MSAC application 1802

Supervised oral food challenge in patients with suspected food allergy

Application for MBS eligible service or health technology

HPP Application number:

HPP200288

Application title:

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

Submitting organisation:

AUSTRALASIAN SOCIETY OF CLINICAL IMMUNOLOGY AND ALLERGY LIMITED

Submitting organisation ABN:

45615521452

Application description

Succinct description of the medical condition/s:

An allergy occurs when a person's immune system reacts to substances that are harmless to most people. With food allergy, a person's immune system reacts to the protein (usually) in a food. When a person with food allergy eats food containing their allergen, they can develop an allergic reaction causing symptoms ranging from mild to moderate, or severe (known as anaphylaxis). Anaphylaxis is a medical emergency that needs immediate treatment with adrenaline (epinephrine). If left untreated, anaphylaxis can result in fatality. Food allergy can develop at any age. It occurs in around 10% of babies, 6.5% of children at 6 and 10 years of age, and about 5% of children at age 14. Although food allergy can be 'outgrown', around 2-4% of adults in Australia will still have a food allergy and some adults will develop a food allergy in their adult years. The most common food allergies are cow's milk (dairy), egg, peanut, tree nuts, sesame, soy, fish, shellfish and wheat.

Succinct description of the service or health technology:

An oral food allergen challenge (OFC) is a procedure where small and gradually increasing amounts of the food a patient is allergic to, is fed to that patient whilst under medical supervision. The patient is monitored to determine if the food being tested causes an allergic reaction. OFC's are a four hour procedure as the patient must be closely observed during the administration of the food, and for at least 2 hours after the last dose of the food. OFC's are mainly used to confirm a diagnosis of

food allergy when the patient's history or allergy tests are unclear, and to determine whether a patient has outgrown their food allergy.

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Applicant

Are you applying on behalf of an organisation, or as an individual?

Organisation

Applicant organisation name:

AUSTRALASIAN SOCIETY OF CLINICAL IMMUNOLOGY AND ALLERGY LIMITED

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?

No

Which list/schedule will the other health technologies be listed on? *(if 'Yes' above)*

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?

New

Relevant MBS items

Please select any relevant MBS items.

MBS item number	Selected reason type

What is the type of service or health technology?

Investigative

Please select the type of investigative health technology: *(if investigative)*

Immunology

PICO sets

Patients (children and adults) with suspected IgE mediated food allergy.

Purposes

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

Population

Describe the population in which the proposed health technology is intended to be used:

Medically supervised oral food challenges (OFC) are intended to be used in patients (children and adults) with suspected IgE mediated food allergy, where the intention of the clinician is to use the outcome of the OFC to alter or guide management.

Select the most applicable Medical condition terminology (SNOMED CT):

Food allergy

Intervention

Name of the proposed health technology:

Supervised oral food challenge (OFC)

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

A supervised OFC is considered the gold standard diagnostic tool to determine tolerance to suspected food allergen/s for confirmed IgE mediated food allergy. The only identifiable comparator for an OFC is standard medical management, that is, in the absence of an OFC.
Standard medical management of food allergy usually comprises:

- 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 – these tests do not have sufficient specificity or reliability to be used as a sole determinant for patient's without a clear history.

- Strict avoidance of food allergen if available data suggest IgE mediated food allergy or results are inconclusive.
- Prescription of adrenaline device/s if patient is considered at risk of anaphylaxis.

*Skin Prick Test (SPT) – Is the primary mode of testing for immediate IgE-mediated allergy, carrying a very low risk of serious side effects, and provides high quality information when performed optimally and interpreted correctly. For patients with severe eczema, the use of SPT may be limited.

**Serum specific IgE (ssIgE) – Measures the amount of IgE antibodies in the blood, specific to particular allergens. ssIgE results may help inform the decision to proceed with an OFC when interpreted in the context of comprehensive patient history and medical assessment.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

OFCs play an important role in confirming the status of food allergies providing diagnostic clarity, empowering both patients and healthcare providers in navigating food allergies more effectively.

The overall outcome of an OFC will be either:

- Positive*, when clear objective signs of allergic reaction appear or repetitive (at least three times) or multiple subjective symptoms in several organ systems occur. A positive OFC result confirms an actual food allergy in a person who has never before reacted to or has persisting allergy to that food. This is an expected outcome in a proportion of patients and key clinical steps are embedded in the OFC procedure to ensure that patient safety is well established and maintained throughout the challenge.
- Negative, when no symptoms occur. A supervised OFC with a negative result has the potential to exclude food allergy or confirm tolerance, indicating that a patient’s food allergy has resolved. This reduces unnecessary allergen avoidance and associated impacts on quality of life.
- Inconclusive/Incomplete if the test is stopped before the required cumulative dose of food is ingested. In young children, 'dose refusal' may occur due to sensory

aversion to food texture or taste, despite efforts by staff to modify or disguise the food. In teenagers and young adults, an OFC may be discontinued due to escalating anxiety. At the discretion of the overseeing clinical immunology/allergy specialist, re-testing may be required to yield a conclusive result.

*A note on positive results:
It is expected, for a proportion of patients, that the OFC will provoke an IgE mediated allergic reaction with a challenge food (allergen). All patients who present for an OFC will undergo a pre-challenge assessment which will identify any potential risk factors that would render them unsuitable to proceed with the challenge. Patients deemed suitable to proceed with the OFC will be under close clinical observation for the duration of the procedure with immediate access to emergency equipment such as adrenaline and oxygen and appropriately trained staff using established protocols.

Proposed MBS items

Proposed item:

AAAAA

MBS item number (where used as a template for the proposed item):

Category number:

DIAGNOSTIC PROCEDURES AND INVESTIGATIONS

Category description:

MISCELLANEOUS DIAGNOSTIC PROCEDURES AND INVESTIGATIONS

Proposed item descriptor:

Supervised oral food challenge (OFC) for the investigation of (IgE mediated) food allergy, usually 4 hours, for a patient if:
a) the necessity for the investigation is determined by a qualified clinical immunology/allergy specialist before the investigation; and
b) there is continuous observation of patient's allergen tolerance and documentation on an OFC record of the following are made in accordance with current professional guidelines:
i) allergen dose,
ii) clinically significant signs of allergic reaction (skin, respiratory, gastrointestinal, cardiovascular/neurological),
iii) treatment administered; and

c) medical professional, or registered nurse with OFC training, is in continuous attendance under the supervision of a clinical immunology/allergy specialist; and
d) OFC record and patient is reviewed by clinical immunology/allergy specialist; and
e) for each particular patient—applicable only in relation to each of the first 6 occasions the investigation is performed in any 12-month period.

Proposed MBS fee:

$392.85

Indicate the overall cost per patient of providing the proposed health technology:

$1,100.00

Please specify any anticipated out of pocket expenses:

$300.00

Provide any further details and explain:

There may be out of pocket costs in the form of gap payments to the clinical immunology/allergy specialist which will be at their discretion and cannot be estimated with any certainty. The amount has been estimated to be $300.00.

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

Supervised OFCs are currently conducted across Australia within public and private settings without reimbursement. Within the private sector, individual patients or their families pay the full cost of the service with no rebate.

Although existing MBS item numbers are available, none provide sufficient remuneration for clinical immunology/allergy specialists to support the delivery of OFC.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Superior

Please state what the overall claim is, and provide a rationale:

The overall claim for an OFC is that it results in superior health outcomes compared to the comparator which, for the purposes of this application, has been identified as standard medical management without an OFC.

The comparator (standard medical management without OFC) relies on the results of allergy testing that does not offer sufficient specificity or reliability to be used as a sole determinant for a patient when the clinical presentation is inconclusive.

The requestor would seek to use a supervised OFC rather than the comparator as an OFC is the most reliable method of determining severity of a patient's IgE mediated food allergy. An OFC provides the most definitive assessment of their tolerance to certain allergenic foods. It is also the only reliable and safe way to ascertain a patient's tolerance to different forms of allergenic foods, such as baked milk or baked egg.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

IgE mediated food allergy is common in the Australian population, affecting people of all ages:

- It is most common in infants under 12 months of age with a prevalence of approximately 11%.
- Across other age groups, the prevalence decreases with age. It affects approximately 6.5% of children at 6 and 10 years of age[9] and approximately 5% of 14 year olds.
- Although some children will 'outgrow' their food allergy, around 2-4% of adults still have a food allergy including those whose food allergy first occurs in adulthood.
- Whilst we do not have current prevalence data for adult-onset food allergy in Australia, globally the prevalence has been recognised as an issue.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

10

Year 2 estimated uptake (%):

15

Year 3 estimated uptake (%):

20

Year 4 estimated uptake (%):

20

Estimate the number of patients who will utilise the proposed technology for the first full year:

8500

Optionally, provide details:

Estimated uptake has been based on the results of a workforce survey conducted by ASCIA between December 2023 and February 2024 (see attached estimated utilisation reference). As at May 2024, there are 256 Full ASCIA members in Australia who are clinical immunology/allergy specialists. All ASCIA Full members were invited to take part in the workforce survey which had a response rate of just under 40% (n=98).

Results of the survey indicated that nationally:
- OFCs are conducted for a total of 634 patients per month in private practice rooms, and for an average of 119 patients per month in private hospitals.
- OFCs are conducted for a total of 489 patients per month in public hospital inpatient clinics, and for an average of 56 patients per month in public hospital outpatient clinics.

A total of 60 out of the 98 private practice survey respondents answered a question about how the introduction of an MBS item for OFC would impact their service:
- 26 specialists advised they would expand on their current service.
- 16 specialists advised they would consider introducing OFCs into their current

service offerings.
- 18 specialists advised they were either the unsure about whether or not this would impact their service offerings (n = 7), would not make a difference to their current service offerings (n = 6), or that the provision of OFCs was not relevant to their current practice (n = 5).

Based on these results, it is expected that funding supervised OFCs would likely result in a 40% - 50% increase in the number of OFCs currently conducted in private clinical immunology/allergy clinics over the next 5 years. The number of patients who will utilise this service in the first full year is unlikely to vary from current usage.

Additionally, a total of 40 heads of departments or their nominated representatives (22 adult, 12 paediatric, and 6 combined) from each region participated in ASCIA's inaugural Heads of Department (Immunology) meeting in Sydney on Friday 2nd and Saturday 3rd August 2024. Topic areas for discussion included the provision of OFCs at each service, where it was revealed that the demand for OFC in public children's hospital allergy clinics has increased due to the introduction of allergy treatments such as peanut oral immunotherapy (OIT) programs.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

Ongoing.

Optionally, provide details:

The duration over which supervised OFCs are provided to a patient with a food allergy is entirely dependent on the patient's individual progress and specific circumstances. Patients may undergo multiple supervised OFCs over the course of several years, especially if they are young and their allergies are expected to evolve with time.

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

Up to 6 times per year.

Optionally, provide details:

The need for multiple supervised OFCs will vary with individual clinical circumstances, particularly when OFC is required for more than one food allergen. There are likely to be circumstances where multiple OFCs are required for an individual patient within a 12 month period.

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entity who provides the health technology/service

- AUSTRALASIAN SOCIETY OF CLINICAL IMMUNOLOGY AND ALLERGY LIMITED
- NATIONAL ALLERGY COUNCIL LIMITED

Entity who requests the health technology/service

- AUSTRALASIAN SOCIETY OF CLINICAL IMMUNOLOGY AND ALLERGY LIMITED

Entity who may be impacted by the health technology/service

- AUSTRALASIAN SOCIETY OF CLINICAL IMMUNOLOGY AND ALLERGY LIMITED

Entity relevant to the proposed service/health technology

- ALLERGY & ANAPHYLAXIS AUSTRALIA

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

No