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

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of 12 standardised quality house dust mite sublingual immunotherapy (12 SQ-HDM SLIT) within its marketing authorisation for treating allergic rhinitis caused by house dust mites in children aged 5 to 11 years.

Background

House dust mites (HDM) are microscopic organisms found in dust that builds up in the house. House dust mite allergy is an immunoglobulin E (IgE)-mediated hypersensitive reaction to proteins in the droppings of dust mites. These proteins can act as allergens (cause an allergic reaction) in the upper or lower respiratory tract causing the symptoms of rhinitis and asthma.[1]

Allergic rhinitis is inflammation of the nose that occurs when the nasal mucosa becomes exposed and sensitised to allergens. Depending on the nature of the allergen, allergic rhinitis has traditionally been categorised as either seasonal allergic rhinitis (e.g., induced by pollen) or perennial allergic rhinitis (e.g., induced by animals or dust mites). In the United Kingdom, the most common allergic trigger for perennial allergic rhinitis is the house dust mite.[2] Rhinitis typically causes symptoms such as sneezing, nasal discharge, itching, and congestion. It may also lead to complications such as sinusitis or middle ear infections as well as the worsening of asthma symptoms.[3]

Allergic rhinitis can be further categorised as either ‘mild’, ‘moderate’ or ’severe’. The definition of moderate disease from the European Academy of Allergy and Clinical Immunology is that symptoms are “bothersome”. Severe rhinitis occurs when symptoms become hard to tolerate, disrupting daily activities or sleep.[4]

Although allergic rhinitis is a common condition, current epidemiological estimates remain imprecise because of a paucity of recent studies, heterogenous terminology and diagnostic criteria, and widespread self-medication practices that contribute to underdiagnosis.[3,5] It is estimated that about 10% of 6 and 7-year-olds and 15% to 19% of 13 and 14-year-olds are affected by allergic rhinitis in England, based on a UK primary healthcare database review (1999–2005).[6]

There is no NICE guidance for treating allergic rhinitis in people 5 to 11 years old. In practice, initial treatment may involve allergy avoidance. This can be followed by pharmacotherapy aimed at symptom control, which may include antihistamines, ocular mast cell stabilisers, topical nasal corticosteroids, and leukotriene receptor antagonists (if asthma is also present). For severe allergic rhinitis that does not respond to usual pharmacotherapy, specific desensitisation with immunotherapy may be considered.[7] Skin prick or specific IgE tests can be used to establish which allergens trigger the immune response if immunotherapy is being considered.

NICE technology appraisal guidance 1045 recommends 12 SQ-HDM SLIT as an option for treating moderate to severe house dust mite allergic rhinitis in people 12 to 65 years that is:

- diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test or specific immunoglobulin E [IgE]) and
- persistent despite use of symptom-relieving medicine.

The technology

12 SQ-HDM SLIT (Acarizax, ALK-Abello) has a marketing authorisation in the UK in children aged 5 to 11 for treating persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication, when diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test or specific IgE. It has been studied in clinical trials compared with placebo in children aged 5 to 11 years who have been diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE), and with persistent moderate to severe house dust mite allergic rhinitis or rhinoconjunctivitis despite use of symptom-relieving medication.

It also has a marketing authorisation for the same indication in children aged 12 to 17 years and adults aged 8 to 65.

Intervention	12 SQ-HDM SLIT as an add-on to standard therapy
Population	People aged 5 to 11 years with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication, diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE)
Comparators	Established clinical management without 12 SQ-HDM SLIT
Outcomes	The outcome measures to be considered include: • combined symptom and medication score • rhinitis symptom scores • complications of allergic rhinitis • medication usage • 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. The availability and cost of biosimilar and generic products should be taken into account. The use of 12 SQ-HDM SLIT is conditional on a positive test for house dust mite sensitisation confirmed with a skin prick test, radioallergosorbent test, fractional exhaled nitric oxide test or blood test for a specific IgE. The economic modelling should include the costs associated with diagnostic testing for house dust mite sensitisation testing in people allergic rhinitis who would not otherwise have been tested. A sensitivity analysis should be provided without the cost of the diagnostic test. See section 4.8 of the guidance development manual (available here: https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation).
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:** 12 SQ-HDM SLIT for treating allergic rhinitis and allergic asthma caused by house dust mites (2025) NICE technology appraisal guidance 1045. Betula verrucosa for treating moderate to severe allergic rhinitis or conjunctivitis caused by tree pollen (2025) NICE technology appraisal guidance 1087. **Related technology appraisals in development:** STG320 for treating allergic rhinitis or rhinoconjunctivitis caused by house dust mites. NICE technology appraisal guidance [ID1278]. Publication date to be confirmed. Betula verrucosa (Itulazax 12 SQ-Bet) for treating moderate to severe allergic rhinitis, conjunctivitis, or both, caused by

	tree pollen in people 5 to 17 years. NICE technology appraisal guidance [ID6537]. Publication to be confirmed. **Related interventional procedures:** Cryotherapy for chronic rhinitis (2023) NICE interventional procedures guidance 771. Intranasal phototherapy for allergic rhinitis (2018) NICE interventional procedures guidance 616. **Related diagnostics guidance:** ImmunoCAP ISAC 112 for multiplex allergen testing (2016) NICE diagnostics guidance 24.

Questions for consultation

Where do you consider 12 SQ-HDM SLIT will fit into the existing care pathway for allergic rhinitis?

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):

For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would 12 SQ-HDM SLIT be a candidate for managed access?

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?

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 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.

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. Demoly P, Emminger W, Rehm D, Backer V, Tommerup L, Kleine-Tebbe J. Effective treatment of house dust mite–induced allergic rhinitis with 2 doses of the sq hdm slit-tablet: Results from a randomized, double-blind, placebo-controlled phase III trial. Journal of Allergy and Clinical Immunology. 2016;137(2)

2. Bauchau, V, Durham, SR Prevalence and rate of diagnosis of allergic rhinitis in Europe. European Respiratory Journal (2004) 24[5] 758-64

3. NHS (2024) Allergic rhinitis. Accessed August 2025

4. Pfaar O, Demoly P, Gerth van Wijk R, et al. (2014) Recommendations for the standardization of clinical outcomes used in allergen immunotherapy trials for allergic rhinoconjunctivitis: An EAACI Position Paper. Allergy 69(7):854-867

5. NICE CKS (2022) Conjunctivitis – allergic. Accessed August 2025

6. Ghouri N, Hippisley-Cox J, Newton J, et al. (2008) Trends in the epidemiology and prescribing of medication for allergic rhinitis in England. Journal of the Royal Society of Medicine 101(9):466-472

7. Scadding GK, Kariyawasam HH, Scadding G, et al. (2017) BSACI guideline for the diagnosis and management of allergic and non-allergic rhinitis (Revised Edition 2017; First edition 2007). Clinical and Experimental Allergy 47(7):856-889