Health Technology Briefing
January 2026

75,000 SQ-T sublingual lyophilisate for treating allergic conjunctivitis or allergic rhinitis

Company/Developer	ALK-Abello Ltd

☐ New Active Substance ☒ Significant Licence Extension (SLE)

NIHRIO ID: 41016	NICE ID: Not Available	UKPS ID: 675277

Licensing and Market Availability Plans

Completed phase III clinical trials.

Summary

75,000 SQ-T sublingual lyophilisate is intended for treatment of allergic conjunctivitis (AC) and/or allergic rhinitis (AR). Both are very common and are caused by an allergic reaction to grass pollen (among other pollens). AR causes a blocked or runny nose, while AC causes red and itchy eyes. It is common to suffer from AR and AC at the same time – this is called rhinoconjunctivitis. There are a several treatment options to relieve the symptoms of AR and AC, for example taking anti-allergy tablets, using nose sprays to relieve blocked nose and avoiding exposure to pollen. However, these treatment options do not target the underlying cause of disease.

75,000 SQ-T sublingual lyophilisate is an allergen extract from the Timothy grass that is administered under the tongue. Immunotherapy with 75,000 SQ-T sublingual lyophilisate is a repeated administration of grass pollen allergens to allergic individuals with the purpose of changing the immune response to the allergen. This reduces the symptoms, and can be long-lasting, reducing the need for medication. Immunotherapy also reduces the inflammation that characterises AR. If recommended by National Institute for Care and Health Excellence (NICE), 75,000 SQ-T sublingual lyophilisate would provide an additional treatment for people with AR and/or AC caused by grass pollen, and the first to target the underlying cause of disease.

Proposed Indication

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was available to comment.

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Disease-modifying treatment of grass pollen induced rhinitis and conjunctivitis in adults and children (5 years or older), with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen.[1,2]

Technology

Description

75,000 SQ-T sublingual lyophilisate (Grazax) is an allergen extract for immunotherapy of Timothy grass pollen-induced allergic rhinitis (AR) and/or allergic conjunctivitis (AC). Allergy immunotherapy with allergen products is the repeated administration of allergens to allergic individuals with the purpose of modifying the immunological response to the allergen. The aim is to induce an immune response against the allergen with which the patient is treated. The complete and exact mechanism of action regarding clinical effect of specific immunotherapy is not fully understood and documented. Treatment has shown to induce a systemic competitive antibody response towards grass, and it induces an increase in specific IgG_4 over 3 years of treatment. 2 years after completed treatment the increase in specific IgG_4 was still present.[3]

75,000 SQ-T sublingual lyophilisate was evaluated in two completed phase III clinical trials (NCT00408616, NCT00227279), in which it was administered sublingually once daily.[1,2]

Key Innovation

Although widely given as first-line treatment for AR and AC, the first-generation sedating antihistamines lack good evidence of efficacy and are known to have adverse effects such as psychomotor retardation and behaviour disturbance.[4] Of the three primary modalities used to manage AR – allergen avoidance, pharmacotherapy, and immunotherapy – the latter is the only treatment that that has a disease-modifying effect through induction of immunologic tolerance.[5]

If recommended by National Institute for Health and Care Excellence (NICE), 75,000 SQ-T sublingual lyophilisate will offer the first disease modifying treatment option for children and adults with grass pollen induced AC and AR not currently controlled by symptomatic treatments.

Regulatory & Development Status

75,000 SQ-T sublingual lyophilisate currently has Marketing Authorisation in the EU and UK for treatment of grass pollen induced AR and AC in adults and children (5 years or older), with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen.[3]

75,000 SQ-T sublingual lyophilisate is not in phase II/III clinical trials for any indication.

Patient Group

Disease Area and Clinical Need

AR is an inflammatory disorder of the nose that occurs when the nasal mucosa becomes exposed and sensitised to allergens. Rhinitis describes inflammation of the nasal mucosa, which causes typical clinical symptoms of sneezing, nasal discharge, itching, and congestion. AR is considered moderate to severe when sleep and/or daily living activities are affected. For example, sleep disturbance, impairment of school or work, leisure or sport.[6] AC is an inflammation or infection of the conjunctiva that causes dilation of conjunctival vessels leading to hyperaemia and oedema of the conjunctiva which may be associated with discharge.[7] Symptoms of AC include red or pink eyes, pain, itchiness and swollen eyelids.[8] Conjunctivitis

can be acute (persisting for less than 4 weeks), chronic (persisting for more than 4 weeks), or recurrent.[7] Timothy grass is one of the leading causes of seasonal allergies in many individuals due to its abundance in many climates.[9]

In the UK, AR prevalence is 26% in adults. Peak prevalence occurs during the 30s to 40s age range, with some evidence for remission during adult life.[10] Between 30–71% of patients with AR also have AC or conjunctival symptoms. AC is a common condition estimated to affect up to 40% of the population.[11] In England, 2024-25, there were 2,927 admissions and 2,911 finished consultant episodes (FCE) for AR due to pollen (ICD-10 code J30.1), resulting in 82 FCE bed days and 2,740 day cases; for AC (ICD-10 code H10.1), there were 107 admissions and 102 finished consultant episodes (FCE), resulting in 44 FCE bed days.[12]

Recommended Treatment Options

There is no treatment option recommended by NICE for grass pollen induced AC or AR.

The National Health Service (NHS) currently recommends the use of antihistamines, decongestant nasal sprays/drops and salt water nasal sprays to treat AR. In the case that pharmacy medicines do not help to ease AR symptoms, steroid nasal sprays and antihistamines are available on prescription.[13] For AC, it is recommended to use mast-cell stabiliser or antihistamine eye drops, and antihistamine tablets.[14]

Clinical Trial Information

Trial	NCT00408616; A Phase III Trial Investigating the Efficacy and Safety of Grazax in Children Aged 5-16 Years With Grass Pollen Induced Rhinoconjunctivitis With or Without Asthma **Phase III**: Completed **Locations:** Germany **Study Completion Date:** November 2007
Trial Design	Randomised, parallel assignment, quadruple-blinded
Population	N=253 (actual); subjects with grass pollen induced rhinoconjunctivitis with or without asthma; children aged 5-16 years
Intervention(s)	75,000 SQ-T sublingual lyophilisate tablet once daily
Comparator(s)	Matched placebo
Outcome(s)	Primary outcomes: • Hayfever symptoms [Time frame: grass pollen season 2007] • Intake of hayfever symptom relieving medication [Time frame: grass pollen season 2007] See trial record for full list of other outcomes
Results (efficacy)	The rhinoconjunctivitis symptom and medication scores and the asthma symptom score were all statistically significantly different between the 2 treatment groups. The differences in medians relative to placebo were 24%, 34%, and 64% in favour of active treatment.[15]

Results (safety)	The most common adverse reaction was oral pruritus, reported by 40 subjects (32%) in the active and 3 (2%) in the placebo group. Six subjects withdrew because of adverse events. No serious adverse events were assessed as treatment-related. Treatment was well tolerated. [15]

Trial	NCT00227279; A Randomised, Parallel-group, Double-blind, Placebo-controlled Phase III Trial Assessing the Efficacy and Safety of ALK Grass Tablet in Subjects With Seasonal Grass Pollen Induced Rhinoconjunctivitis **Phase III**: Completed **Locations:** Denmark **Study Completion Date:** September 2009
Trial Design	Randomised, parallel assignment, triple-blinded
Population	N=634 (actual); adult subjects with grass pollen induced rhinoconjunctivitis with a positive skin prick test to grass and/or positive specific IgE to grass
Intervention(s)	75,000 SQ-T sublingual lyophilisate tablet once daily
Comparator(s)	Matching placebo
Outcome(s)	Primary outcomes: • Recording of rhinoconjunctivitis symptoms [Time frame: daily recordings during the entire grass pollen seasons 2007, 2008 and 2009] • Recording of use of rescue medication [Time frame: daily recordings during the entire grass pollen seasons 2007, 2008 and 2009] See trial record for full list of other outcomes
Results (efficacy)	The primary efficacy analysis showed a reduction of 30% in rhinoconjunctivitis symptom score (P < .0001) and a reduction of 38% in rhinoconjunctivitis medication score (P < .0001) compared with placebo.[16]
Results (safety)	Side effects mainly comprised mild itching and swelling in the mouth that was in general well tolerated and led to treatment withdrawal in less than 4% of participants. There were no serious local side effects and no severe systemic adverse events.[16]

Estimated Cost

75,000 SQ-T sublingual lyophilisate is already marketed in the UK for treatment of grass pollen induced AR or AC; a pack of 30 tablets cost £80.12.[17]

Relevant Guidance

NICE Guidance

- NICE interventional procedure guidance. Intranasal phototherapy for allergic rhinitis (IPG616). June 2018.
- NICE diagnostic guidance. ImmunoCAP ISAC 112 for multiplex allergen testing (DG24). May 2016.

NHS England (Policy/Commissioning) Guidance
• NHS England. NHS Standard Contract for Specialised Allergy Services (Adults). B09/S/b. 2025. • NHS England. 2013/14 NHS Standard Contract for Paediatric Medicine: Specialised Allergy Services. E03/S/j.
Other Guidance
• The British Society of Allergy and Clinical Immunology. BSACI guideline for the diagnosis and management of allergic and non-allergic rhinitis. Revised Edition 2017.[4] • The European Academy of Allergy and Clinical Immunology. EAACI Guidelines on Allergen Immunotherapy: Allergic rhinoconjunctivitis. 2018.[18]

References

1 ClinicalTrials.gov. *Efficacy and Safety of Grazax in Children*. *Trial ID: NCT00408616*. 2006. Status: Completed. Available from: https://clinicaltrials.gov/study/NCT00408616 [Accessed 12 November 2025].

2 ClinicalTrials.gov. *A Trial of the ALK Grass Tablet in Subjects With Hayfever*. *Trial ID: NCT00227279*. 2004. Status: Completed. Available from: https://clinicaltrials.gov/study/NCT00227279 [Accessed 12 November 2025].

3 Electronic Medicines Compendium (EMC). *GRAZAX 75,000 SQ-T oral lyophilisate*. 2025. Available from: https://www.medicines.org.uk/emc/product/315/smpc [Accessed 12 November 2025].

4 Scadding GK, Kariyawasam HH, Scadding G, Mirakian R, Buckley RJ, Dixon T, et al. BSACI guideline for the diagnosis and management of allergic and non-allergic rhinitis (Revised Edition 2017; First edition 2007). *Clinical and Experimental Allergy*. 2017;47(7):856-89. Available from: https://doi.org/https://doi.org/10.1111/cea.12953.

5 Wise SK, Damask C, Roland LT, Ebert C, Levy JM, Lin S, et al. International consensus statement on allergy and rhinology: Allergic rhinitis – 2023. *International Forum of Allergy & Rhinology*. 2023;13(4):293-859. Available from: https://doi.org/https://doi.org/10.1002/alr.23090.

6 National Institute for Health and Care Excellence (NICE). *Allergic rhinitis: What is it?* 2024. Available from: https://cks.nice.org.uk/topics/allergic-rhinitis/background-information/definition/ [Accessed 17 November 2025].

7 National Institute for Health and Care Excellence (NICE). *Conjuctivitis - allergic: What is it?* 2022. Available from: https://cks.nice.org.uk/topics/conjunctivitis-allergic/background-information/definition/ [Accessed 17 November 2025].

8 National Institute for Health and Care Excellence (NICE). *Conjunctivitis - allergic: What are the clinical features of allergic conjunctivitis?* 2022. Available from: https://cks.nice.org.uk/topics/conjunctivitis-allergic/diagnosis/clinical-features/ [Accessed 17 November 2025].

9 Frontier Allergist. *Timothy Grass Allergy – Symptoms and Treatment*. 2023. Available from: https://www.frontierallergist.com/timothy-grass-allergy/ [Accessed 17 November 2025].

10 National Health Service (NHS). *Barts Health Adult Allergic Rhinitis Guidelines*. Available from: https://primarycare.northeastlondon.icb.nhs.uk/wp-content/uploads/2023/07/Allergic-rhinitis-guidelines-Barts-health-Final-2019-v01.pdf [Accessed 17 November 2025].

11 National Institute for Health and Care Excellence (NICE). *Conjunctivitis - allergic: How common is it?* 2022. Available from: https://cks.nice.org.uk/topics/conjunctivitis-allergic/background-information/prevalence/ [Accessed 17 November 2025].

12 NHS Digital. *Hospital Admitted Patient Care Activity, 2024-25*. 2025. Available from: https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2024-25 [Accessed 7 October 2025].

13 National Health Service (NHS). *Allergic rhinitis*. 2022. Available from: https://www.nhs.uk/conditions/allergic-rhinitis/ [Accessed 12 November 2025].

14 National Health Service (NHS) East Sussex Healthcare. *Patient information - Conjuctivitis (Allergic)*. 2020. Available from: https://www.esht.nhs.uk/wp-content/uploads/2020/11/0871.pdf [Accessed 12 November 2025].

15 Bufe A, Eberle P Fau - Franke-Beckmann E, Franke-Beckmann E Fau - Funck J, Funck J Fau - Kimmig M, Kimmig M Fau - Klimek L, Klimek L Fau - Knecht R, et al. Safety and efficacy in children of an SQ-standardized grass allergen tablet for sublingual immunotherapy. *Journal of Allergy and Clinical Immunology,*. 2009;123(1):167-73. https://pubmed.ncbi.nlm.nih.gov/19130937/.

16 Dahl R, Kapp A Fau - Colombo G, Colombo G Fau - de Monchy JGR, de Monchy Jg Fau - Rak S, Rak S Fau - Emminger W, Emminger W Fau - Rivas MF, et al. Efficacy and safety of sublingual immunotherapy with grass allergen tablets for seasonal allergic rhinoconjunctivitis. *Journal of Allergy and Clinical Immunology*. 2006;118(2):434-40. https://pubmed.ncbi.nlm.nih.gov/16890769/.

17 National Institute for Health and Care Excellence (NICE). *Deucravacitinib - Medicinal forms*. 2025. Available from: https://bnf.nice.org.uk/drugs/deucravacitinib/medicinal-forms/ [Accessed 4 December 2025].

18 Roberts G, Pfaar O, Akdis CA, Ansotegui IJ, Durham SR, Gerth van Wijk R, et al. EAACI Guidelines on Allergen Immunotherapy: Allergic rhinoconjunctivitis. *Allergy*. 2018;73(4):765-98. Available from: https://doi.org/https://doi.org/10.1111/all.13317.

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