**EDITORIAL**

**NICE and easy? Ensuring equitable access to NICE-approved treatments in children and young people**

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The National Institute for Health and Care Excellence recently approved Palforzia®, an oral immunotherapy product for the treatment of peanut allergy in peanut-allergic children aged 4 to 17.1 Palforzia contains precise amounts of defatted peanut powder, and can be used to gradually increase the body’s ability to tolerate small amounts of peanut. It may also help reduce the severity of allergic reactions after being exposed to peanut.

The approval of Palforzia represents a major step forward for the management of food-allergic patients in the NHS. There are approximately 140,000 eligible patients with peanut allergy, but only a handful of specialist services able to provide the multiple visits needed to administer the treatment. These visits require significant space and staff resources, which many services lack. As a result, NHS England is limiting the number of eligible patients to 600 in the first year (and up to 2000 per annum thereafter).2

Treatments recommended by NICE in its technology appraisal programmes must be funded by the NHS, under the Health and Social Care Act 2012, through what is called the ‘funding directive’.3 Normally, when the funding directive is applied, NHS England (NHSE) has 90 days to make the treatment available. This is to allow local Clinical Commissioning Groups (CCGs) to make arrangements to support the NICE recommendation, and does not apply to the availability of the treatment by individual NHS Trusts. Such a timeline can be delayed by NICE until such a time that “(i) training is, (ii) certain health service infrastructure requirements including goods, materials or other facilities are, or (iii) other appropriate health services resources, including staff, are, in place" to support patient safety. However, such a stipulation must be included by NICE in its recommendation, for such a delay to be allowed. In the case of Palforzia, no stipulation was made.1

In the absence of such a stipulation, given the pressure from expectant parents, as a result of a high-profile pronouncement relating to the availability of Palforzia, as well as clinicians keen to offer new treatments there remains a real risk that pressure to provide it in the context of current service limitations will negatively impact other patients. There is also a concern that the treatment may be offered to those who are able to better advocate for their children, thus further exacerbating existing socioeconomic disparities in access to specialist allergy services in the NHS. It still remains unclear as to how the resource required to support infrastructure development will be obtained, other than through individual NHS Trusts developing their own local business cases for commissioners. How NHS Trusts and commissioners will be held accountable for service delivery is also unclear, and there is a risk that resource will be drawn from the same funding currently allocated to existing allergy services.

This would not be the first example of a treatment approved by NICE requiring implementation in the NHS, but no consideration given as to how the treatment is to be funded outside the cost of the medicinal product itself. During a debate held in the House of Commons on 30 November 2021, Anne Marie Morris MP, Chair of the All-Party Parliamentary Group on Access to Medicines and Medical devices, noted that “*when drugs are approved, exactly how they are going to be delivered is not approved at the same time… as things stand, it can often take three years and much argument before hubs are established and the funding can then flow*.” 4

We are concerned as to the disconnect between the public promotion of the treatment following NICE authorisation and 'on the ground' reality of delivery, with no clarity around funding mechanisms and no apparent clear accountability for this delivery. Despite the NICE committee noting “that treatment with Palforzia is resource intensive” and acknowledging “that the model should have included all costs related to setting up oral immunotherapy treatment in NHS practice”,1 the cost-effectiveness analysis used by NICE failed to include the cost of delivery in the NHS.

Ironically, this situation may be less of an issue for other NICE-approved treatments. NHS England has separate arrangements for commissioning treatments for patients aged under 18 years, where NICE has approved a treatment within the Technology or Highly Specialised Technology Appraisals process in adults.5 Therefore, paradoxically, there are funding arrangements when NICE-approved treatments for adults are used in children and young people, but not when NICE-approved treatments for children are implemented! This is just one example of the disconnect between approval of a treatment by NICE and its implementation in the NHS, something recently highlighted as a concern by the All-Party Parliamentary Group on Access to Medicines and Medical devices in a letter to the Academy of Medical Royal Colleges in the UK.

Given the potential for allergic reactions due to a treatment dose, including potentially life-threatening anaphylaxis,1 there is a need for NHS Trusts to ensure that staff are adequately trained and that appropriate safety mitigation strategies are in place prior to offering Palforzia. Given the anticipated mismatch of demand and capacity, the British Society for Allergy and Clinical Immunology (BSACI) is currently developing guidance to support healthcare professionals who wish to establish an oral immunotherapy service using Palforzia, which should be available by October 2022.

Only through these measures can the safety profile of Palforzia, demonstrated in clinical trials, be replicated in the clinical setting. Healthcare professionals should note that the timelines stipulated in legislation do not apply to individual NHS Trusts, and therefore not feel under pressure to implement a new treatment without sufficient resource and safety-netting being in place. At the same time, any delays in implementation will result in older children missing the opportunity to access this treatment, as Palforzia can only be initiated in young people up between 4 and 17 years of age. Clarity is needed from NHSE with regards to funding support, to enable the infrastructure and staff changes required to deliver this – and other pioneering treatments for children and young people – safely.

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