

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

AR101 for treating peanut allergy

Final scope

Final remit/appraisal objective

To appraise the clinical and cost effectiveness of AR101 within its marketing authorisation for treating peanut allergy.

Background

Food allergy is an adverse immune response to food allergens. Peanut allergy is Immunoglobulin E-mediated and one of the most common food allergies¹. Symptoms of an allergic reaction to peanuts are acute and have rapid onset. Allergic reactions may be characterised by angioedema (facial swelling), asthma or other respiratory symptoms (such as wheezing), conjunctivitis, oral allergy syndrome, rhinitis (inflammation of the nose), urticaria (blotchy red rash). Reactions may also become severe, life-threatening and generalized or systemic (anaphylaxis)¹.

Peanut allergy is often present in children, though some may grow out of it over time¹. It can have a great impact on people and their families because the constant vigilance required to avoid peanuts and potentially other tree nuts (due to cross-contamination or multiple nuts allergies) and a constant fear of an allergic reaction.

In the UK, peanut allergy affects between 0.5% and 2% of children⁴ and has been increasing in recent decades. It also accounts for 16% of all fatal food-induced anaphylaxis cases in children and 22% of adults².

Current management of peanut allergy is focused on avoidance of peanuts through education and vigilance with checking food labelling. In the event of an allergic reaction, mild events are treated with oral antihistamines and severe events are treated with adrenaline (auto-injector pens).

The technology

AR101 (Palforzia, Aimmune Therapeutics) is an oral immunotherapy that aims to desensitise people with peanut allergy and reduce the chance of severe allergic reactions including anaphylaxis that may occur with accidental exposure to peanuts. The treatment involves taking a small dose of AR101 initially but gradually increasing under clinical supervision over approximately 6 months until a maintenance dose level is achieved.

AR101 has a marketing authorisation in the UK for treating peanut allergy in children from 4 to 17 years of age and people who become adults whilst on treatment. While taking this treatment, people continue avoiding peanuts.

Intervention	AR101
Population	Children with peanut allergy aged 4-17 years and adults who started treatment as a child.
Comparators	Established clinical management without AR101 (including allergen avoidance, symptomatic treatments such as antihistamines and emergency medication)
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • peanut allergy desensitization • systemic allergic reactions (including anaphylaxis) • frequency and severity of symptoms after accidental exposure to peanut • discontinuation of treatment • adverse effects of treatment • health-related quality of life.
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
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 and NICE Pathways	<p>Related Guidelines:</p> <p>Food allergy in under 19s: assessment and diagnosis (2011). NICE guideline 116. Review date September 2018.</p> <p>Anaphylaxis: assessment and referral after emergency treatment (2011). NICE Clinical guideline CG134. Review date November 2016.</p> <p>Related Quality Standards:</p>

	<p>Food allergy (2016). NICE quality standard QS118.</p> <p>Anaphylaxis.(2016) Quality standard QS119.</p> <p>Related NICE Pathways:</p> <p>Food allergy in under 19s overview (2017) NICE pathway.</p> <p>Related Diagnostic guidance:</p> <p>ImmunoCAP ISAC 112 and Microtest for multiplex allergen testing diagnostics guidance (2016). NICE Diagnostic Guidance 24.</p>
<p>Related National Policy</p>	<p>The NHS Long Term Plan, 2019. NHS Long Term Plan</p> <p>NHS England (2018/2019) Chapter 59 NHS manual for prescribed specialist services (2018/2019)</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 1, 2 and 5.</p> <p>https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</p>

References

1. American College of Allergy, Asthma and Immunology. [Food Allergy](#). [Accessed July 2020]
2. Turner PJ, Gowland MH, Sharma V, et al. (2015) Increase in Anaphylaxis-Related Hospitalizations but No Increase in Fatalities: An Analysis of United Kingdom National Anaphylaxis Data, 1992-2012. *The Journal of Allergy and Clinical Immunology*. 2015;135(4):956-63.e1
3. Stiefel, G, Anagnostou K, Boyle RJ, et al. (2017) BSACI guideline for the diagnosis and management of peanut and tree nut allergy. *Clinical and Experimental Allergy* 47: 719-39.
4. Ewan P for the British Society for Allergy and Clinical Immunology. (2006) The nature and extent of allergy in the United Kingdom. A report to the Department of Health Review of Allergy Services