NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

AR101 for treating peanut allergy

Draft scope

Draft 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 allergies[1]. 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 time[1]. It can have a great impact on people and their families because the constant vigilance required to avoid peanuts or 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 children[4] and has been increasing in recent decades. It also accounts for 16% of all fatal food-induced anaphylaxis cases in children and 22% of adults[2].

Current management of peanut allergy is focused on avoidance of peanuts and other tree nuts 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 decrease the response of the body to peanut protein and reduce the chance of having an anaphylactic reaction if accidentally exposed to peanuts. AR101 contains a very small amount of the protein found in peanuts that is insufficient to cause a reaction; the amount administered is slowly increased until desensitisation is achieved.

AR101 does not currently have marketing authorisation for peanut allergy. It has been studied in clinical trials in comparison with placebo in children and adults with peanut allergy.

Intervention	AR101
Population	People with peanut allergy
Comparators	Established clinical management without AR101 (including allergen avoidance and emergency medication)
Outcomes	The outcome measures to be considered include: • Tolerance to the treatment • Peanut allergy desensitization • Symptom severity • Discontinuation of treatment • Adverse events, including: ▪ Systemic allergic reactions (including anaphylaxis and use of adrenaline) ▪ Gastrointestinal symptoms ▪ Respiratory symptoms ▪ Immune system symptoms ▪ Skin symptoms • 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.
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	**Related Guidelines:** Food allergy in under 19s: assessment and diagnosis (2011). NICE guideline 116. Review date September

	2018. Anaphylaxis: assessment and referral after emergency treatment (2011). NICE Clinical guideline CG134. Review date November 2016. **Related Quality Standards:** Food allergy (2016). NICE quality standard QS118. Anaphylaxis.(2016) Quality standard QS119. **Related NICE Pathways:** Food allergy in under 19s overview (2017) NICE pathway. **Related Diagnostic guidance:** ImmunoCAP ISAC 112 and Microtest for multiplex allergen testing diagnostics guidance (2016). NICE Diagnostic Guidance 24.
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) Chapter 59 NHS manual for prescribed specialist services (2018/2019) Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 1, 2 and 5. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

Questions for consultation

Within the population of people with peanut allergy, who would receive immunotherapy treatment? Would this be affected by age or severity of peanut allergy?

Would AR101 be used in conjunction with a peanut-avoidance diet?

Have all relevant comparators for AR101 been included in the scope? Which treatments are considered to be established clinical practice in the NHS for peanut allergy?

Are the outcomes listed appropriate? What outcomes are important for people with peanut allergy and clinicians? Would immunotherapy treatment be expected to last for a lifetime?

Are there any subgroups of people in whom AR101 is expected to be more clinically effective and cost effective or other groups that should be examined separately?

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 AR101 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.

Do you consider AR101 to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of AR101 can result in any potential significant and 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 Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

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