National Institute for Health and Care Excellence

Health Technology Evaluation

12 SQ-HDM SLIT for treating allergic rhinitis caused by house dust mites in children 5 to 11 years [ID6510] 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	ALK Abello	The company agrees that NICE should consider this topic for appraisal. The single technology appraisal route is the most appropriate route for ACARIZAX®.	Thank you for your comment.
	Neonatal and Paediatric Pharmacy Group (NPPG)	Supportive of a TA on this topic. Technology has been on some formularies for the same indication and age group for many years.	Thank you for your comment.
Wording	ALK Abello	The wording of the remit is accurate, and the company suggests no further changes.	Thank you for your comment.
Timing issues	ALK Abello	Despite appropriate administration and compliance with existing treatments, a subset of moderate-to-severe allergic rhinitis (AR) patients have uncontrolled disease and as such their treatment satisfaction is low. Currently, there are no oral allergy immunotherapies (AITs) licensed for 5–11-year-olds with HDM allergy in the UK, with current disease modifying treatments limited to	Thank you for your comments. This evaluation has been

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		subcutaneous immunotherapy and unlicensed treatments, leaving treatment with general antihistamines and avoidance practices as the main treatment strategies for HDM-induced AR. ACARIZAX® is an AIT in the form of a sublingual immunotherapy (SLIT) lyophilisate tablet, providing an alternative treatment option for patients with moderate-to-severe AR induced by HDM allergens, whose symptoms are inadequately controlled despite compliant use of existing treatments. With a lack of treatment options available for this population, AIT offers a novel and innovative treatment option, being the only treatment available that is able to target the underlying mechanisms of the disease, and change its course, inducing immune tolerance, and preventing disease progression. It is therefore of high importance that NICE consider this intervention for approval for the paediatric population. Early treatment of AR improves long term outcomes for patients particularly preventing asthma development. In a 2024 study, Hamelmann, et al., used a Markov model to quantify the long-term benefits of early initiation of SLIT in childhood for the treatment of AR. They found that over a 20-year period, 24% of children who began SLIT at age 7 and 29% at age 12 developed allergic asthma (AA), whereas only 19% developed AA when treatment was initiated at age 5. This analysis demonstrates the importance of wider access to SLIT for paediatric patients to improve their long-term outcomes. Clinical experts in an advisory board conducted in September 2025 have highlighted several important considerations in terms of early intervention in the treatment of moderate-to-severe AR. Without early treatment, children can develop issues such as facial development problems and speech difficulties due to chronic nasal obstruction. Furthermore, the impact of symptoms on sleep can result in impaired growth in children, as well as impaired performance at school. Early management of the disease can also	scheduled into the work programme.

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		improve quality of life not just for the child, but for the whole family and caregivers who may be impacted by the child's symptoms.	

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	ALK Abello	The background is defined appropriately.	Thank you for your comment.
Population	ALK Abello	The population is defined appropriately.	Thank you for your comment.
Subgroups	ALK Abello	There are no subgroups that should be considered separately.	Thank you for your comment.
Comparators	ALK Abello	The comparators for the appraisal are defined appropriately.	Thank you for your comment.
Outcomes	ALK Abello	The outcomes are defined appropriately.	Thank you for your comment.
Equality	ALK Abello	Children from lower socioeconomic backgrounds are disproportionately affected by HDM-induced allergic rhinitis due to poor housing conditions. Their families often face financial barriers to reducing exposure and are less able to take time off work to attend specialist appointments, unlike those from more affluent groups.	Thank you for your comments. Potential equalities issues will be noted on the equalities impact assessment and relevant issues will be considered by the

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		Additionally, children from lower socioeconomic groups are affected disproportionately due to their caregivers being less able to afford and/or take time off work to travel to appointments in secondary care. Furthermore, the symptoms of the condition impact school performance and, thus, future employment prospects for children who are already disadvantaged. We believe that SLIT offers a treatment option that will address these issues by allowing patients to be managed closer to home (potential for repeat prescriptions in primary care following initiation by a specialist) and provide long-term disease modification, reducing patient symptoms and improving QoL.	committee as part of the evaluation.
Other considerations	ALK Abello	The company believes no other issues need to be considered.	Thank you for your comment.
	Neonatal and Paediatric Pharmacy Group (NPPG)	Current model noted in one centre is to supply all doses via specialist allergy team, with some patients supplied via Homecare. However, no strong objections to patients being managed in primary care following initiation at a specialist centre. Medication is relatively well tolerated and dosing is simple.	Thank you for your comments.
Questions for consultation	ALK Abello	**Where do you consider 12 SQ-HDM SLIT will fit into the existing care pathway for allergic rhinitis?** ACARIZAX® is expected to be used as an add-on therapy to established clinical management.	Thank you for your comments.

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		ACARIZAX® is indicated in adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with at least one of the following conditions: • persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication • house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis. Patients' asthma status should be carefully evaluated before the initiation of treatment ACARIZAX® is also indicated in children (5-17 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication. AR patients are typically treated in UK clinical practice with a range of symptomatic therapies, in line with NICE guidelines in primary care and BSACI and ARIA guidelines in secondary care. (9-11) The overall treatment pathway for AR in the UK is based on the BSACI rhinitis treatment algorithm (9). Notably, the BSACI guidelines recommend allergy immunotherapy (AIT) for the treatment of AR in patients with a seasonal allergy to pollen whose symptoms persist despite maximal drug therapy, combinations of intranasal corticosteroid and antihistamine taken regularly. (9) The current ARIA guidelines recommend the consideration of AIT for patients with AR and AA comorbidity caused predominantly by allergen exposure, with poor symptom reduction despite adequate pharmacotherapy during the allergy season and/or change in natural allergy history. (11) In line with these guidelines ACARIZAX® is expected to be used as an add-on therapy for paediatric patients with a clinical history of symptoms despite the use of symptom-relieving medication. (12)	

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		Please select from the following, will 12 SQ-HDM SLIT 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):** Option B – Initiation in secondary care with repeat prescriptions in primary care, as concluded in the previous NICE recommendation for ACARIZAX® SLIT (TA1045) and consistent with clinical opinion in both the TA1045 (ACARIZAX) and TA1087 (ITULAZAX) (13, 14). **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.** Comparator treatments for 12 SQ-HDM include symptomatic pharmacotherapy which can be prescribed in both primary and secondary care. **Would 12 SQ-HDM SLIT be a candidate for managed access?** No. **Do you consider that the use of 12 SQ-HDM SLIT can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** Paediatric quality of life (QoL) measures are often completed by proxy, which may not accurately reflect the child's own experience, especially since some children are too young to complete such questionnaires themselves due to cognitive and emotional factors (15), as supported by Section 4.3.14 of the NICE manual (16).	

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		Additionally, aspects such as school performance, future attainment, and the ability to engage in play and other childhood activities are often overlooked or inadequately captured by existing QoL tools. The burden of frequent medical appointments, combined with the variability in access to allergy services across the UK can significantly extend the journey to receiving appropriate care and the burden of the patient's condition. Furthermore, the mental wellbeing and quality of life of carers are also affected and not captured in the tools, as well as the fact that they may need to take time off work and face financial burden associated with management of their child's AR. **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** Clinical expert opinion and published literature on the impact of AR on paediatric patient quality of life. **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 12 SQ-HDM SLIT is 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.**	

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		Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts. N/A	