syptoms despite regular already available treatment such as nasal steroids, washes, antihistamines etc.	Thank you for your comment. No action required.
	AstraZeneca	N/A	Thank you for your comment.
	Sanofi	None	Thank you for your comment.
Questions for consultation	Association of Respiratory Nurses	Would this be administered under specialist clinics or given under homecare services if licenced? Is this to be a add on therapy? Will it cost the same as it does for its licence in severe asthma?	Thank you for your comment. The positioning, clinical setting and cost of treatment will be discussed during the course of the appraisal. No action required.
	AstraZeneca	**Where do you consider tezepelumab will fit into the existing care pathway for severe chronic rhinosinusitis with nasal polyps?**	Thank you for your comment. The

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		Tezepelumab will be an add-on treatment to INCS for adult patients with severe CRSwNP following one or more surgeries. As outlined above, the rationale for this positioning is informed by European guidelines and UK expert consensus. **What treatments are considered established clinical management for severe chronic rhinosinusitis with nasal polyps?** Based on clinical guidelines and initial clinician feedback, AstraZeneca believes that ECM is comprised of INCS and/or SCS and/or revision ESS. **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 see the response to the subgroup question above. **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.**	committee will consider the potential uncaptured benefits of tezepelumab during the course of the appraisal. No action required.

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		AstraZeneca anticipates tezepelumab will be prescribed in secondary care with routine follow up in secondary care. **Would tezepelumab be a candidate for managed access?** AstraZeneca does not consider tezepelumab in this setting to 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?** As there are currently no approved therapies which directly target the underlying type 2 inflammation in CRSwNP, the introduction of tezepelumab offers several important health-related benefits that extend beyond those captured in the QALY calculation. AstraZeneca would like to highlight these additional benefits, particularly those that ease the burden on the NHS and meaningfully improve patient lives, acknowledging patients as central to the healthcare system. Tezepelumab delivers more effective and sustained disease control than the current ECM in the UK, enabling many patients to be discharged to homecare. This shift results in lower costs for the NHS and offers patients greater convenience, reducing time, travel expenses, and the indirect costs of missed work or arranging childcare. The socioeconomic burden of CRSwNP is significant, stemming from its high prevalence, chronic nature, frequent exacerbations, lack of curative options, lengthy postoperative recovery for ESS, and notably impaired HRQoL. Since most CRSwNP patients are of working age, indirect costs manifest through workplace absenteeism, reduced productivity, and household disruption.[14,15] Importantly, HRQoL impacts unique to CRSwNP, such as loss of sense of smell, are not fully captured by generic questionnaires like EQ-5D. Loss of	

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		smell severely limits daily life, from diminished enjoyment and nutritional risks to compromised safety, emotional relationships, and even memory and overall connection to the world. These profound challenges can persist for years, especially in patients with recurring symptoms post-surgery, while conventional HRQoL measurements underrepresent their significance. Reducing the need for revision ESS through therapies that effectively target type 2 inflammation, like tezepelumab, would help lower NHS economic pressures and shorten surgical waiting times, further improving patient outcomes. Moreover, the mental health consequences associated with CRSwNP, particularly feelings of hopelessness, anxiety, and depression due to a lack of effective treatment, are rarely captured in QALY analyses but are routinely reported by patients and clinicians. In summary, AstraZeneca urges NICE to consider these broader, patient-centred benefits and the far-reaching impact of tezepelumab, which are not fully reflected within traditional economic models. **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** N/A **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.** N/A	

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		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.** N/A	
	Sanofi	None	Thank you for your comment.
Additional comments on the draft scope	Association of Respiratory Nurses	I would consider Tezepelumab to fit at the end of the existing pathway of treatment for severe chronic rhinosinusitis with polyps and would expect it would be prescribed in a secondary/tertiary care specialist clinic.	Thank you for your comment. No action required.

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	AstraZeneca	No comment.	Thank you for your comment.
	Sanofi	None	Thank you for your comment.

The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope

SmellTaste