NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report: Palforzia for treating peanut allergy in children and young people (TA769)

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Summary

NICE has recommended Palforzia for treating peanut allergy in children aged 4 to 17 years.

We estimate that:

- Around 141,000 children in England with peanut allergy are eligible for treatment with Palforzia.
- Around 3,000 children in England will start treatment with Palforzia in year 2026/27 once uptake has reached around 2%.

It is anticipated that the uptake of Palforzia will be impacted by its contraindications, regimen requirements, self-injection prerequisite, potential issues around taste aversion for children who switch to dietary peanut and the long-term commitment required to maintain peanut tolerance. Uptake of Palforzia is also expected to be affected by capacity within food allergy clinics.

The resource impact report and template include the expected uptake for the first 5 years of Palforzia being available. Capacity is expected to increase over time with around 3,000 children expected to start treatment in year 2026/27. For every 1,000 children treated with Palforzia the cumulative resource impact is expected to be around £13m.

The estimated annual cost of implementing this guidance for the population of England based on the uptake in the resource impact assumptions is shown in table 1. Based on the assumptions used for England, this is equivalent to a cost of around \pounds 1.7m and \pounds 1.2m in 2026/27 for Wales and Northern Ireland respectively.

	2022/23	2023/24	2024/25	2025/26	2026/27
Uptake rate for Palforzia (%)	0.44%	0.89%	1.50%	1.80%	2.11%
Children starting Palforzia each year	626	1,261	2,112	2,542	2,972
Children already receiving Palforzia at the start of the year	0	521	1,541	2,829	4,016
Total children receiving treatment during each year	626	1,782	3,654	5,371	6,988
Children who discontinue Palforzia during the year	(105)	(241)	(825)	(1,355)	(2,007)
Total children who continue treatment to following year	521	1,541	2,829	4,016	4,981
Number of administration appointments	7,512	15,132	25,344	30,504	35,664
Number of additional monitoring appointments	0	1,504	3,681	6,626	9,027
Total additional appointments	7,512	16,636	29,025	37,130	44,691
Drug cost (£000)	1,387	5,040	10,469	16,111	21,040
Administration cost (£000)	1,845	3,716	6,224	7,491	8,759
Additional monitoring cost (£000)	0	359	877	1,579	2,152
Total resource impact (£000)	3,232	9,114	17,570	25,182	31,950

Table 1 Estimated annual cost of implementing the guidance in England

The table does not include appointments or costs for children who move to dietary peanut. This should be assessed locally in the resource impact template.

This report is supported by a <u>resource impact template</u> which may be used to calculate the resource impact of implementing the guidance by amending the variables.

This technology is commissioned by clinical commissioning groups. It is expected to be provided in allergy clinics within NHS hospital trusts.

1 Palforzia

- NICE has recommended Palforzia, within its marketing authorisation, as an option for treating peanut allergy in children aged 4 to 17.
- 1.2 For people with peanut allergy, strictly avoiding peanuts and being ready to respond to an emergency are, currently, the main ways to protect against reactions to accidental exposure.
- 1.3 Clinical trial evidence shows that Palforzia improves tolerance to peanut protein when precise amounts are used in a food challenge test. It is likely that children will need lifetime treatment with Palforzia or to regularly include peanuts in their diet to maintain tolerance to peanuts.
- 1.4 The committee concluded that clinicians and people affected by peanut allergy would welcome a treatment option that would reduce the risks of accidental peanut exposure and improve quality of life of children with peanut allergy and their carers.

2 Resource impact of the guidance

- 2.1 We estimate that:
 - Around 141,000 children in England with with peanut allergy are eligible for treatment with Palforzia each year.
 - Around 3,000 children in England will start treatment with Palforzia in year 2026/27 once uptake has reached around 2%.
- 2.2 The future uptake figure assumptions are based on the company submission estimates and are shown in the resource impact template. Expert clinical opinion suggests that the uptake of Palforzia may be lower because of capacity constraints due to the low number of clinics (around 20 in England) that may deliver treatment. There are a number of additional factors that may affect uptake including contraindications, strict regimen Resource impact report: Palforzia for treating peanut allergy in children and

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requirements and adrenaline self-injection prerequisite. People not regularly including peanuts in their diet after Palforzia treatment may lose tolerance and will need to return to strictly avoiding peanuts and being prepared for emergencies. Whether or not people keep peanuts in their diet after Palforzia treatment may be linked to taste aversion, motivation, adverse effects, restrictions around meals and exercise, and support received. Alternative uptake estimates may be modelled using the resource impact template.

2.3 The estimated annual cost of implementing this guidance for the population of England based on the uptake in the resource impact assumptions is shown in table 2. The cost in year 2026/27 is equivalent to around £57,000 per 100,000 population (see table 3).

Table 2 Resource impact of implementing the guidance using NICEassumptions for the population of England

	2022/23	2023/24	2024/25	2025/26	2026/27
Uptake rate for Palforzia (%)	0.44%	0.89%	1.50%	1.80%	2.11%
Children starting Palforzia each year	626	1,261	2,112	2,542	2,972
Children already receiving Palforzia at the start of the year	0	521	1,541	2,829	4,016
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Number of additional monitoring appointments	0	1,504	3,681	6,626	9,027
Total additional appointments	7,512	16,636	29,025	37,130	44,691
Drug cost (£000)	1,387	5,040	10,469	16,111	21,041
Administration cost (£000)	1,845	3,716	6,224	7,491	8,759
Additional monitoring cost (£000)	0	359	877	1,579	2,152
Total resource impact (£000)	3,232	9,114	17,570	25,182	31,950

Note: Table includes rounded figures.

The table does not include appointments or costs for children who move to dietary peanut. This should be assessed locally in the resource impact template.

Table 3 Resource impact of implementing the guidance using NICEassumptions per 100,000 population

	2022/23	2023/24	2024/25	2025/26	2026/27
Uptake rate for Palforzia (%)	0.44%	0.89%	1.50%	1.80%	2.11%
Children starting Palforzia each year	1	2	4	5	5
Children already receiving Palforzia at the start of the year	0	1	3	5	7
Total children receiving treatment during each year	1	3	7	10	12
Children who discontinue Palforzia during the year	(0)	(0)	(1)	(2)	(4)
Total children who continue treatment to following year	1	3	5	7	9
Number of administration appointments	13	27	45	54	63
Number of additional monitoring appointments	0	3	7	12	16
Total additional appointments	13	30	52	66	79
Drug cost (£000)	2	9	19	29	37
Administration cost (£000)	3	7	11	13	16
Additional monitoring cost (£000)	0	1	2	3	4
Total resource impact (£000)	6	16	31	45	57

Note: Table includes rounded figures.

The table does not include appointments or costs for children who move to dietary peanut. This should be assessed locally in the resource impact template.

2.4 This report is supported by a <u>resource impact template</u> which may be used to calculate the resource impact of implementing the guidance by amending the variables.

Savings and benefits

2.5 Clinical trial evidence shows that it is likely that Palforzia improves people's quality of life once they are receiving a stable dose.

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3 Implications for commissioners

- 3.1 This technology is commissioned by clinical commissioning groups. It is expected to be provided in allergy clinics within NHS hospital trusts.
- 3.2 Palforzia needs to be delivered under the care of a specialist healthcare professional qualified in the diagnosis and treatment of allergic diseases (stated in the <u>Summary of Product</u> <u>Characteristics (SmPC)</u>) and therefore, the capacity to offer Palforzia treatment in England is likely to be restricted to a small number of specialist secondary and tertiary paediatric allergy services. Not all specialist allergy clinics are expected to be able to deliver Palforzia treatment. There are expected to be around 20 clinic providers in England during each of the first 5 years of Palforzia being available that can offer the treatment.
- 3.3 The resource impact template and report model an uptake level that is low. This is based on treatment with Palforzia involving several risks for the patient (strict peanut avoidance and emergency preparedness continue during treatment) and requiring extensive monitoring from carers who are often risk averse. In addition to this the uptake of Palforzia is also expected to be affected by capacity within food allergy clinics during the next five years.
- It is assumed that no new allergy centres are likely to open during the next 5 years.
- 3.5 The template may be amended to reflect local capacity and uptake assumptions.
- 3.6 It is expected that providing Palforzia within allergy clinics would require additional investment, particularly in capacity and training of staff. These costs are not included in the resource impact template and should be assessed locally.

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- 3.7 Palforzia should be made available for use in England within 3 months of publication of the guidance.
- 3.8 Palforzia falls within the programme budgeting category 03XDisorders of Blood.

4 How we estimated the resource impact

The population

4.1 There are around 9.4 million children aged 4 to 17 years in England. Around 1.5% of children are estimated to have peanut allergy based on a mid-point of the range 0.5%-2.5% based on a <u>meta-analysis of European studies</u>. This gives an eligible population of around 141,000 children.

Population	Proportion of previous row (%)	Number of people		
Total population		56,286,961		
Children aged 4 to 17 years		9,408,923		
Prevalence of peanut allergy ¹	1.50%	141,134		
Total number of children eligible for treatment with Palforzia		141,134		
Total number of people estimated to start treatment with Palforzia in 2026/27	2.11% (rounded)	2,972		
¹ BSACI guideline for the diagnosis and management of peanut and tree nut allergy				

Table 3 Number of people eligible for treatment in England

Assumptions

- 4.2 The resource impact template assumes that:
 - Uptake will reach around 2% of the eligible population after 5 years, based on capacity within clinics, as discussed in 3.2 and 3.3 above.
 - No off-setting comparator costs are included because other

preventative treatments are not currently available; strictly Resource impact report: Palforzia for treating peanut allergy in children and young people (February 2022) 9 of 13 avoiding peanuts and being ready to respond to an emergency are the main ways to protect against reactions to accidental exposure.

- 16.7% of children are expected to have discontinued treatment with Palforzia after 6 months, 21.5% after 12 months and 87.25% after 24 months (Company BI submission, based on PALISADE trial). The resource impact template assumes that children who have not discontinued treatment with Palforzia will receive long-term treatment for at least the 5-year treatment duration of the model. However, this is considered a prudent estimate because the committee concluded that fewer people than modelled are likely to continue treatment with Palforzia lifelong in NHS practice.
- Children start and discontinue treatment with Palforzia in the middle of the year, including in the first year. This is consistent with expected capacity constraints in clinics thus requiring a phasing of children starting treatment during each year. Therefore, in the first year, children are expected to receive an average of 6 months of treatment, after which some discontinue treatment, and some continue to receive treatment in year 2. The 12-month discontinuation rate is applied in year 3.
- The list price of Palforzia is £10.12 per day. A flat price is applied for each Palforzia dose (range 0.5 to 300 mg).
- Initial dose escalation is administered by a healthcare professional in sequential order on a single day beginning at 0.5 mg and completing with 6 mg. An administration cost of £325 is applied (National Tariff 2021/22 Daycase rate for HRG code WH05Z Allergy or Adverse Allergic Reaction).

- Up-dosing consists of 11 dose levels: starting at 3 mg dose and increasing to 300mg. The first dose of each level is administered by a healthcare professional and children should be observed for at least 60 minutes. An administration cost of £238.37 is applied for the first dose of each level (National Schedule of NHS Costs Year: 2019-20 Outpatient Attendances DataService code 255, Paediatric Clinical Immunology and Allergy Service, consultant-led, follow-up). The SmPC states that patients should be observed for at least 60 minutes after administering the first dose of a new up-dosing level until suitable for discharge. Expert clinical opinion suggests that, in some clinics, it may be required for some up-dosing appointments to be delivered as a day case appointment. The tariff and number of appointments can be amended in the resource impact template to reflect this, as appropriate.
- Additional monitoring appointments and costs are expected for children receiving Palforzia. Expert clinical opinion is that children avoiding peanuts would currently have one outpatient appointment per year on average and children receiving treatment with maintenance Palforzia would have around four monitoring appointments per year. A cost of £238.37 is applied for each monitoring appointment (National Schedule of NHS Costs Year: 2019-20 - Outpatient Attendances DataService code 255, Paediatric Clinical Immunology and Allergy Service, consultant-led, follow-up). Monitoring appointments are included after 6 months of treatment for children who continue to receive Palforzia.
- There may be further costs associated with providing Palforzia treatment that are not included in the resource impact template and should be assessed locally. These include:

- A pre-assessment outpatient appointment for explanation of

treatment, consent and confirmation of diagnosis. This may Resource impact report: Palforzia for treating peanut allergy in children and young people (February 2022) 11 of 13 include a diagnostic food challenge. The number of outpatient appointments in the template may be amended.

 Out of hours specialist medical cover may be required to provide advice to patients receiving Palforzia at home who will need dose adjustment advice.

- Some children who stop treatment with Palforzia will start dietary peanuts and adhere to a diet that includes peanuts. This will require careful adherence support initially. At committee, the clinical experts explained that people not regularly including peanuts in their diet after Palforzia treatment may lose tolerance and will need to return to strictly avoiding peanuts and being prepared for emergencies. The resource impact template includes additional outpatient appointments for children who receive dietary peanuts and based on expert clinical opinion, it is assumed they will require four outpatient appointments in the first year, three outpatient appointments in the second year and then one appointment annually afterwards. The template can be amended locally to reflect a different number of appointments as appropriate, and the unit cost may be amended to reflect a day case tariff. The proportion of children who start dietary peanuts is unknown and can be input to the template. Additional costs such as psychological support and additional food challenge should be assessed locally.
- The resource impact template does not include potential savings as a result of avoiding accidental peanut exposure.

About this resource impact report

This resource impact report accompanies the NICE guidance on <u>Palforzia for</u> <u>treating peanut allergy in children and young people</u> and should be read with it.

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