NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Epicutaneous immunotherapy for treating peanut allergy in children

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of epicutaneous immunotherapy within its proposed marketing authorisation for treating children with 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 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 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 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

Epicutaneous immunotherapy for peanut allergy (Viaskin Peanut, DBV Technologies) is an allergen immunotherapy designed to develop allergy desensitisation. Epicutaneous describes the administration method through a wearable patch, which delivers a small amount of peanut allergen to intact skin.

It does not currently have a marketing authorisation for peanut allergy. It has been studied in clinical trials compared with placebo in children with peanut allergy.

Intervention	Epicutaneous immunotherapy for peanut allergy
Population	Children with peanut allergy
Comparators	Established clinical management without epicutaenous immunotherapy (including allergen avoidance, symptomatic treatments such as antihistamines and emergency medication)
Outcomes	The outcome measures to be considered include: • 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	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?

Have all relevant comparators for epicutaneous immunotherapy 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?

Are there any subgroups of people in whom epicutaneous immunotherapy 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 epicutaneous immunotherapy 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 epicutaneous immunotherapy 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 epicutaneous immunotherapy 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.