

MSAC Application 1802

Supervised oral food challenge (OFC) in patients with suspected food allergy

**Applicant: Australasian Society of Clinical Immunology
and Allergy Ltd**

PICO Confirmation

Ratified PICO Confirmation –August 2025 PASC Meeting

Summary of PPICO criteria to define question to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1 PICO for supervised oral food challenge (OFC) in children and adults with suspected IgE-mediated food allergy

Component	Description
Population	Patients (children and adults) with suspected immunoglobulin E (IgE)-mediated food allergy for whom the results of an OFC have the potential to alter management of their food allergy. This includes • Patients who have experienced allergy symptoms following exposure to a food • Patients with an existing allergy • Patients who are sensitised to certain foods (for example, positive skin prick test, SPT, to a food but the patient has never eaten the food or experienced allergy symptoms following exposure to the food)
Prior tests	Standard medical management of food allergy comprising of: • Detailed patient clinical history • Skin prick tests (SPT) or • Serum- specific immunoglobulin E tests (ssIgE) • ± Component resolved diagnosis test (CRD)
Intervention	A supervised oral food challenge (OFC) in addition to standard medical management (i.e. following SPT or ssIgE)
Comparator	No OFC (standard medical management of food allergy as defined above alone)
Reference standard	Double-blind placebo-controlled challenge (DBPCC)
Outcomes	Test information: • Diagnostic accuracy (of the comparator using OFC as reference standard, or the comparator or OFC compared to DBPCC) • Allergic response after reintroduction (including rates of re-introduction failure after false negative results) Change in management • Reintroduction of food or alternate form of food (e.g. baked egg in cooking) and failure to reintroduce after a negative test result • Active treatment such as oral immunotherapy • Reduction in requirement for adrenaline devices Health outcomes (either direct from test to health outcomes or linked evidence) • Improved nutrition, growth and development • Improved quality of life • Psychological wellbeing (including levels of fear or food-related anxiety, from true positives or false positives) Safety • Harm to patients incurred by the test (experience of severe allergic reaction, anxiety) • Harms from inconclusive or incomplete tests (If the test is stopped early) Costs and cost-effectiveness • Cost per additional test for individual patients with multiple allergies • Cost of monitoring (such as specialist appointments) • Cost savings of not requiring adrenaline devices • Cost-effectiveness

Component	Description
	Other relevant considerations • Social wellbeing (e.g. exclusion from peer activities) • Value of knowing (e.g. ability to make informed choices) • Acceptability of testing for family members
Assessment question	What is the safety, effectiveness and cost-effectiveness of supervised oral food challenges in addition to standard medical management versus standard medical management alone in people with suspected IgE-mediated food allergy?

^aText in *italics* represents alternative options to be considered by PASC.

Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing for supervised oral food challenge (OFC) tests was received from the Australasian Society of Clinical Immunology and Allergy Ltd (ASCIA) by the Department of Health, Disability and Ageing.

The application stated that supervised OFCs result in superior health outcomes compared to standard medical management of food allergy, via improved effectiveness in navigating food allergies. No explicit claim was made regarding the comparative safety of OFC, but it was claimed that a supervised OFC is the only safe way to ascertain a patient's tolerance to different forms of allergenic food, implying superior safety to standard medical management.

PICO criteria

Population

Medically supervised oral food challenges (OFC) are intended to be used in patients (children and adults) with suspected immunoglobulin E (IgE)-mediated food allergy, where the intention of the clinician is to use the outcome of the OFC to alter or guide management. Alterations in current management of patients based on the outcome of an OFC may include reintroduction of the food allergen or alternate form of the food into the diet, commencement of active treatment such as oral immunotherapy, or reinforcement of continued avoidance in appropriate patients.

Food allergy is defined as an adverse immunologic response that is triggered by normally innocuous food protein antigens (Calvani et al. 2020). Food allergies can be broadly classified as responses that are IgE-mediated, responses that are mediated by both IgE-dependent and IgE-independent pathways (mixed) or responses that are not IgE-mediated. IgE-mediated allergic reactions to food are characterised by the acute onset of symptoms (Santos et al. 2023), affecting respiratory, gastrointestinal, dermatological and cardiovascular systems, typically within minutes to 1 hour following exposure to a specific food allergen. The responses involve IgE antibodies which bind to mast cells and basophils leading to a release of histamine and other chemicals that cause allergic symptoms. Non-IgE-mediated allergy responses are characterised by longer onsets with symptom presentation that occurs several hours or days after exposure. In addition, these responses involve a T-cell mediated immune response (Spergel 2006), with responses that primarily occur in the gastrointestinal tract and include abdominal discomfort, vomiting and diarrhoea.

The symptoms of food-induced IgE allergic reactions can occur in multiple organ systems. Responses can vary from mild to moderate such as localised facial angioedema, acute urticaria (hives or welts) and a tingling mouth, to severe, life-threatening reactions involving the cardiac and respiratory systems that require medical attention. Anaphylaxis is a potentially life-threatening condition which requires immediate treatment, including the administration of adrenaline (epinephrine). Delayed treatment of anaphylaxis with adrenaline can result in death or disability.

At PASC, the applicant clarified that the only reliable predictor of anaphylaxis risk is a previous history of anaphylaxis to the suspected allergen. This history provides direct evidence of the patient's propensity to develop a severe reaction. The severity of allergic reactions, including those meeting criteria for anaphylaxis, is influenced by multiple patient-specific factors, such as:

- Degree of sensitisation to the allergen
- Threshold dose
- Age at the time of diagnosis
- Comorbidities (for example, asthma or concurrent viral illness)
- Presence of cofactors such as sleep deprivation, concomitant medications, or alcohol use.

Given this variability, all individuals with a confirmed food allergy are considered at risk of anaphylaxis, and in principle, nearly 100% should be prescribed an adrenaline device.

The applicant stated that this underscores the importance of confirming food allergy diagnoses with an oral food challenge (OFC) in cases where skin prick testing (SPT) or specific IgE (ssIgE) testing yields inconclusive results. Accurate diagnosis ensures that individuals without true food allergy do not experience further burdens associated with carrying an adrenaline device.

The nine most common food allergens are egg, milk, peanut, tree nuts, fish, crustacea, soy, sesame, and wheat; these are the food allergens most likely to be challenged, although other culturally relevant foods may require a challenge for some patients. For patients with more than one allergen, a triage process would be used to determine which food allergen is to be tested; this would be based on prioritisation of staple foods in the diet, and the risk of accidental exposure.

Patient selection for the OFC involves the careful consideration of a range of medical and family factors. Medical factors include the patient's reaction history, time since the most recent reaction, presence of cofactors (other non-IgE-mediated allergies or adverse responses to other foods which occurs in conditions such as Oral Allergy Syndrome, or other allergies), nutritional impact of the challenge food, and the status of other atopic or medical conditions. Patient and family factors include quality of life associated with the inclusion or otherwise of the food, interest in adding food to the diet, ability to co-operate with OFC procedures, anxiety about the procedure and potential outcomes, risk-taking behaviour, and interest in commencing treatment for food allergy such as oral immunotherapy programmes.

A list of signs and symptoms is presented in Table 2.

Table 2. Examples of symptoms of IgE-mediated food allergy

Organ or system	Symptoms and signs
Skin	Urticaria Angio-oedema Pruritus Flushing Immediate erythema in the predilection sites of eczema Ear or palm itching
Gastrointestinal	Oral/pharyngeal pruritus Oral/pharyngeal swelling Vomiting Nausea Abdominal cramps Diarrhoea Abdominal pain
Ocular	Conjunctival erythema Pruritus Lacrimation
Respiratory	Rhinitis (rhinorrhoea, sneezing, nasal obstruction, pruritus) Hoarseness Stridor/laryngeal oedema Cough Dyspnoea Chest tightness Wheezing Cyanosis
Cardiovascular	Pallor Cold sweats Heart palpitations Pre-syncope / Syncope Tachycardia Hypotension Shock
Neurological	Anxiety Change in behaviour Irritability Apathy Lethargy Seizures Syncope/Loss of consciousness
Other	Uterine contractions resulting in abdominal pain and bleeding Shivering

Source: Table 1, p3 of PICO set 1802

The true cost of allergy in Australia is multifaceted, encompassing social and financial burdens, and a range of costs to the healthcare system. The avoidance of multiple foods can have substantial impacts on nutritional adequacy, growth and development; the effects can be particularly pronounced for children experiencing these at critically important stages in their growth and development (Peters et al. 2024). Dietary restrictions are also known to have an impact on quality of life both for the patient and their family

(Nguyen et al. 2023). Evidence suggests that feeding disorders such as avoidant/restrictive food intake disorder may be more common among people with food allergy (Nocerino et al. 2024) than in the general population; prevalence estimates of feeding difficulties in children with food allergies range between 13.6 to 40%. A higher prevalence of feeding difficulties was associated with multiple food allergies (Hill et al. 2024).

Food allergies have multiple impacts on quality of life for affected individuals and their families beyond the symptoms of an allergic reaction (Miller et al. 2020; Nguyen et al. 2023; Patel et al. 2023a). Limitations in family activities because of a child's food allergy was found to affect quality of life for all family members. Fear and anxiety regarding accidental exposures and life-threatening reactions are associated with social isolation, as individuals may avoid social gatherings or eating out due to concerns about food contamination. Children with allergies may experience a lack of access to early child education, bullying and exclusion at school, and may exclude themselves from peer activities including school excursions and overnight camps (Stockhammer et al. 2020); these can have negative impacts on their social and emotional development (Proctor, Ramos & Herbert 2023).

To optimise patient safety and OFC results, the OFC is contraindicated if any of the following exclusion criteria are present:

- intercurrent illness such as fever, cough, vomiting and/or diarrhoea
- active/uncontrolled asthma requiring reliever medication
- demonstration of tolerance to the challenge allergen since booking
- severe atopic dermatitis (eczema) flare
- current urticaria (hives, welts)
- poorly controlled allergic rhinitis (hay fever)
- antihistamine taken in the last 72 hrs (excluding nasal sprays used to treat allergic rhinitis).

Given most of the contraindications listed above are likely to be transient in nature, it is envisaged that most patients with suspected IgE-mediated food allergy would be eligible for an OFC at some point. The applicant also stated that an OFC should not be undertaken if a patient or their family does not intend to include the allergen-containing food in the diet regularly in the event of a negative OFC result.

Size of target population

In Australia, IgE mediated food allergy is common and affects people of all ages. The prevalence of food allergy in infants under 12 months of age is approximately 11% (Hua et al. 2022). Although prevalence of food allergy decreases with age, it affects approximately 6.5% of children at 6 and 10 years of age (Peters et al. 2024; Sasaki et al. 2018) and approximately 5% of 14-year-olds (Peters et al. 2024). Some children will 'outgrow' their food allergy (Peters et al. 2024); however, 2-4% of adults either continue to have a food allergy or have an allergy that first occurs in adulthood (Tang & Mullins 2017). In addition, although there are no current prevalence data for adult-onset food allergy in Australia, the worldwide prevalence of adult-onset food allergy has been recognised as an important health issue (Calvani et al. 2020).

PASC noted the proposed population was children and adults with a suspected IgE-mediated food allergy.

PASC noted the applicant's comments that children with Food Protein Induced Enterocolitis Syndrome (FPIES) may also be appropriate to include within the proposed population. The applicant stated that FPIES is the only non-IgE-mediated food allergy for which OFCs are required. FPIES-related reactions are characterised by delayed, severe gastrointestinal symptoms, but do not involve IgE related symptoms such as skin rashes or respiratory symptoms. FPIES-related reactions are not considered to be life-threatening.

PASC noted the applicant's estimates that FPIES affects 1 in 15,000 children, some of whom will have positive SPT results. Clinical advice from the applicant indicated the number of children with suspected FPIES who would undergo OFC in an outpatient setting utilising the proposed item number would be very small. Only patients with mild symptoms relating to suspected FPIES would be suitable for OFC in an outpatient setting, although many would be suitable for home-based challenges as well. Patients with more severe symptoms relating to suspected FPIES who require OFC will likely have OFC in an inpatient setting, due to the potential for severe gastrointestinal symptoms to occur.

Given these factors, PASC advised that the population should be limited to children and adults with IgE-mediated allergy only, and the inclusion of patients with FPIES would not be appropriate.

PASC noted that, in addition to the most common food allergens, other foods may require a challenge for some patients, such as foods of cultural relevance. The most common foods currently being challenged will vary between Australian centres but generally reflect the relative prevalence of each allergy in that specific population.

Intervention

The proposed intervention is a supervised OFC in patients with suspected IgE-mediated food allergy. This would occur in addition to standard medical management (the comparator). The supervised OFC would be offered for the investigation of IgE-mediated food allergy if the necessity for the investigation is determined by the clinical immunology/allergy specialist prior to the OFC, with continuous observation and documentation of the patients' allergen response in accordance with current professional guidelines.

The process for an OFC involves consumption of incremental amounts of the allergen-containing food under direct observation in a supervised clinical setting by a registered health professional (a medical doctor with a specialty in immunology or allergy or a registered nurse who is appropriately trained in supervised OFCs under the supervision of a clinical immunology/allergy specialist) for the duration of the OFC (Anvari et al. 2019; Proctor, Ramos & Herbert 2023). The allergen-containing food would be fed to a patient at intervals over a 2-hour period, followed by 2 hours of observation by the aforementioned clinical personnel.

At PASC, the applicant clarified that patients may undergo a supervised OFC on either an inpatient or outpatient basis, depending on their risk of a serious reaction to the allergen to be tested. These decisions are guided by clinical risk stratification based on the patient's allergy history, test results (e.g. skin prick test, specific IgE), and anticipated severity of reaction. Outpatient OFCs (e.g. in private rooms or outpatient clinics) are suitable for patients with a low to moderate risk of allergic reaction, based on a detailed pre-challenge assessment. Conversely, inpatient OFCs in a day admission ward or a hospital-based facility are indicated for patients with a higher risk of severe or rapid-onset anaphylaxis, a history of previous systemic reactions, significant co-morbidities (e.g. poorly controlled asthma), or a requirement for closer monitoring or access to resuscitation facilities.

The applicant remarked that the distinction between inpatient and outpatient may also reflect the physical location or administrative designation of the service, rather than a meaningful difference in clinical care. Some hospital-based services may "admit" patients for billing or administrative reasons, even though the OFC is performed in a clinic-style setting. Regardless of the setting, clinical oversight, safety protocols, and decision-making processes are aligned with national standards to ensure patient safety.

Regardless of location, the protocol for the supervised OFC would be the standardised approach developed by the Australasian Society of Clinical Immunology and Allergy (ASCIa); these guidelines have been peer-reviewed, based on expert opinion, and aligned with other published OFC protocols used in international jurisdictions. The supervised OFC enables clinical staff to provide timely intervention in the event of a mild, moderate or severe allergic reaction in accordance with practical allergy [\(PRACTALL\) guidelines](#) which are a set of guidelines for conducting OFCs. These guidelines are provided in a link in Appendix 1 (Sampson et al. 2024a).

The PRACTALL guidelines provide recommendations for the management of safety considerations in supervised OFCs. The guidelines provide safety criteria to assess whether a patient should be considered eligible for an OFC, relating to the presence of co-morbidities that may interfere with the assessment, and health conditions or medications that could mask or potentially worsen the severity of allergic reaction, including increasing the risk of anaphylaxis. Safety considerations during the challenge are also outlined, including considerations around the purpose of the OFC, types of allergic symptoms, and the patient's previous history of allergic reactions. The personnel conducting OFC procedures require both specific training in managing acute allergic reactions and periodic practice drills in anaphylaxis management (Sampson et al. 2024a). All necessary medications should be readily available if required during the food challenge, including adrenaline, oxygen, antihistamines, inhaled beta-agonists and intravenous fluids (Sampson et al. 2024a).

Upon arrival for the OFC, a set of baseline vital signs (temperature, pulse, blood pressure, respiratory rate) are recorded. An OFC record will be completed for patients undergoing a challenge and includes:

- documentation of previous test results
- the pre-determined dose of adrenaline to be administered via intramuscular injection in the event of anaphylaxis
- details of the food allergen being challenged, including previous reactions and/or exposures
- the incremental doses of the food protein given to the patient in (tsp/mL/mg)
- the presence of any reactions observed during the challenge at dedicated intervals corresponding with the doses of the food allergen.

The designated intervals are usually 15-20 minutes from each dose but may be altered as appropriate by the clinical immunology/allergy specialist. Reactions to the allergen may include, but are not limited to, cutaneous, respiratory, gastrointestinal or cardiovascular symptoms, or subjective symptoms including abdominal pain or mood changes. The details of any treatment given to the patient including antihistamines, corticosteroids or adrenaline via infusion or intramuscular injection during the challenge would also be documented.

Observation of the patient would continue for a minimum of 2 hours following the last dose of the food allergen to assess the patient's immediate and latent tolerance to the allergen. If symptoms consistent with an allergic reaction occur (indicative of a positive result), treatment for the allergic reaction is provided by staff supervising the challenge. The OFC may continue if appropriate in accordance with PRACTALL guidelines for symptom management (Sampson et al. 2024b); a longer time period to complete the OFC may be required.

The outcome of the OFC would then be used to guide or alter clinical management. An OFC outcome of "negative" is defined as where the amount of food protein ingested is equivalent to a normal serving of

the food prepared in a typical manner and has been consumed and tolerated with no adverse symptoms. For most foods, symptom-free ingestion of a total cumulative dose relative to the challenge food protein is considered sufficient to rule out a food allergy to that specific food or achieve resolution of a food allergy. An OFC result is deemed “positive” if a patient develops adverse symptoms at any dose of ingested food protein up to and including a normal serving size. This confirms that the patient has a new diagnosis of IgE-mediated food allergy, or in patients with an existing food allergy, that the allergy is persistent and remains unresolved.

However, there are differing definitions, and some disconnect regarding the definition of a “negative OFC test” outcome between what is stated in the application and summarised above, and advice received from clinicians at the pre-PASC meeting suggested that the experience of mild oral symptoms only during the OFC could be evidence of resolution of an allergy, and on the basis of this, would encourage the re-introduction of the allergen-containing food.

In the event of a supervised OFC being stopped before the required cumulative dose of food is ingested, the test outcome would be regarded as “incomplete”. In young children, dose refusal may occur due to sensory aversion to food texture or taste, despite efforts to modify or disguise the food. In older children, teenagers or young adults, an OFC may be discontinued due to escalating anxiety, and re-testing may be required at the discretion of the overseeing immunology/allergy specialist.

Patients being considered for OFC will usually be avoiding the foods containing particular allergens. The options for management based on the outcome of an OFC include:

- The reintroduction of the food allergen into the diet in the event of a negative OFC.
- The reintroduction of the allergen in an alternate form e.g., baked goods containing egg or milk for patients with egg or milk allergies.
- Commencement of active treatment including oral immunotherapy (OIT).
- Reinforcement of continuing avoidance in appropriate patients; this may include the prescription of an adrenaline/epinephrine device if the patient is diagnosed as at risk of anaphylaxis.

PASC acknowledged there was some uncertainty regarding the definition of a negative OFC, and noted that the classification of an OFC outcome as “positive” or “negative” depends on the context in which the challenge is being conducted, either as part of a clinical research study (as reported in published studies, where outcomes are more tightly defined using pre-determined stopping criteria) or routine clinical care (where clinical judgement plays a central role, and the presence of mild, non-progressive systems may still be deemed a negative result).

Therefore, PASC agreed with advice from the applicant that, in clinical practice, a “negative” OFC may include mild subjective symptoms if these do not prevent recommendations for inclusion of the allergen in the patient’s diet, and both the patient and clinician agree on continued consumption.

Expected utilisation of OFC

Three different approaches have been used to try and estimate the likely uptake of an MBS item for an OFC:

- An estimated proportion of all patients seen by immunology/allergy specialists (applicant’s estimate based on ASCIA workforce survey results).

- Estimated based on current OFC use and expected increase in use if an MBS item is created (based on ASCIA workforce survey results).
- Using an epidemiological approach.

PASC acknowledged there are several approaches that could be used to estimate potential MBS utilisation for OFCs but that there was uncertainty in each of the three proposed approaches, including that not all of the estimates provided by the applicant were able to be verified. PASC advised that further work would need to be done (in consultation with the department) to more accurately estimate utilisation, and that this should be addressed in the assessment report.

Utilisation as a proportion of all patients seen

An estimate provided by the applicant indicated that approximately 8,500 patients would utilise an MBS-funded, supervised OFC for the first full year, based on 10% of patients seeing an allergist/immunologist having an OFC. This estimate was based on the results of a workforce survey conducted by ASCIA from December 2023 and February 2024 of 98 clinical immunology/allergy specialists, which represented 40% of full ASCIA members. Prior to the PASC meeting, the applicant clarified that the results from the workforce survey demonstrated there was a combined uptake of 690 outpatient OFCs per month across private practice and public hospital clinics. This figure was multiplied by 12 for an annual figure of 8,280 OFCs, and then rounded to 8,500 to account for non-response among ASCIA members. However, the link between these survey results and the overall number of patients seeing an allergist/immunologist is not clear. The method states this represents 10% of all patients seen, but the total number of patients seen and its source were not provided. The uptakes for Years 2 and 3 were estimated to be 15% and 20%, respectively. The utilisation estimates are presented in Table 3. Data was not available regarding workforce details, such as patient population treated by the individual ASCIA members surveyed (e.g. adults vs children, private vs public, inpatient or outpatient).

Table 3 Estimates for number of patients who would use OFC if an MBS item were created

	2026 (Year 1)	2027 (Year 2)	2028 (Year 3)
Number of patients expected to use OFC (based on workforce survey estimates by ASCIA)	8,500	12,750	17,000

ASCIA = Australasian Society of Clinical Immunology and Allergy; OFC = oral food challenge

The applicant also stated the availability of an MBS item for an OFC may lead to an expectation that clinical immunology/allergy specialists would use OFCs for all eligible patients; however, advice provided during the pre-PASC teleconference suggested that 10-20% of all patients with allergies would *not* be offered a supervised OFC. Patients would not typically be offered an OFC if a positive OFC result would be unlikely to influence the psychosocial management of the patient, or unlikely to lead to an alternate strategy apart from strict avoidance of the allergen. Medical considerations for patient selection for an OFC are reaction history, time elapsed since the most recent reaction, the presence of cofactors (other non-IgE-mediated allergies or adverse responses to other foods which occurs in conditions such as Oral Allergy Syndrome, or other allergies), the nutritional impact of the food to be challenged (staple food or otherwise), and the status of other atopic and medical conditions. A range of patient and family factors also require consideration in the selection of patients for an OFC; these encompass quality of life associated with the inclusion or exclusion of the food, interest in adding food to the diet, ability to cooperate with OFC procedures, any anxiety or apprehension about the procedure and outcomes, risk-taking behaviour (e.g.,

intentional ingestion at home if the OFC is not offered) and interest in commencing oral immunotherapy treatment for the food allergy.

Utilisation based on current OFC use and expected increase

In the event of provision of an MBS number for a supervised OFC, 26 specialists (43.3%) indicated in the survey they would expand their current service, and 16 specialists (26.7%) reported they would introduce OFCs to their current service offerings. Other specialists were unsure if the introduction of an MBS item for OFCs would affect their service offerings (n = 7; 11.7%), and 6 specialists suggested this would result in no change to their service (10%). A further 5 specialists stated the provision of supervised OFCs were not relevant to their practice. Based on these survey findings, the applicant estimated that MBS funding of supervised OFCs would result in a 40-50% increase in the number of OFCs currently conducted in private clinical immunology/allergy clinics over the next five years.

The results of the ASCIA survey indicated that OFCs were conducted for a total of 634 patients per month in private practice rooms with 119 patients per month undergoing supervised OFCs in private hospital outpatient clinics. In public settings, OFCs are conducted for 489 patients per month in public hospital inpatient clinics; 56 patients per month have a supervised OFC in public hospital outpatient clinics.

PASC noted that the distributions of current numbers of OFC services in both outpatient and inpatient clinics are highly skewed, so that the average numbers may not be methodologically robust. Approximately 57% of the survey respondents seeing 0-5 OFC patients per month in outpatient settings, and 50% reported the same for inpatient settings. Only 2 out of 30 respondents saw more than 50 OFC outpatients per month, while 1 out of 19 respondents saw 21-50 OFC inpatients per month.

Currently, the wait time for a supervised OFC is dependent on a range of factors including the type of food, (e.g. essential or non-essential), the patient's age, the presence of other allergies and the rationale for conducting the challenge. In addition, the capacity of services as determined by resource limitations also contribute to wait times. The average wait times for OFC appointments as an inpatient are 3.9 months and 9.8 months in the private and public systems respectively. The average outpatient wait times in the private and public health systems in Australia are 5.3 months and 8.6 months respectively. The wait times for OFCs in the public sector are regarded as particularly problematic, because a delay in the introduction of foods in young infants is associated with increased risks of developing long term allergies in young children (Jones et al. 2022).

Utilisation based on epidemiological approach

This approach is based on Australian studies on peanut allergies only. Clinical expert advice from the applicant suggested that all babies with peanut allergies should have an OFC, to determine the safe starting dose for a peanut oral immunotherapy (OIT) program¹, the Allergy Development to an Accelerated Pathway to Tolerance (ADAPT) OIT program. Children would also have another OFC at the end of the program to determine whether they have developed a tolerance to peanut². From Table 4 and based on findings of the HealthNuts study, it was estimated that each year, 19,200 Australian 1-year olds would be suspected of having a peanut allergy (based on peanut allergy symptoms and a positive SPT), and approximately 8,700 of them would be confirmed to have a peanut allergy by OFC. However, not all of the 19,200 would be investigated for a peanut allergy, so a conservative estimate of the number investigated

¹ Paediatric allergist/immunologist, pre-PASC teleconference 23rd June 2025.

² <https://www.nace.org.au/research/food-allergy/>

may be the number that actually has a peanut allergy (8,700 per birth cohort). If all of these children have two OFCs, this would result in 17,400 OFCs per birth cohort just due to peanut allergies, across both the public and private sectors. Table 4 provides an example of how estimates of resource utilisation are derived from data from the HealthNuts study (Osborne et al. 2011) and how this can lead to different estimates of resource utilisation than the other methods (a proportion of all patients seen, and current OFC use and expected increases as stated in the application from the ASCIA survey).

In Australia, approximately 2% of infants are estimated to have a dairy allergy while approximately 9% of infants up to 12 months old are estimated to have an egg allergy. By the age of two years, egg allergy was reported to be resolved in 47% of children with diagnosed egg allergy with baked egg tolerance at 12 months associated with resolution of this allergy (Koplin et al. 2015). Shellfish allergy prevalence in Australian infants is relatively low, with estimates suggesting 0.9% of infants have a challenge-proven allergy to shellfish (Osborne et al. 2011). The prevalence of peanut allergy in Australian infants at 12 months is approximately 3% (Koplin et al. 2015). Although an estimated 0.1% of infants have a tree nut allergy, at six years of age, the prevalence of challenge-confirmed tree nut allergy is approximately 3% (McWilliam et al. 2019).

The use of milk and egg “ladders” (gradual home-based introduction of increasing amounts of allergens) are gaining popularity (Gallagher et al. 2024), and in cases where infants have had allergen-related anaphylaxis, it may be appropriate to use an OFC to determine the safe starting dose for the ladder¹.

Clinical advice from the pre-PASC discussion suggested that refusal to participate in an OFC is more common in older children/adolescents.

Table 4 Possible eligibility for OFC using an epidemiological approach

Study / source of estimates	Age range	Prevalence of suspected IgE-mediated food allergy (% of people eligible for at least one OFC)	OFC confirmed food allergy (eligible for recurring OFCs)	Estimates relevant to Australia (study data applied to Australian population in age-group)		
				No. in age-group (approximately no. of births per year)	No. eligible for at least one OFC (due to SPT result)	No. eligible for recurring OFCs (due to having a confirmed allergy on OFC)
HealthNuts cohort (Osborne et al. 2011)	1 year	11.7% clinically relevant sensitisation to raw egg (SPT ≥3mm)	9.0% allergic to raw egg	~300,000	35,100 SPT ≥3mm	27,000 with allergy on OFC
		6.4% clinically relevant sensitisation to peanut (SPT ≥3mm)	2.9% allergic to peanut	~300,000	19,200 with SPT ≥3mm	8,700 with allergy on OFC

IgE = immunoglobulin E; OFC = oral food challenge; SPT = skin prick test

Comparator(s)

The proposed comparator is standard medical management.

Standard medical management of food allergy usually comprises the attainment of a detailed patient clinical history, skin prick tests (SPT) and/or serum-specific immunoglobulin E (ssIgE) tests to determine the likelihood of an IgE mediated food allergy. If these data suggest IgE-mediated food allergy, patients are advised to avoid the food allergen, be referred for oral immunotherapy treatment, and/or be prescribed an adrenaline device/s if they are considered at risk of anaphylaxis.

The SPT and the ssIgE are the primary modes of testing for immediate IgE-mediated allergy. Although the SPT test is associated with a low risk of side effects, its use may be limited for patients with severe eczema. The ssIgE blood test measures the amount of IgE antibodies in the blood; these antibodies are specific to allergens. However, an individual may have positive results for both SPT and ssIgE tests but experience no clinical symptoms, as shown in 5 below (i.e. they may be appropriate rule-in tests, but not appropriate as rule-out tests).

Table 5. Key differences between allergen sensitisation and allergy

	SPT/ssIgE result	Clinical symptoms	Immune response stage	Clinical relevance
Food Allergen Sensitisation	Positive	Negative	Immune system is prepared to react to the food allergen (initial stage).	Indicates potential for developing a food allergy (allergen sensitisation) but is not conclusive on its own. Potential for overdiagnosis.
Food Allergy	Positive	Positive	Immune system reacts to the food allergen, leading to signs and symptoms of allergic reaction (subsequent stage).	Confirms that the individual has an adverse immune response to the food allergen (food allergy). Potential for resolution.

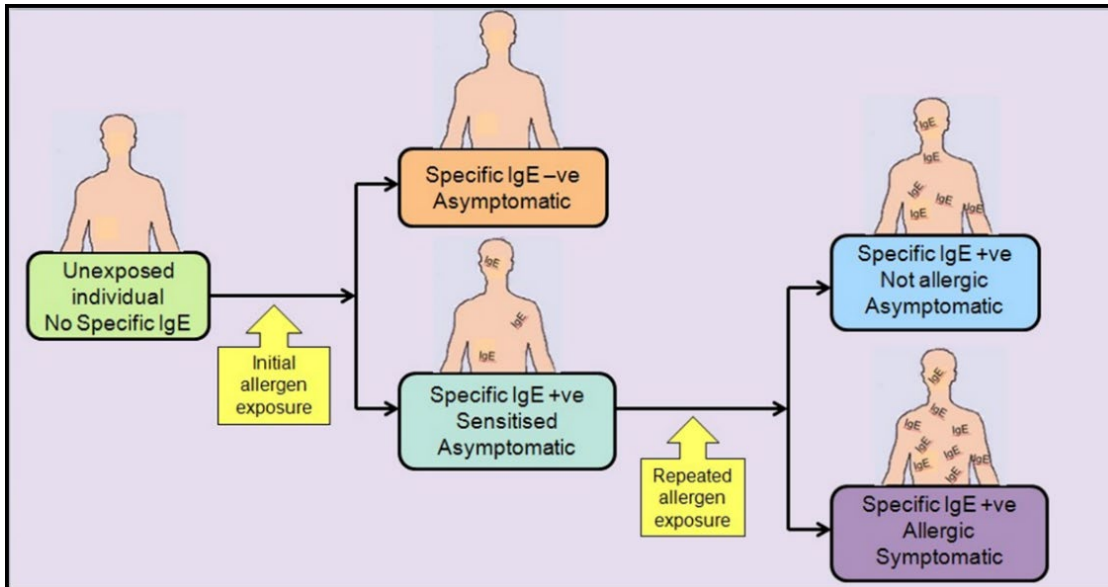
Source: p21 of PICO set 1802

The positive predictive value (PPV) of SPT and ssIgE is reported to vary between foods, and the level of the test result (magnitude of sensitisation) does not correlate with severity of reactions (Foong et al. 2021; Turner et al. 2022; Wang 2023). False positives can occur, which means that although the SPT or ssIgE test is positive, the patient may eat the food without any symptoms. This suggests that the patient is ‘sensitised’ to that allergen rather than allergic to the specific allergen, as illustrated in Figure 1. False negative SPT and ssIgE tests are less common than false positive tests for most food allergens. Apart from sensitisation, false positive results can also occur because the immune system may react to the proteins in one food that are similar to those in another food (e.g., someone allergic to peanuts might test positive for other legumes, or they may have oral allergy syndrome after eating certain fruits, vegetables or nuts that may be due to cross-reactivity with pollen allergens than a true food allergy (Siekierzynska et al. 2021).

The applicant advised that false positive results in OFCs are theoretically possible, which is why double-blind placebo-controlled challenges (DBPCCs) are sometimes performed, particularly in research settings. However, it is important to acknowledge that significant objective symptoms due to a false positive OFC are very rare, especially in young children and infants.

The applicant advised that when uncertainty exists, particularly with subjective symptoms or atypical objective signs, a DBPCC may be performed to clarify the diagnosis.

Figure 1. Sensitisation to a food allergen compared to food allergy



Source: p22 of PICO set 1802

Overall, the positive predictive value of allergy tests varies between foods, and the level of the test (magnitude of the sensitisation) does not correlate well with severity of reactions (Patel et al. 2023b).

The confirmation of a positive (or negative) allergy test is important to prevent unnecessary avoidance of food/s which can lead to nutrition deficiencies and associated nutrition and growth implications. It is also important to prevent both unnecessary prescription of adrenaline devices with associated costs to the Pharmaceutical Benefits Scheme (PBS), and additional burdens to families of ongoing management of food allergies and associated psychological and social impacts.

A range of other diagnostic tests may be potential comparators; these include the component resolved diagnostics (CRD) test. The CRD focuses on the identification of specific proteins within allergens that are causing allergic responses and may help determine the severity of allergic reactions and identify patients with higher risks for severe reactions (Mears et al. 2025). However, the result from a CRD cannot provide an indication of whether an alternative form of the food (e.g., milk or egg in baked products) can be tolerated by patient with allergies to particular foods.

PASC acknowledged that the introduction of an MBS item may result in some patients receiving an OFC in the private system, who otherwise would have undergone an OFC in the public system. Although the MSAC guidelines recommend that the financial analysis incorporate current use of the technologies, PASC advised that the assessment report should focus on the comparison between OFC and no OFC. This means that the comparator for the financial analysis would also be no OFC, rather than incorporating state/territory-funded OFCs.

Reference standard (for investigative technologies only)

The supervised OFC is said to be the gold standard for the diagnosis of food allergies, and determination of the severity of food allergy. An alternate reference standard would be “all available information”, which would include outcomes of post-OFC management including the outcomes of re-introduction of allergen-containing foods.

DBPCC is also a potential reference standard, which is often used in the evidence as a gold standard or comparator for OFC. Although DBPCC is not often used in clinical practice, the MSAC guidelines state (TG 2.4) that the reference standard does not need to be a viable substitute for the proposed intervention. DBPCC is not currently funded in Australia, however, the MSAC guidelines do not state that the reference standard needs to be publicly funded in Australia.

The DBPCC consists of two test days; on the first day the potential food allergen is introduced using a masked version and on the second day a placebo is offered to the patient (de Weger et al. 2022). This enables the introduction of the allergen-containing food in such a way that neither the child, caregiver or the health professional knows when the food allergen is being given, therefore eliminating a source of bias. The principal drawback is that the DBPCC is resource-intensive, time-consuming and expensive due to the requirement for randomised blinding procedures, and multiple testing days for the patient (de Weger et al. 2022).

PASC noted that possible reference standards included 'all available information' and DBPCCs. PASC noted that, in research settings, DBPCC is considered the gold standard for diagnosing food allergy. This is reflected in its widespread use in research trials due to its ability to minimise bias, particularly for subjective symptoms, and to decrease the potential for false positive test results of an OFC.

PASC noted that DBPCCs are rarely performed in routine clinical practice, because they are complex, resource-intensive and blinding can be difficult or impractical. However, PASC noted that, per MSAC Guidelines, the reference standard does not have to be commonly used in clinical practice, rather it should be the test that is the most error free method of determining whether a disease is present or not. PASC therefore advised that DBPCC was the most appropriate reference standard.

Outcomes

It is assumed that both a direct and linked evidence approach will be taken in the assessment report (see assessment framework section).

As supervised OFC is considered the gold standard, the majority of accuracy studies assume that OFC is 100% sensitive and specific, with the outcome of "test accuracy" only being applicable for the comparator. As such, there is an assumption that any lack of concordance between standard testing and OFC is due to inferior accuracy in standard testing methods. However, the specificity of OFC may be possible to determine by use of "all available information", taking into account clinical response after reintroduction of allergens where the allergy was determined to be resolved following a supervised OFC, including false negatives (where a patient has an allergic reaction after notification of a negative OFC result due to factors such as transient desensitisation or insufficient top dose of the allergen during the OFC) and true negatives (successful re-introduction of allergen-containing foods either in their natural form or in baked products). The difficulty with the assessment of clinical response is that advice from the applicant has suggested that mild oral symptoms (typical allergy symptoms) may not be cause for stopping reintroduction of foods. This may lead to discordance between the clinician's interpretation of an OFC result, and how the patient/parent interprets the appropriate response to symptoms. This difference in interpretation would not suggest an incorrect OFC result.

There are a range of test safety outcomes that require evaluation, such as harm to patients incurred by the test including the experience of severe allergic reactions during the procedure. In addition, it would be important to evaluate anxiety experienced by patients during the test with potential outcomes including cessation of tests due to anxiety regarding receiving higher doses of an allergen, and harms associated with false positive tests.

Direct from test to health outcomes would form an important part of an assessment. These include the success of active treatment such as immunotherapy for the treatment of specific food allergies, and nutrition, growth and/or developmental outcomes. Quality of life outcomes to be assessed would include food-related anxiety, and outcomes related to social and psychological wellbeing, and the value of having a diagnosis and a management plan (particularly the ability to make informed choices).

The applicants claimed that an MBS item would result in patients receiving an OFC faster (as more patients may receive an OFC in the private healthcare setting, which has shorter waitlists than the public system). As such, a range of workforce issues require consideration regarding the ability to fulfil the demand for supervised OFCs. This comparator may be relevant for the financial analysis, but not for the assessment of safety/effectiveness (as the safety/effectiveness of the OFC should not differ based on who is funding the procedure). However, an OFC may provide certainty that a patient has had resolution of their food allergy or confirmation of their food allergen tolerance earlier than standard medical management, which has a poor positive predictive value. If evidence is identified that OFCs do result in earlier confidence of allergy resolution/tolerance, then a linked-evidence approach comparing early versus late reintroduction of foods would be appropriate.

There are a range of healthcare costs associated with having food allergies; these would include costs of tests, specialist appointments for allergy management and nutrition considerations, costs of adrenaline devices, and costs of hospitalisation and treatment for severe allergic reactions associated with unintended consumption of the allergen. Beyond the healthcare system, there would also be the additional costs associated with alternative foods that avoid the relevant allergen(s). Alternatively, in the event of a negative test result, there may be cost savings due to avoidance of further specialist appointments and adrenaline devices. There may also be cost savings for patients and families through firstly, not pursuing unorthodox, non-evidence-based, and non-approved allergy testing methods, and secondly, resumption of eating staple foods that were previously excluded or substituted for more expensive alternative foods.

There may be more benefits associated with supervised OFCs for 'value of knowing' outcomes, if this proposed intervention is shown to improve the diagnostic precision of the severity of a food allergy. There may be an improvement of patient and caregiver empowerment to make plans for the management of their allergy or allergies; this may lead to changes in quality of life, and social and psychological outcomes.

A summary of the outcomes of interest proposed is provided below.

Test information:

- Diagnostic accuracy (using DBPCC as reference standard)
- Allergic response after reintroduction
- Time to confirmation of resolution of allergy or food allergen tolerance

Change in management

- Reintroduction of food or alternate form of food (e.g. baked egg in cooking)/failure to reintroduce after a negative OFC
- Active treatment such as oral immunotherapy
- Reduction in requirement for adrenaline devices
- Appropriate treatment; avoidance of anaphylaxis

Health outcomes

- Improved nutrition, growth and development
- Improved quality of life
- Psychological wellbeing (including levels of fear or food-related anxiety, from true positives or false positives)

Safety

- Harm to patients incurred by the test (experience of severe allergic reaction, anxiety)
- Harms from inconclusive or incomplete tests (If the test is stopped early)

Costs and cost-effectiveness

- Cost per additional test for individual patients with multiple allergies
- Cost of monitoring (such as specialist appointments)
- Cost savings of not requiring adrenaline devices
- Cost savings through not requiring alternative, unorthodox and non-approved allergy testing methods including but not limited to hair testing, reflexology, applied kinesiology and/or electrodermal testing.
- Cost-effectiveness

Other relevant considerations

- Social wellbeing (e.g. exclusion from peer activities as a consequence of requirements to avoid allergen-containing foods)
- Value of knowing (e.g. ability to make informed choices)
- Acceptability of testing for family members
- Workforce and training factors

PASC advised that the outcomes of “cost savings through not requiring non-approved allergy testing methods” and those related to wait times to diagnosis were to be removed from the outcomes of interest for this PICO.

PASC noted that the applicant stated that it is possible to differentiate between a false-negative OFC result and the development of a new allergy after a negative challenge, primarily based on the timing and circumstances of re-exposure.

PASC advised that the development of a new allergy, following OFC, should be included as an outcome of interest.

Assessment framework (for investigative technologies)

The application made a claim of clinical superiority; the overall claim for the supervised OFC as an add-on test to those currently approved as part of current management is that it results in superior health outcomes compared to the proposed comparator, standard medical management. Standard medical management relies on the results of allergy testing that does not offer sufficient specificity or reliability to be used as the sole determinant for the severity of a food allergy for patients. The applicant stated that OFC is the most reliable method of determining the severity of a food allergy, and a patient’s tolerance to different forms of allergenic foods (e.g. baked dairy products or baked egg).

Clinical claims of superiority require evidence of improved health outcomes. For this application, evidence is required that the information from the supervised OFC will alter decision-making and/or clinical management.

A graphical representation of each step in the linked evidence analysis is shown in the assessment framework in Figure 2. Each step is an evidentiary requirement and corresponds to a research question.

1. Are there any health impacts in terms of quality of life, or changes in nutrition, growth and cognitive development, as a result of gaining a diagnosis via a supervised OFC compared to standard medical management alone?
2.
 - a. What is the evidence regarding the diagnostic accuracy of the standard medical management versus OFC for the diagnosis of food allergy/allergies in patients with suspected IgE-mediated food allergy?
 - b. What is the time to classification of resolution of allergy with the use of OFC versus standard medical management in patients with suspected IgE-mediated food allergy?
 - c. How often would use of OFC mean the avoidance of other forms of testing e.g., applied kinesiology, electrodermal testing, hair analyses, pulse testing or reflexology, that are not funded or not approved for the diagnosis of food allergy in Australia?
3. Do the findings from the supervised OFC lead to changes in management compared to that for standard medical management (e.g. faster implementation of management strategies such as oral immunotherapy, avoidance of unnecessary and non-evidence-based tests for food allergies, and any differences in adherence to recommended dietary restrictions?)
4. Is there any evidence that changes in management (identified in question 3) lead to changes in health outcomes? (e.g. Does early reintroduction of prior allergens result in different health outcomes than late reintroduction? Does greater adherence to dietary restrictions result in different health outcomes? How effective are oral immunotherapy protocols?)
5.
 - a. Are there any adverse impacts of supervised OFCs, or harms incurred by undertaking this diagnostic test?
 - b. If absence of OFC results in a higher likelihood of non-evidence-based, unorthodox methods of allergy testing, what are the adverse effects of this testing?
6. Are there additional benefits regarding the 'value of knowing' a test result provided by the supervised OFC above that of diagnosis via standard medical management (e.g. benefits to the persons' life beyond their health status, such as social wellbeing)?

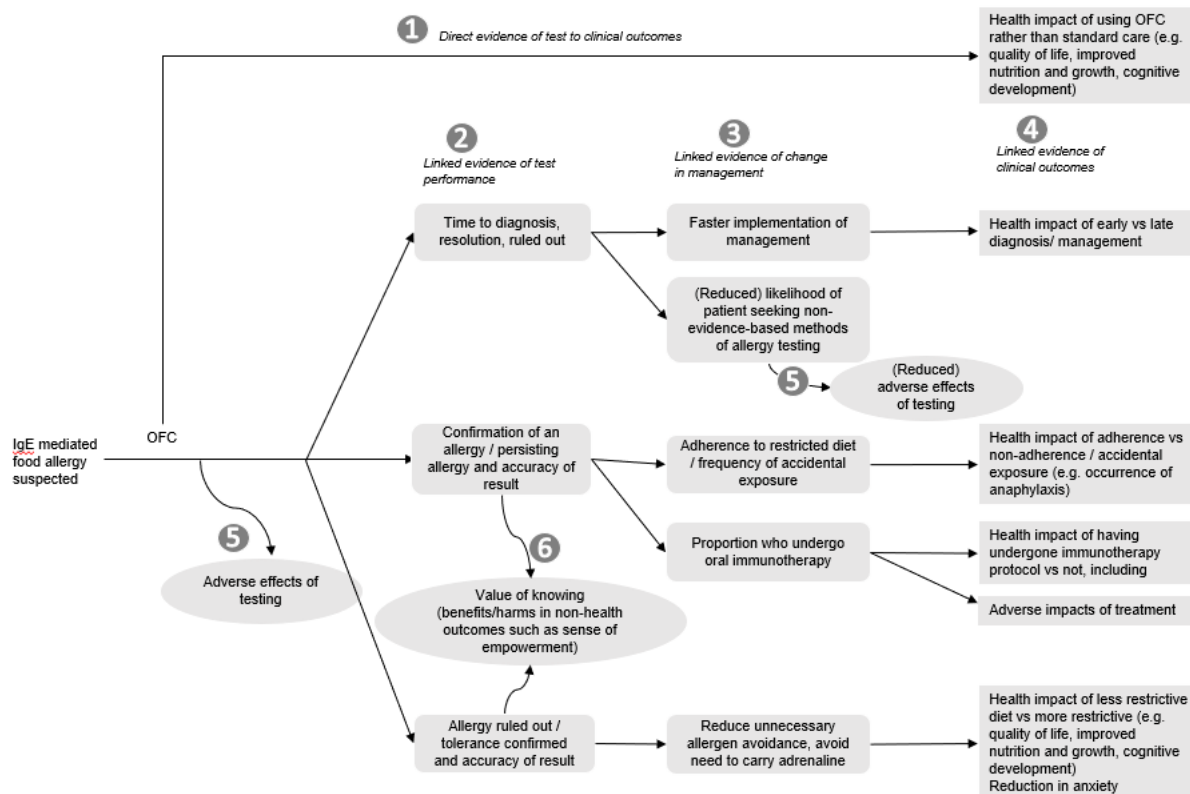


Figure 2 Assessment framework showing the links from the test population to health outcomes as claimed in the application for 1802

Figure notes: 1: direct from test to health outcomes evidence; 2: test accuracy/outcomes; 3: change in diagnosis/treatment/management; 4: influence of the change in management on health outcomes; 5: adverse events due to testing; 6: value of knowing

PASC noted that the assessment framework was complex, but considered the overall steps included to be appropriate.

Clinical management algorithms

Current clinical practice

The current clinical management algorithm is shown in Figure 3. It shows the tests and investigations currently in use in the identified population. Presently, patients are referred to a clinical immunology/allergy specialist if they have a clinical history suggestive of a IgE-mediated food allergy. Where the specialist considers it appropriate, the patient then undergoes an SPT or an ssIgE test. Additional testing (such as the CRD) may also take place at this time, although it is not offered by all laboratories and there is no associated Medicare rebate for the test. If the findings of these tests are not indicative of IgE-mediated food allergy, the patient is further evaluated for alternative diagnoses.

If the findings of these tests indicate an IgE-mediated food allergy, the allergy is managed under the supervision of the immunology/allergy specialist. The patient is advised to avoid the allergen in foods with advice provided by multi-disciplinary teams involving nursing, nutrition and dietetics advice provision, pharmaceutical services, and psychology assistance for the management of mental, emotional and social considerations. The patient may also require prescription of an adrenaline/epinephrine device, and education on how to use this in the event of an anaphylactic reaction to an inadvertent exposure to the allergen. Some patients with food allergies may also be eligible to commence a programme of oral

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immunotherapy for these allergens; some oral immunotherapy protocols require the result of an OFC to establish an initial dose of allergen as part of the programme.

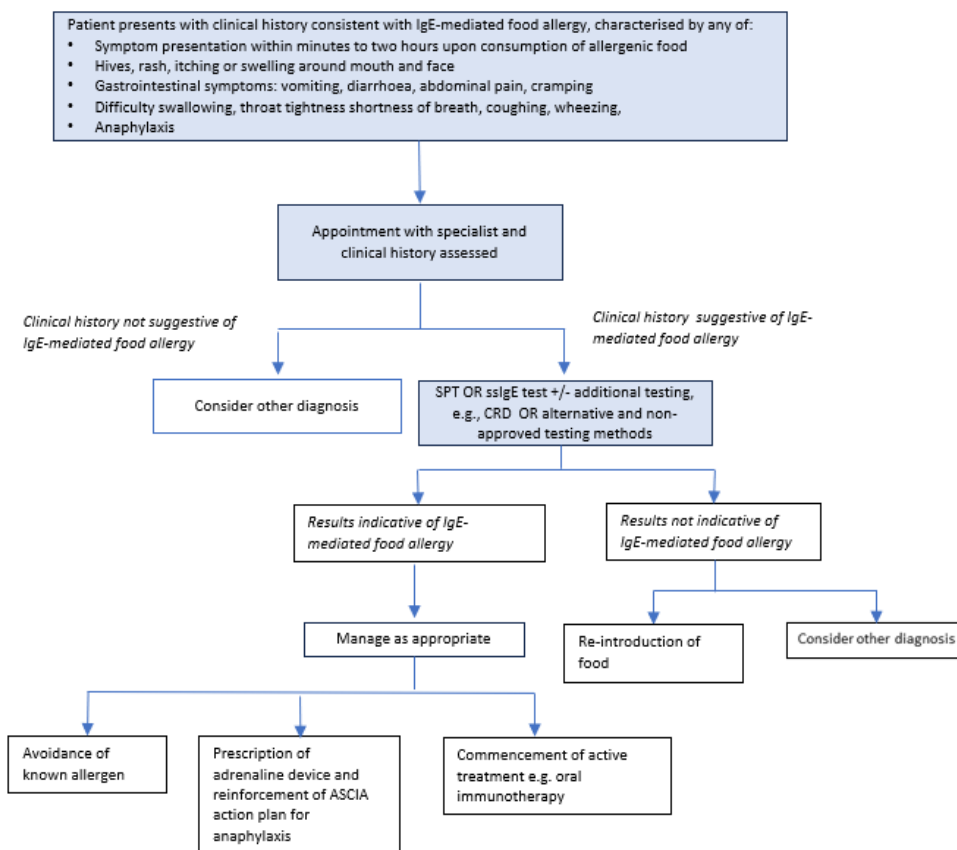


Figure 3 The current clinical management algorithm for patients with suspected IgE-mediated food allergy (in the absence of OFC)

Figure Notes: ASCIA = Australian Society of Clinical Immunology and Allergy; CRD = Component Resolved Diagnostics; IgE = immunoglobulin E: a type of antibody produced by the immune system; SPT = skin prick test; sslgE = serum-specific IgE

The proposed clinical algorithm

The proposed clinical algorithm in Figure 4 outlines the diagnostic process including OFC. This is the same as the current algorithm up to and including the completion of the SPT or sslgE tests. After this point, for patients with suspected IgE-mediated food allergy, the clinician would decide whether the findings from the OFC have the potential to alter clinical management for the patient. If a change in management is likely to occur, the clinician may recommend a supervised OFC for the patient. The purpose of the OFC test is to provide greater diagnostic clarity to empower patients and healthcare providers to navigate the management of food allergies more effectively. The management outcomes after a positive test result (confirmation of a food allergy) would be the same as those in the current practice algorithm for patients with a suspected IgE-mediated food allergy.

If an OFC was terminated prior to the ingestion of a final dose of the required cumulative dose of allergen, the test result would be regarded as “inconclusive”; another OFC may be repeated for the patient at the discretion of the specialist. Premature termination of a supervised OFC may occur in the event of a serious allergic reaction, or if a patient experienced distress or anxiety during the challenge or refused to participate in the OFC prior to the administration of the last dose of the allergen-containing food. A subset of the latter group of patients may be offered a repeat OFC at the discretion of their specialist if the outcome of a completed challenge had the potential for alteration of allergy management. Patients with inconclusive results would also be advised to continue avoidance of the allergen-containing foods. Some patients may also have a negative OFC result that is indicative of resolution of the food allergy; these individuals may then receive guidance on the re-introduction of foods containing the allergen to their diet.

PASC noted that, although there is some inherent uncertainty in defining the threshold of subjective symptoms sufficient to label an OFC result as positive or negative, a practical criterion is that if the patient has mild subjective symptoms and is advised to continue regular ingestion of the food as part of their diet following the OFC, the challenge outcome could be considered negative. However, PASC considered that determining whether an OFC is positive or negative will be up to the discretion of the supervising allergist/immunologist.

PASC noted that the requirement for a repeat OFC after commencement of oral immunotherapy (OIT) varies depending on clinical goals and patient preference. As such, while most patients will undergo at least one OFC during OIT management, it is not universally required for all patients.

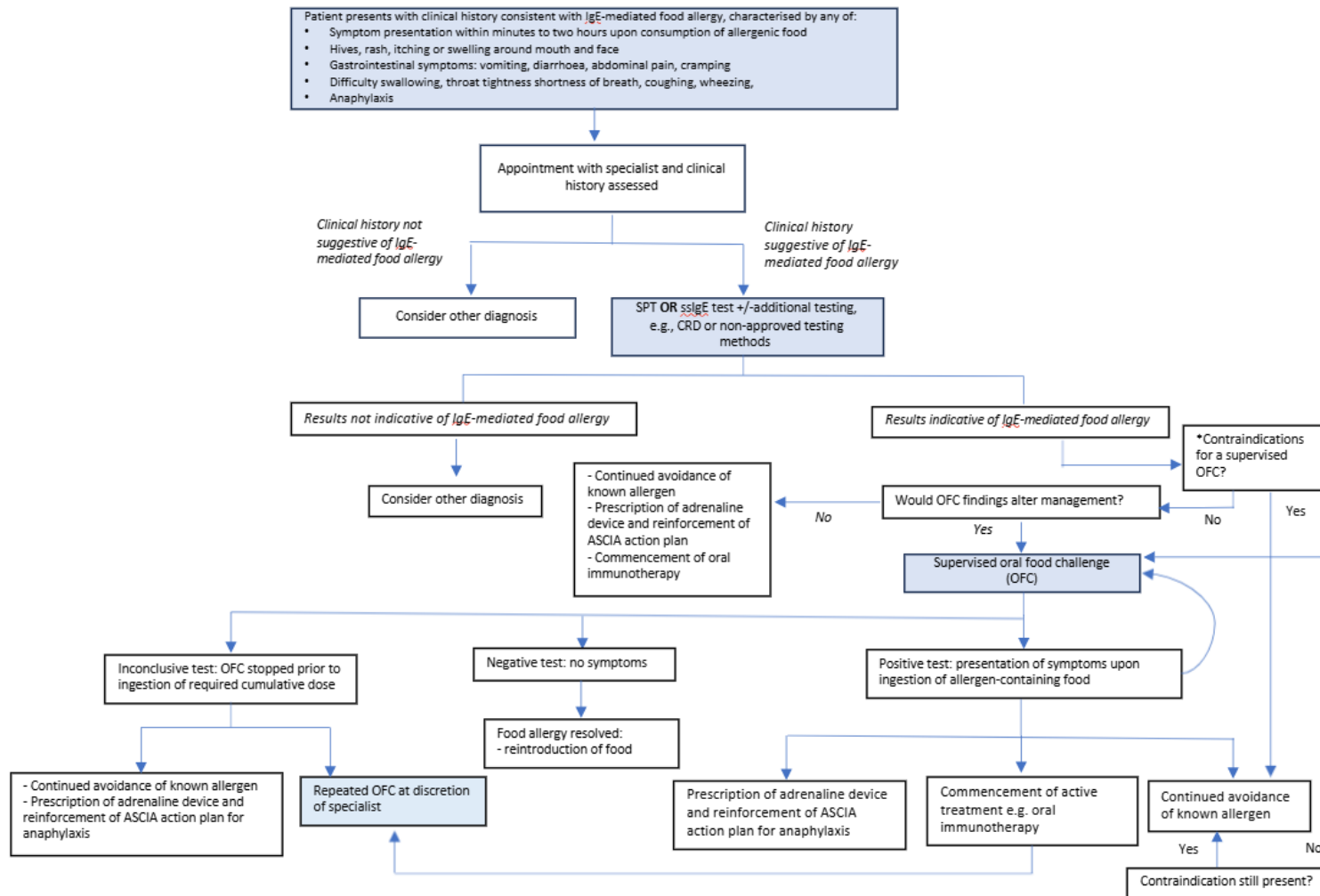


Figure 4. The proposed clinical management algorithm for patients with suspected IgE-mediated food allergy.

Figure Notes: ASCIA = Australian Society of Clinical Immunology and Allergy; CRD = Component Resolved Diagnostics; IgE = immunoglobulin E: a type of antibody produced by the immune system; SPT = skin prick test; sslgE = serum-specific IgE

*Contraindications to OFC include: intercurrent illness such as fever, cough, vomiting and/or diarrhoea, active/uncontrolled asthma requiring reliever medication, demonstration of tolerance to the challenge allergen since booking, severe atopic dermatitis (eczema) flare, current urticaria (hives, welts), poorly controlled allergic rhinitis (hay fever), antihistamine taken in the last 72 hrs (excluding nasal sprays used to treat allergic rhinitis)

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Other considerations

The remit of MSAC is to advise the federal health minister on whether a medical service, health technology or health program should be publicly funded, and what circumstances, if any, should apply to such funding based on an assessment of the comparative safety, clinical effectiveness, cost-effectiveness and total cost using the best available evidence. However, MSAC may also consider aspects such as ethical, patient and social considerations. The “Other relevant considerations” section of the assessment report could include consideration of issues such as:

- Informed consent, particularly where there is some risk of harms incurred because of the exposure to an allergen, which may cause an adverse allergic reaction.
- Social stigmatisation and isolation, which has been identified as a negative outcome for children with one or more food allergies.
- Equity and access to testing, as cost has been cited as a barrier for patients to undergo a supervised OFC, and out-of-pocket costs may still limit access even with an MBS item.
- Organisational considerations (clinical immunology/allergy specialist capacity to deliver OFC in private practice).

PASC acknowledged that the introduction of an MBS item will not remove all barriers to accessing OFCs for patients, as there will still be out of pocket costs and workforce limitations. PASC noted the applicant’s statements that a multifaceted approach was being taken to address the workforce limitations, including the establishment of a national allergy council to look at improving care, and how to ensure shared care for allergic disease. This has the aim of utilising the entire health workforce for allergy care, so that allergy/immunology specialists can focus on the areas that need their expertise (such as OFCs), or models of care where patients can be cared for by other clinicians, in consultation with allergy specialists. The national allergy council is also supporting outreach programs for specialist services to travel to rural, regional and remote areas

Proposed economic evaluation

The application made a claim of superior effectiveness, compared to standard medical management. The supervised OFC is also currently regarded as the gold standard for food allergy testing. Based on this assumption, the appropriate economic evaluation would be a cost-effectiveness analysis or cost utility analysis as shown in Table 6.

PASC noted that the principal comparison in the economic evaluation should be current practice with no OFC versus an OFC. PASC advised that either a cost-effectiveness analysis (CEA) or cost utility analysis (CUA) would be appropriate given the clinical claim of superiority of the OFC compared to standard management of food allergy alone with no OFC, but noted that a CUA is generally preferred.

Table 6 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation.

Comparative safety	Comparative effectiveness			
	Inferior	Uncertain ^a	Non-inferior ^b	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain ^a	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Non-inferior ^b	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

CEA=cost-effectiveness analysis; CMA=cost-minimisation analysis; CUA=cost-utility analysis

? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis

^a 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations

^b An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence

Proposal for public funding

The applicant has proposed public funding of supervised OFCs through the MBS. Currently, there is no specific MBS item number to cover the cost of this procedure. Supervised OFCs are conducted across Australia within public and private settings. For OFCs currently performed in the private outpatient setting, individual patients can access MBS rebates for the medical practitioner consultation via standard attendance items. Private patients accessing OFCs in hospital settings can also access private health rebates for associated hospital costs. The applicant stated that current MBS rebates are insufficient for OFCs and that individual patients or families bear the cost of the service. In the application, the applicant stated that the introduction of allergy treatments such as peanut oral immunotherapy programmes has led to an increase in demand for oral food challenges in public hospital allergy clinics.

Supervised OFCs are highly resource-intensive and are expensive to establish and perform over four hours. The total overall cost per patient of providing a supervised OFC is estimated to be approximately \$950 (Table 7). This price includes two hours for the preparation and delivery of the challenge food containing the specific allergen every 15-20 minutes over 6-8 intervals, with clinical observation by a registered nurse and a clinical immunology/allergy specialist present the entire time. There is also a post-challenge observation period of up to two hours by the nurse or specialist, and a further 15-30 minutes post-challenge for patient education by the nurse or specialist.

Table 7. Estimated total cost of supervised OFCs excluding administrative fees

Item	Cost (\$)
Specialist fee (rounded)	500.00
Nurse fee (rounded)	300.00
Consumables	75.00
Facility fee	75.00
Total estimated cost of OFC: \$950.00	

The MBS item numbers for the professional attendances are outlined in Table 8 below.

Table 8 Example of professional attendance MBS item that may be co-claimed with proposed MBS item

Category 1 – Professional attendances
MBS Item 110 Professional attendance at consulting rooms or hospital, by a consultant physician in the practice of the consultant physician's specialty (other than psychiatry) following referral of the patient to the consultant physician by a referring practitioner-initial attendance in a single course of treatment Fee: \$178.70 Benefit: 75% = \$134.05 85% = \$151.90
MBS item 116 Professional attendance at consulting rooms or hospital, by a consultant physician in the practice of the consultant physician's specialty (other than psychiatry) following referral of the patient to the consultant physician by a referring practitioner-each attendance (other than a service to which item 119 applies) after the first in a single course of treatment Fee: \$87.30 Benefit: 75% = \$65.50 85% = \$74.25

The proposed prerequisite tests SPT and ssIgE are funded through the MBS as shown in Table 9 below. Clinical advice provided during the pre-PASC teleconference suggests the majority of patients would undergo a SPT; patients with severe eczema would be more likely to be referred for a ssIgE test.

Table 9 MBS funded diagnostic tests for IgE-mediated food allergy

MBS item	Descriptor
12003	Skin prick testing for food and latex allergens, including all allergens tested on the same day, not being a service associated with a service to which item 12012, 12017, 12021, 12022 or 12024 applies Fee: \$44.35 Benefit: 75% = \$33.30 85% = \$37.70
71079	Detection of specific immunoglobulin E antibodies to single or multiple potential allergens, 1 test Fee: \$26.80 Benefit: 75% = \$20.10 85% = \$22.80

An OFC may be required multiple times per patient on an ongoing basis for several years, particularly if a patient is young and their allergy or allergies are expected to evolve over time. This evolution may include resolution of the allergy, or increased severity of an allergy in which responses to the allergen might

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become more serious over time. The duration over which supervised OFCs are offered to a patient is dependent on the patient's individual progress and specific circumstances, particularly if the patient has multiple food allergies. It is envisaged a patient may undergo more than one supervised food challenge per year. The applicant stated that most patients would not have more than 3-4 OFCs per year.

The MBS item as proposed by the applicant following the pre-PASC meeting is shown in Table 10. The OFC is proposed to be claimed and supervised by specialists accredited in clinical immunology and allergy (with specialist recognition by the Royal Australasian College of Physicians), although the delivery may be delegated to appropriately trained medical or nursing professionals with experience in recognising and treating allergies.

Table 20 Proposed MBS item for OFC

Category 2 – Diagnostic Procedures and Investigations	
MBS item XXXX	
Supervised oral food challenge (OFC), for at least 4 hours, performed for confirmation of IgE-mediated food allergy, where the challenge is undertaken under the supervision of a clinical immunology/allergy specialist for a patient when; - the patient has been referred by a medical practitioner to a clinical immunology/allergy specialist who has determined the OFC necessary and appropriate; and - prior to the initiation of an OFC, the clinical immunology/allergy specialist performs: - a review of the patient's clinical history; and - an assessment of the patient's suitability to undergo OFC; and - a review of previous skin prick test (SPT) and/or serum-specific IgE (ssIgE) test results; and - a physical examination; and - the OFC is initiated by a suitably qualified registered nurse who is in continuous attendance for the duration of the OFC under supervision of a clinical immunology/allergy specialist; and - there is continuous observation of the patient undergoing OFC by a registered nurse who will conduct the OFC and record the following in accordance with current professional guidelines: - allergen dose administered; and - clinically significant signs of allergic reaction (skin, respiratory, gastrointestinal, cardiovascular/neurological); and - treatment administered if and when required; and - the supervising clinical immunology/allergy specialist at any time during the OFC: - performs a physical examination on the patient when clinically indicated; and - makes clinical management decisions regarding the conduct or cessation of the OFC; and - the supervising clinical immunology/allergy specialist at the conclusion of the OFC; - reviews documentation and interprets the results of the OFC; and - based on that review and interpretation, provides written management advice to the patient. Not to be used in conjunction with 110, 116, 132, 133 on the same day. Claimable once per food per day.	
Fee: \$497.85 Benefit: 75% = \$373.40; 85% = \$398.30	

There is a significant gap between the estimated cost of providing an OFC and the proposed MBS fee. This difference arises because the MBS can only remunerate for a professional service being delivered to an individual patient. Table 7 includes the cost of delivering one individual OFC to one individual patient where both the medical practitioner and the nurse are directly attending the patient for the entirety of the OFC. This does not reflect the real-world implementation where multiple patients are tested concurrently under the care of the same clinician and nurse. The proposed OFC item permits nursing staff or other medical staff to provide elements of care on behalf of the clinical immunology/allergy specialist billing the service. This is considered clinically appropriate and reflective of real-world practice. However, applying legislative requirements to the costs in Table 7 means for an OFC being billed to the MBS, where different

practitioners are involved in the provision of a complete medical service and may be delivering the same service to multiple patients at the same time, only the actual time spent with an individual patient is remunerable. While a medical practitioner may be present in the building, if they are not directly attending an individual patient, as a nurse is supervising the delivery of the OFC, the medical practitioner time is not remunerable.

The applicant stated there may be out of pocket costs incurred by the patient or their family in the form of gap payments to the clinical immunology/allergy specialist. The variability in the model and MBS legislation which permits providers charging above and beyond the MBS rebate, means out of pocket costs cannot be estimated with any certainty and will be at the discretion of each clinic/specialist. Furthermore, patients may still need to cover the costs of nursing and facility fees out-of-pocket, depending on the location of the study and private health insurance policy inclusions.

To ensure flexibility and equity of access, PASC advised that the MBS item descriptor be agnostic to the physical setting, allowing clinicians to use their judgement in determining the most appropriate and safe environment for each patient. This would also enable private providers to offer OFCs either in clinic rooms (where only the MBS item is claimed) or in private hospital day facilities (where the MBS item is combined with private health insurance funding, similar to surgical or procedural models).

PASC noted policy advice that legislation requirements mean only the time any individual clinician spends with a patient can be remunerated, and that currently clinicians cannot claim the same attendance item multiple times in the same day for a continuing episode of care. PASC noted that the OFC process involves clinician time for an initial assessment, followed by an OFC, and in some cases management of anaphylaxis. PASC noted several clinicians may be involved in delivering an OFC and a supervising medical practitioner may be overseeing multiple patients undertaking OFC at the same time. PASC noted if all elements of an OFC are combined into a single OFC item, with a flat fee, there is a challenge in determining an appropriate fee as only a proportion of patients will require funding for anaphylaxis treatment. PASC considered separate items, each with appropriate fees, may allow for appropriate remuneration for patients who require additional services, whilst minimising the risk of 'double counting' of clinician time. The applicant suggested that some patients may display borderline anaphylaxis symptoms during an OFC and require close monitoring but would not meet the criteria for incurring an item for anaphylaxis. As such, an item solely for anaphylaxis management may not account for the resources involved in monitoring patients with borderline anaphylaxis symptoms during the OFC.

PASC noted there may continue to be out-of-pocket costs because MBS items cannot double-count clinician time when OFCs are simultaneously conducted on more than one patient and there are costs associated with OFCs that cannot be covered by the MBS.

PASC noted the applicant had stated that most patients would not have more than 3-4 OFCs per year, and that some feedback indicated the initially proposed frequency restriction of 6 OFCs in 12 months was excessive and may inappropriately encourage single allergen challenges where mixed challenges were appropriate. Other feedback supported a restriction of 6 OFCs per year. PASC considered that a clinically appropriate frequency restriction should be included in the item descriptor.

PASC considered that further work was required to develop the proposed item descriptor(s) and fees to ensure all policy and implementation issues are addressed.

Summary of public consultation input

PASC noted and welcomed consultation input from 5 organisations and 77 individuals, 69 of whom were consumers and 8 were health professionals. The 5 organisations that submitted input were:

- *Allergy and Anaphylaxis Australia (A&AA)*
- *Allergy Support Hub - Director Family Services*
- *Australian Paediatric Society*
- *National Allergy Council*
- *The National Allergy Centre of Excellence (NACE).*

Consultation input was supportive of public funding for supervised OFC in patients with suspected food allergy.

Consumer Input

Most of the consumer input came from individuals or carers of individuals who have food allergies that impacted them socially and financially. These individuals usually have to avoid some foods because of the lack of access to OFC and fear about introducing some of those foods at home rather than in a controlled environment with the required health professional support.

Input highlighted that supervised OFC would allow individuals to confirm an actual food allergy rather than being anxious about the extent of a potential allergy, and whether the reaction would be better or worse as time went on. Additionally, input stated that OFC currently have significant costs which can pose as a barrier, leading to delayed challenges.

Some individual inputs stated that due to fear around food allergies, children had developed avoidant restrictive food intake disorder (ARFID), which severely impacted their life further. Input from carers stated that the eating disorder was far more difficult and stressful to manage than avoiding foods which may contain allergens.

Input from individuals and carers highlighted the need for mental health support, stating that severe food allergies can have a negative impact on people's mental health and cause stress for carers. Input described the difficulty managing social activities and life threatening allergies, stating that children often miss sports, school, going to friend's houses and camps. Many individuals required access to a hospital, refrigeration for medication and access to safe food and food preparation areas in order to travel.

Benefits and Disadvantages

The main benefit of public funding reported in the consultation input included greater access to OFC, making an enormous difference to daily life if those foods could then be safely reintroduced. Benefits of increased access to OFC included shorter waiting times, less burden and stress for individuals and families, better patient management, cost savings for individuals and the health system due to fewer people requiring adrenaline devices and regular healthcare visits.

The key disadvantages of public funding identified in the consultation were likely out of pocket costs for patients in the private sector, the lack of trained specialists to administer OFC and that an MBS item will not address the need for dedicated spaces and equipment, including the option to admit patients to hospital.

Population, Comparator (current management) and Delivery

The consultation input largely agreed with the proposed population, noting that the majority of individuals who undertake OFC are in the paediatric age group, however it is important that the adult population is included in plans to increase access. Input from a health professional stated that individuals with Food Protein Induced Enterocolitis Syndrome (FPIES) can undergo OFC and would also benefit from inclusion in the population.

Input commented on ensuring equitable access for priority groups, including First Nations people, people in rural and regional areas, and people with disabilities, as these populations currently face disproportionate barriers to accessing allergy services. The Australian Paediatric Society stated that the majority of OFC in regional areas would be performed in a public hospital, however an MBS item would assist those travelling to capital cities for OFC.

Input agreed that in the absence of OFC, the standard treatment is medical management of allergies using skin tests, blood tests and avoidance of foods. NACE emphasised that individuals living outside of major metropolitan areas often had significantly limited access to standard care. The National Allergy Council stated there is no comparator for an OFC as it is the gold standard diagnostic tool for food allergy.

PASC noted the consultation feedback, and acknowledged feedback was received from a large number of individuals. PASC acknowledged that food allergy is common in Australia, with many people impacted. PASC noted that feedback raised concerns around equitable access to OFCs. PASC noted the applicant's response to this highlighted an increase in allergy/immunology trainee positions available to increase the size of the workforce, and an effort to redistribute the nature of allergy work. For example, the applicant stated that some younger specialists have moved to areas that have not had specialist services before (such as Darwin, Tasmania, the ACT and Orange in NSW). The applicant also noted the establishment of an outreach program in Western Australia to provide specialist allergy services, to increase equity for rural and remote individuals.

MBS Item Descriptor and Fee

The health professional input agreed with the proposed item descriptor, with NACE recommending that allergy-trained nurse practitioners be considered appropriately qualified alongside clinical immunology and allergy specialists to determine the necessity of undergoing an OFC.

Health professional input largely agreed with the proposed MBS item fee, with some input stating that the MBS item fee should be higher to include the cost of testing and resuscitation equipment and the risk profile of conducting OFC. The National Allergy Council and A&AA stated that the proposed MBS item fee was lower than the estimated cost of performing an OFC, and that patient out of pocket expenses should be kept to a minimum.

Next steps

To be confirmed after the PASC meeting.

PASC noted that the assessment report would progress as a department contracted assessment report (DCAR), as requested by the applicant. PASC reiterated that more work on the expected uptake of OFCs would be required, along with further work on the proposed MBS item descriptor(s) and fees.

Applicant Comments on Ratified PICO

We appreciate the opportunity to review the ratified PICO confirmation and have no comments.

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Ratified PICO Confirmation –August 2025 PASC Meeting

33 Application 1802– Supervised oral food challenge (OFC) in patients with suspected food allergy

Appendix 1 – PRACTALL Guidelines

The PRACTALL guidelines for the standardising and management of oral food challenges is provided below:

Sampson et al. (2024) AAAAI-EAACI PRACTALL: Standardizing Oral Food Challenges – 2024 Update.
Pediatric Allergy and Immunology, 35 (11)pg 1-24, DOI: 10.1111/pai.14276.

Appendix 2 – Additional detail provided by the applicant at PASC (for the development of the assessment report)

Patient prioritisation and triaging

The applicant clarified that, currently, there is some prioritisation for patients to undergo earlier challenges by a “triaging” process based on clinical urgency and potential impact on patient outcomes. Patients who are generally prioritised for earlier challenges include:

- Infants with suspected allergy to staple foods (e.g. egg, milk, wheat, peanut), particularly where there is a critical dietary or developmental need
- Candidates for oral immunotherapy (OIT), where OFC is required as a baseline or eligibility assessment
- Patients with multiple food allergies impacting nutrition or growth
- Cases where OFC is needed to resolve diagnostic uncertainty that is causing significant psychosocial or functional distress

These patients may receive shorter wait times relative to those with non-staple or lower-priority allergens (e.g. sesame, kiwi) or those where the outcome of the OFC is unlikely to significantly alter management in the short term.

Despite triage processes, clinic capacity remains limited, and many services operate at or near their resource ceiling. Consequently, although priority patients are currently seen more quickly, the overall demand continues to grow and wait times for these higher-priority cases may begin to increase over time in the absence of expanded capacity. Supervised OFCs take place for the detection of cow’s milk, egg, peanut and tree nuts in children for the purpose of primary diagnosis and to determine natural resolution of these allergies. Crustacean (shellfish) and nut challenges are relatively more common in adults due to the prevalence of adult-onset allergies to these allergens.

For patients with more than one allergen, a triage process would be used to determine which food allergen is to be tested; this would be based on prioritisation of staple foods in the diet, whether timing of challenge may alter the natural history of the allergy, and the risk of accidental exposure. For example, in an infant with possible cow’s milk, peanut and crustacean allergies, priority would be given to challenges to cow’s milk, as it is a staple food, with high risk of accidental exposure, and peanut, as a sensitised, non-allergic infant is at significantly increased risk of future peanut allergy if it is avoided in the diet. These challenges would be prioritised ahead of crustaceans, which are non-staple foods where there is a relatively lower risk of accidental exposure. Although any food is capable of causing a severe allergic reaction (anaphylaxis), food allergens more commonly associated with anaphylaxis include cow’s milk, egg and wheat are common staple foods in most Australian diets, with a high risk of accidental exposure. By comparison, peanut, sesame and tree nuts (particularly cashew and walnut) are less common foods in most Australian diets (with the exception of some cultures), but accidental exposure can still occur.

Patients likely to be offered an OFC

The applicant supplied information regarding key allergens and age groups that would have an OFC. In clinical practice, OFCs are typically offered:

- To clarify the diagnosis when history or test results (e.g. SPT/ssIgE) are inconclusive.
- To assess tolerance to related nuts (e.g. almond in a cashew-allergic patient).
- As a threshold challenge prior to initiating oral immunotherapy (OIT).

For infants and toddlers:

- A high proportion (potentially up to 90%) may be offered an OFC, especially where there is diagnostic uncertainty or as part of an OIT assessment.
- However, some OIT protocols omit pre-treatment OFCs in children with a very high likelihood of allergy based on clinical history and sensitisation profiles. If these children are excluded from the estimate, the proportion undergoing OFC in this age group would likely halve.

Older children, adolescents, and adults:

- The proportion of patients with cashew (or another tree nut) allergy undergoing OFC is typically much lower, estimated at 10% or less.
- OFCs in this group are generally reserved for:
 - i. Confirming allergy status in the context of diagnostic uncertainty.
 - ii. Determining tolerance to other tree nuts.
 - iii. Guiding dietary expansion or reintroduction following prior avoidance.

Estimating the average number of OFCs that individuals with suspected or confirmed food allergies undergo over their lifetime is challenging and varies widely based on allergy type, age at diagnosis, and clinical management goals. However, based on clinical experience:

- For typical nut-allergic infants, a common pattern might include:
 - An initial OFC to confirm diagnosis.
 - A subsequent OFC around primary school age (or earlier) to assess for allergy resolution.
 - Possibly a further OFC during adolescence or young adulthood to re-evaluate tolerance.
- If the allergy persists into adulthood, additional OFCs become less common, with long intervals (5+ years) between assessments, or none at all.
- For food allergies that often resolve in early childhood (such as egg, milk, wheat, or kiwi), children may undergo multiple OFCs in early years (e.g. 3 challenges over 5–6 years), followed by fewer and more spaced OFCs as they age (e.g. one every 3–5 years) if the allergy persists.
- Many children who naturally outgrow their allergy may only have 1 or 2 OFCs in total, corresponding to diagnosis confirmation and subsequent tolerance testing.

Comments on the proposal for public funding

The applicant stated that they did not expect the introduction of an MBS item number for OFCs to generate a substantial increase in overall demand for OFC, for the following reasons:

- Most referrals for OFC are already clinically indicated and arise from existing diagnostic pathways.
- The proposed item number would be restricted to clinical immunology/allergy specialists – currently there are only 246 of these specialists in Australia, and less than 200 work in private practice (including part time combined with public).

Rather, the applicant expected the primary impact of the item number to be on:

- Decreased wait times and improved access by increased feasibility of providing OFC in private practice, with modest scaling-up by specialists already offering OFCs.
- Decreased wait times and burden on public services, by some redistribution of OFCs from public to private practice.

The applicant stated that, currently, a substantial proportion of patients are reliant on the public hospital system for access to OFCs, contributing to long wait lists and delayed management. There is a cohort of patients who are currently medically suitable for oral food challenge (OFC) but are effectively excluded from accessing the service due to cost or lack of availability, particularly in private practice. At present, patients who are clinically eligible for OFC but unable to afford private clinic fees are often referred to public hospital-based OFC services. However, these services are heavily resource-constrained, and prioritisation frameworks typically favour patients with high-risk allergens, multiple food allergies, or have allergies with substantial nutritional/psychosocial impact. As a result, patients with less urgent indications (e.g. single allergen or non-staple foods with low nutritional impact) may be placed on indefinite wait lists, or in some cases, not referred at all, due to the treating clinician's understanding that access will not realistically be available. The absence of an MBS item number for OFC is a key barrier to expanding services in private practice, which limits the capacity of clinical immunology/allergy specialists in private practice to offer this service.

If an MBS rebate was introduced, the clinical appropriateness criteria for OFC would remain unchanged. Patients who are not currently considered suitable for OFC based on clinical judgement (e.g. due to risk, history, or other contraindications) would continue to be excluded, regardless of the availability of an MBS item. Upon introduction of an MBS item number, the applicant stated:

- A proportion of these excluded patients could access OFCs privately, reducing the financial burden and creating a viable pathway for those previously unable to afford testing.
- This would free up capacity in public hospital clinics, thereby improving access for higher-priority patients as well.
- Overall, access would become more equitable, with a better distribution of patients across public and private services and reduced wait times.

Although there is capacity within the private sector to accommodate an increase in oral food challenge (OFC) services, growth will be incremental and constrained by workforce and infrastructure factors including:

- Provider experience
- Limited infrastructure such as physical clinic space
- Staffing availability such as lack of nursing or resuscitation support for managing potential anaphylaxis
- Time