



Australian Government

Department of Health

1561 Application Form

**(18 July 2019 Applicant's reconfigured version
of earlier Application 1561)**

(New and Amended

Requests for Public Funding)

(Version 2.4)

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires in order to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

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PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):

Australasian Society of Clinical Immunology and Allergy (ASCIA)

Corporation name: Australasian Society of Clinical Immunology and Allergy Limited

ABN: 45 615 521 452

ACN: 608 798 241

Business trading name: ASCIA

Primary contact name: Jill Smith, ASCIA CEO

Primary contact numbers

Business: 02 8039 2140

Mobile: 0425216402

Email: jill@allergy.org.au

Alternative contact name: Dr Brynn Wainstein, ASCIA President

Alternative contact numbers

Business: (02) 9369 5757

Mobile: 0412 826 604

Email: brynnascia@gmail.com

2. (a) Are you a lobbyist acting on behalf of an Applicant?

No

(b) If yes, are you listed on the Register of Lobbyists?

Not applicable

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Food allergen challenges MBS item number application

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

Food allergy occurs in approximately 5% of children and 2% of adults. The most common triggers are egg, cow's milk, peanut, tree nuts, sesame, soy, fish, other seafood and wheat. Currently the only treatment is avoidance of the food/s.

Severe food allergies can cause potentially life-threatening allergic reactions known as anaphylaxis. Food allergies have been consistently demonstrated to also impair quality of life for children and their carers.

Most food allergies in children are not severe and may be 'outgrown' with time. However, severity of reactions is not predictable, so all children with food allergy and their families need to maintain a high level of dietary vigilance and be prepared for the possibility of severe reactions upon accidental exposure. Overall, peanut, tree nut, seed and seafood allergies are much less likely to be outgrown and can be lifelong allergies.

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

Food allergen challenges are standardised procedures where incremental amounts of a particular food are fed to a patient over a period of 2-3 hours, whilst under medical supervision (clinical immunology/allergy specialist or experienced/postgraduate qualified paediatrician). The patient is monitored to determine if the food being tested causes an allergic reaction, and observed for at least 2 hours after the last dose or reaction.

Food allergen challenges are standard of care in managing food allergy and appear in worldwide practice guidelines. They attract codes for provision of the service in many countries including the US and UK.

Food allergen challenges are primarily used to determine if a:

- child has outgrown an existing confirmed food allergy.
- suspected food allergy is an actual allergy (when clinical history or allergy tests are unclear).
- child with confirmed food allergens can safely eat alternative but related foods (such as other types of nuts).

6. (a) Is this a request for MBS funding? Yes

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether? New MBS item

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service.

Not applicable

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

Not applicable

- An amendment to the way the service is clinically delivered under the existing item(s)
- An amendment to the patient population under the existing item(s)
- An amendment to the schedule fee of the existing item(s)
- An amendment to the time and complexity of an existing item(s)
- Access to an existing item(s) by a different health practitioner group

- vi. Minor amendments to the item descriptor that does not affect how the service is delivered
- vii. An amendment to an existing specific single consultation item
- viii. An amendment to an existing global consultation item(s)
- ix. Other (please describe below):

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

- i. **A new item which also seeks to allow access to the MBS for a specific health practitioner group**
- ii. A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
- iii. A new item for a specific single consultation item
- iv. A new item for a global consultation item(s)

(f) Is the proposed service seeking public funding other than the MBS? No

(g) If yes, please advise. Not applicable

7. What is the type of service:

- Therapeutic medical service
- Investigative medical service**
- Single consultation medical service
- Global consultation medical service
- Allied health service
- Co-dependent technology
- Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):

- i. To be used as a screening tool in asymptomatic populations
- ii. **Assists in establishing a diagnosis in symptomatic patients**
- iii. Provides information about prognosis
- iv. Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- v. **Monitors a patient over time to assess treatment response and guide subsequent treatment decisions**

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

- Pharmaceutical / Biological
- Prosthesis or device
- No**

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

- Yes
- No**

(b) If yes, please list the relevant PBS item code(s):

Not Applicable

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

- Yes (please provide PBAC submission item number below)
- No**

Insert PBAC submission item number here

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical? Not applicable

Trade name: Insert trade name here

Generic name: Insert generic name here

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Protheses List?

No

(b) **If yes, please provide the following information (where relevant)** Not applicable

Billing code(s): Insert billing code(s) here

Trade name of prostheses: Insert trade name here

Clinical name of prostheses: Insert clinical name here

Other device components delivered as part of the service: Insert description of device components here

(c) **If no, is an application in the process of being considered by a Clinical Advisory Group or the Protheses List Advisory Committee (PLAC)?**

No

(d) **Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?**

No

(e) **If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s).**

Not applicable

Insert sponsor and/or manufacturer name(s) here

(f) **Please identify any single and / or multi-use consumables delivered as part of the service?**

Not applicable

Single use consumables: Insert description of single use consumables here

Multi-use consumables: Insert description of multi use consumables here

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

This section is not applicable to this application

12. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

Type of therapeutic good: Insert description of single use consumables here

Manufacturer's name: Insert description of single use consumables here

Sponsor's name: Insert description of single use consumables here

- (b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

- Class III
 AIMD
 N/A

13. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

- Yes (If yes, please provide supporting documentation as an attachment to this application form)
 No

- (b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

- Yes (if yes, please provide details below)
 No

ARTG listing, registration or inclusion number: Insert ARTG number here

TGA approved indication(s), if applicable: Insert approved indication(s) here

TGA approved purpose(s), if applicable: Insert approved purpose(s) here

14. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

- Yes (please provide details below)
 No

Date of submission to TGA: Insert date of submission here

Estimated date by which TGA approval can be expected: Insert estimated date here

TGA Application ID: Insert TGA Application ID here

TGA approved indication(s), if applicable: If applicable, insert description of TGA approved indication(s) here

TGA approved purpose(s), if applicable: If applicable, insert description of TGA approved purpose(s) here

15. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

- Yes (please provide details below)
 No

Estimated date of submission to TGA: Insert date of submission here

Proposed indication(s), if applicable: If applicable, insert description of proposed indication(s)

Proposed purpose(s), if applicable: If applicable, insert description of proposed purpose(s) here

PART 4 – SUMMARY OF EVIDENCE

16. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1.	International consensus document	ICON: food allergy	Within the framework of the International Collaboration in Asthma, Allergy and Immunology, a series of consensus documents called International Consensus ON (ICON) are being developed to serve as an important resource and support physicians in managing different allergic diseases.	J Allergy Clin Immunol (JACI) 2012 Apr;129(4):906-20. doi: 10.1016/j.jaci.2012.02.001. https://www.jacionline.org/article/S0091-6749(12)00254-0/fulltext	2012
2.	Guidelines	Guidelines for the diagnosis and management of food allergy in the United States: Report of the National Institute of Allergy and Infectious Diseases (NIAID) Sponsored Expert Panel	These Guidelines provide clinical recommendations and additional guidance on points of current controversy in the management of patients with food allergy.	J Allergy Clin Immunol (JACI) 2010; 126 (suppl): S1-58. https://www.jacionline.org/article/S0091-6749(10)01566-6/pdf	2010
3.	Manual (DBPCFC)	Double blind placebo controlled food challenge (DBPCFC) as an office procedure: a manual	This manual discusses the practical methods required for the allergist to undertake DBPCFC in routine practice.	J Allergy Clin Immunol (JACI) 1988; 82:986-7 https://www.jacionline.org/article/0091-6749(88)90135-2/pdf	1988

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication ***
4.	International Position Paper	Standardisation of food challenges in patients with immediate reactions to foods-position paper from the European Academy of Allergology and Clinical Immunology (EAACI)	This Position Paper provides advice on how standardised food challenges can be performed in patients with immediate allergic reactions to foods.	Allergy 2004; 59:690-7 https://onlinelibrary.wiley.com/doi/full/10.1111/j.1398-9995.2004.00466.x	2004
5.	International consensus report (DBPCFC)	Standardizing double-blind, placebo-controlled oral food challenges (DBPCFC) American Academy of Allergy, Asthma & Immunology (AAAA) and European Academy of Allergy and Clinical Immunology (EAACI) PRACTALL consensus report	This PRACTALL (Practical Allergy) consensus document on the conduct and interpretation of the DBPCFC was developed by food allergy experts from AAAAI and EAACI.	J Allergy Clin Immunol (JACI) 2012; 130;6 https://www.jacionline.org/article/S0091-6749(12)01663-6/pdf	2012
6.	Expert review	Diagnosis of food allergy in children: toward a standardisation of food challenge	This review presents the current status of the indication and performance of controlled oral food challenges in children with suspected food-related symptoms. It includes indications, contraindications, blinding, diet pre-challenge, practical performance, medication, interpretation of test results, suitable testing locations, safety considerations and procedures after a period of avoidance.	J Paed Gastroent Nutrition 2007; 45:399-404 https://journals.lww.com/jpgn/Fulltext/2007/10000/Diagnosis_of_Food_Allergy_in_Children_Toward_a.2.aspx	2007

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
7.	Working group report	Work group report: oral food challenge (OFC)	This article provides a practical and comprehensive guide to aid allergists/immunologists, who are uniquely qualified to perform diagnostic OFCs, in the use of the procedure for patient care in a scientifically sound, safe, and practical manner. It describes approaches used in the US and incorporates critically reviewed published international experience.	J Allergy Clin Immunol (JACI) 2009; 123(suppl): S365-83 https://www.jacionline.org/article/S0091-6749(09)00562-4/fulltext	2009
8.	Insert study design	Insert title	Insert description	Insert website link	Insert date

* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

**Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.

*** If the publication is a follow-up to an initial publication, please advise.

17. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

Not Applicable

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.	For yet to be published research that may have results relevant to your application, insert the type of study design in this column and columns below	For yet to be published research that may have results relevant to your application, insert the title of research (including any trial identifier if relevant) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a short description of research (max 50 words) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a website link to this research (if available) in this column and columns below	For yet to be published research that may have results relevant to your application, insert date in this column and columns below
2.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

**Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.

***Date of when results will be made available (to the best of your knowledge).

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

- 18. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

Australasian Society of Clinical Immunology and Allergy www.allergy.org.au

National Allergy Strategy <https://nationalallergystrategy.org.au/>

- 19. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

Not applicable

- 20. List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

Allergy & Anaphylaxis Australia www.allergyfacts.org.au

- 21. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

Not applicable

- 22. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

Name of expert 1: Professor Dianne Campbell

Telephone number(s): 0402 241 574

Email address: campbell@med.usyd.edu.au

Justification of expertise: Lead author of ASCIA Food Allergen Challenge Protocols and ASCIA Food Allergen Challenge Register, past Chair, ASCIA Paediatric committee, Chief investigator Centre for Food & Allergy Research (CFAR).

Name of expert 2: Dr Preeti Joshi

Telephone number(s): 0417 604 226

Email address: preeti.joshi@health.nsw.gov.au

Justification of expertise: Chair, ASCIA Paediatric committee, National Allergy Strategy project lead and Chair, Allergy & Anaphylaxis Australia Medical Advisory Board.

Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

23. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:

Allergic diseases are amongst the fastest growing chronic disease and public health issues in Australia. They include food, insect and drug allergies (which can lead to potentially life threatening severe allergic reactions called anaphylaxis), asthma, allergic rhinitis (hay fever) and eczema. Allergic diseases, particularly food allergy are increasing in prevalence, complexity and severity.

These issues are highlighted by the following facts:

- Almost 20% of the Australian population has a confirmed allergic disease and this prevalence is increasing.
- Hospital admissions for anaphylaxis have increased 5-fold in the last 20 years.
- Hospital admissions for food allergy induced anaphylaxis have increased 4-fold in the last 14 years.
- Recent studies show that 10% of infants have an immediate food allergy.
- Access to appropriate and timely medical care for allergic diseases is difficult, even in metropolitan areas, and particularly in rural and remote areas. This is due to the high number of patients and the relatively low number of appropriately trained healthcare professionals, resulting in long waiting times to see a specialist and to have food allergen challenges.

We currently have an incomplete understanding of why allergy, especially food allergy, has increased so rapidly in recent years, particularly in young children. It appears to be a complex interplay between a western lifestyle, environment and a genetic predisposition with no single trigger factor identified. However, the following risk factors are starting to emerge from epidemiological and controlled studies:

- Development of food allergy due to skin exposure to allergens (e.g. use of nut oil-based moisturisers in infants with eczema).
- Filaggrin loss of function gene mutations has been identified as a major risk factor for eczema (atopic dermatitis).
- Delayed introduction of allergenic foods (e.g. egg and peanut).

In people with allergies, Immunoglobulin E (IgE) antibodies to allergens are usually raised. This is why ‘true’ allergies (which can result in anaphylaxis) are called IgE mediated allergies. Whilst skin prick tests (SPT) and blood tests for allergen specific IgE can help to confirm or exclude potential triggers, food allergen challenges are required to identify the cause in some cases, particularly in young children.

One of the main purposes of food allergen challenges is to ‘de-label’ patients who no longer have a food allergy. This has significant cost saving, quality of life and developmental implications. For example, a ‘negative’ food allergen challenge can result in:

- Patients no longer needing to carry an adrenaline (epinephrine) autoinjector (e.g. EpiPen). This has significant cost savings, particularly when food allergen challenges are performed in children prior to starting school, thus avoiding years of prescriptions and associated health care visits.
- Improved quality of life for patients and their families.
- Patients no longer having to restrict foods. Food restriction has significant developmental and growth implications, particularly in children.

After a ‘negative’ food allergen challenge the challenge food/s needs to be regularly included in the diet. It is recommended that the food is eaten at least once a week. The reason for this is because some people who do not eat the food for long periods may become sensitised once more and have allergic reactions again. It is therefore very important to confirm food allergy in cases of suspected unproven food allergy, where history of exposure is unknown, or tests and history are equivocal.

The value in confirming a suspected food allergy is for education around avoidance and preparedness for severe allergic reactions. The unpredictability of severe reactions over time means that all children with a diagnosed food allergy (and their family and school) need to be prepared to treat anaphylaxis. Timely treatment of anaphylaxis is a factor in positive outcome and will substantially reduce the risk of fatality.

24. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

Food allergen challenges are mainly used in patients who have had previous allergic reactions to food/s and/or previous positive allergy tests to food/s.

Food allergen challenges are used to determine if a:

- Patient has outgrown an existing food allergy.
- Suspected food allergy is an actual allergy, when the history or allergy tests are unclear.
- Patient with confirmed food allergens can safely eat alternative foods.
- Positive food allergy test is associated with an actual food allergy, in a person who has never before reacted to that food.

25. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

Criteria for challenges which require medical supervision are outlined below. In general food challenges are currently conducted in the clinic setting where there is a risk of anaphylaxis or significant allergic reaction which may require resuscitation. Where the likelihood of a reaction is considered very high, based upon the clinical history and complementary allergy testing (usually above the 95% likelihood), a food challenge is deemed unnecessary, and the child is considered to be food allergic. Likewise, irrespective of the likelihood of reactions, where a family do not consent to include the food regularly in the diet, a food challenge is usually not conducted.

Criteria used to determine which patients require medically supervised food allergen challenges with medium-high risk/probability of allergy include:

- Skin prick test (SPT) result equal to or > 4mm.
- Children with history of food allergy to the proposed challenge food.
- All suspected baked milk challenges where milk allergy has been demonstrated.
- All wheat challenges.

Criteria which would indicate a very high likelihood of allergic reaction at food challenge- therefore food challenge not required :

- Egg, cow's milk or peanut if SPT result >95% PPV unless valid clinical reason.
- Peanut - AraH2 levels > 1.0 KUa/L if SPT > 6mm.

PART 6b – INFORMATION ABOUT THE INTERVENTION

26. Describe the key components and clinical steps involved in delivering the proposed medical service:

Food allergen challenges are procedures where small and incremental amounts of a particular food are fed to a patient while under medical supervision. The patient is monitored to determine if the food being tested causes an allergic reaction in the patient.

Food allergen challenge protocols have been developed by ASCIA and are available on the members' section of the ASCIA website. These protocols have been in routine use throughout Australia for many years, and are similar to protocols used worldwide for food challenges.

The first doses of a food challenge typically start at 1-10mg of food protein, and then increase in semi-logarithmic doses at 20 minute intervals. Where symptoms appear, consistent with allergy, the food challenge is stopped and treatment for the allergic reaction is provided by the nursing and medical staff supervising the food challenge. For most foods, a total cumulative dose of approximately 4-6 grams of food protein is considered sufficient to rule out a food allergy to that specific food.

Most challenges involve a time period of 2 to 3 hours to eat the required doses of food, followed by at least 2 hours of observation. This may change where severe allergic reactions during the food challenge occur, and longer periods of observation can be required.

If the food allergen challenge is completed without an allergic reaction, it is '**negative**'. If an allergic reaction occurs, the challenge is '**positive**' and the diagnosis of a food allergy is confirmed.

Each current ASCIA food challenge protocol used in clinical practice includes the following disclaimer:

Precautions:

- Food challenges should only be undertaken for patients who have been carefully selected by clinical immunology/allergy specialists or appropriately qualified and experienced medical practitioners in consultation with clinical immunology/allergy specialists.
- Food challenges may provoke an allergic reaction in sensitised individuals and should therefore only be performed under medical supervision with immediate access to emergency treatment for anaphylaxis.
- ASCIA takes no responsibility for any adverse outcomes that may occur using these protocols.

27. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

No, however the protocols are only available on the ASCIA members section of the ASCIA website to ensure that they are used by medical practitioners with training and experience in managing patients with allergic diseases.

28. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

Not applicable

29. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

The patient being challenged must be well on the day of the challenge with no fever.
If asthma is present, it must be stable with no recent wheezing.

30. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:

- If an allergic reaction occurs during the challenge it will be treated with medications (including adrenaline autoinjectors), and any other medical measures as needed.

- It is also necessary for the patient to stay under medical supervision for a period of time after the challenge.
- If the patient being challenged has a prescribed adrenaline autoinjector this should be brought to the food allergen challenge. If a severe allergic reaction occurs, it may be an opportunity for the person (if old enough and well enough), or parent to administer the adrenaline autoinjector in a controlled setting.
- Staff will always have a supply of adrenaline available even if the patient has their own adrenaline autoinjector with them.

31. If applicable, advise which health professionals will primarily deliver the proposed service:

Food allergen challenges should **only** be performed:

- **In carefully selected patients** by clinical immunology/allergy specialists or appropriately qualified and experienced medical practitioners, in consultation with clinical immunology/allergy specialists.
- **Under medical supervision** with immediate access to emergency treatment for a severe allergic reaction (anaphylaxis).

32. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

Food allergen challenges are performed in a controlled medical environment with medical and nursing staff experienced in treating anaphylaxis.

Whilst experience nursing staff are usually involved, the food allergen challenges must be supervised by clinical immunology/allergy specialists or appropriately qualified and experienced medical practitioners, in consultation with clinical immunology/allergy specialists.

33. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

Food allergen challenges are performed in a controlled medical environment with medical and nursing staff experienced in treating anaphylaxis. The way an allergic reaction is managed in a hospital may vary slightly from the instructions on the ASCIA Action Plan for Anaphylaxis. This is because hospital staff have ready access to blood pressure and oxygen checks, oxygen masks and other equipment.

Challenges are generally performed in a food challenge clinic with several people having challenges to different foods in the clinic on the same day. Medical and nursing staff in these clinics are trained to prevent cross contamination of foods they are challenging separate patients with.

34. If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery:

Clinical immunology/allergy specialists are registered medical practitioners with Fellowship of the Royal Australasian College of Physicians (FRACP) which includes advanced training in allergy and clinical immunology. These medical specialists are usually Full (Ordinary) members of ASCIA.

35. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings):

- Inpatient private hospital
- Inpatient public hospital
- Outpatient clinic
- Emergency Department
- Consulting rooms
- Day surgery centre
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

Specify further details here

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

Clinical immunology/allergy specialists work in public and private hospital clinics as well as private consulting rooms. Food challenges are currently routinely conducted in all of these settings by clinical immunology/allergy specialists.

36. Is the proposed medical service intended to be entirely rendered in Australia?

Yes

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

37. 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 (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

There is no comparator for a food challenge, which is considered the gold standard for the diagnosis of food allergy. The food challenge is currently conducted across Australia within public and private settings without attracting an item number. Inability to bill for this service in the private sector limits the availability of this service outside of public hospitals. Within the private sector, families pay the full cost of the service with no rebate.

Allergy testing either by allergy skin prick tests (SPT) or blood tests for allergen specific IgE cannot substitute for the food challenge, but can be used in conjunction with the clinical history to understand the pre test probability of being allergic. Neither SPT nor serum allergen IgE is sensitive or specific enough to substitute for a food challenge in instances where the positive predictive value of being allergic is assessed at being <95% by either test.

A “positive” food allergy test using skin prick tests (SPT) or blood tests for allergen specific IgE means that a patient’s immune system has produced an antibody response to that food. This is known as being sensitised to an allergen. Positive allergy tests do not correlate well with true clinically reactivity, and false positives frequently occur, which means that the test is positive yet the person can eat the food without any symptoms. Likewise, there can sometimes be false negative allergy testing, although that is less common with most food allergens than false positive allergy skin or serum testing. 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.

For this reason, it can be important in some circumstances to confirm the significance of a positive (or negative) allergy test with a food allergen challenge, to prevent unnecessary avoidance of food and unnecessary prescription of adrenaline autoinjectors.

Therefore, food allergy testing using skin prick tests (SPT) or blood tests for allergen specific IgE are not considered as comparators.

38. Does the medical service that has been nominated as the comparator have an existing MBS item number(s)?

Yes (please provide all relevant MBS item numbers below)

No

Specify item number/s here

39. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources):

There is no flowchart attached to this application as there is no comparator.

One of the main purposes of food allergen challenges is to ‘de-label’ patients who no longer have a food allergy, because they have outgrown their allergy by natural tolerance acquisition. This has significant cost, quality of life and developmental implications. For example, a ‘negative’ food allergen challenge can result in:

- Patients no longer needing to carry an adrenaline (epinephrine) autoinjector (e.g. EpiPen). This has significant cost saving implications, particularly when food allergen challenges are performed in children prior to starting school, thus avoiding years of prescriptions and associated health care visits.

- Improved quality of life for patients and their families.
- Patients no longer having to restrict foods. Food restriction has significant developmental and growth implications, particularly in children.

After a 'negative' food allergen challenge the challenge food/s needs to be regularly included in the diet. It is recommended that the food is eaten at least once a week. This is very important as some people who do not eat the food for long periods may become sensitised once more and have allergic reactions again.

A 'positive' food allergen challenge result is also very useful, as it confirms a food allergy, and enables appropriate avoidance measures to be taken, to minimise the risk of allergic reactions, including anaphylaxis.

40. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)? Not applicable

- Yes
 No

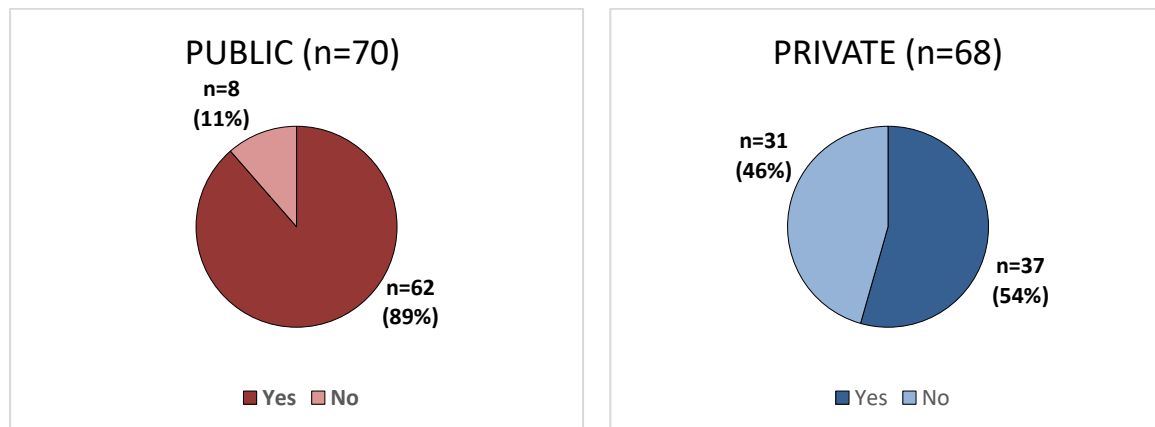
(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted:

Outline service/comparator substitution here

41. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline):

The prevalence of food allergy and waiting times to see clinical immunology/allergy specialists (particularly in public hospital allergy clinics) are both continuing to increase. The introduction of an MBS item number for food allergen challenges for use in private and hospital clinics would greatly assist in reducing specialist appointment waiting times. The MBS Item number would allow more timely access to food allergen challenges, which are currently the gold standard tests for diagnosing food allergy.

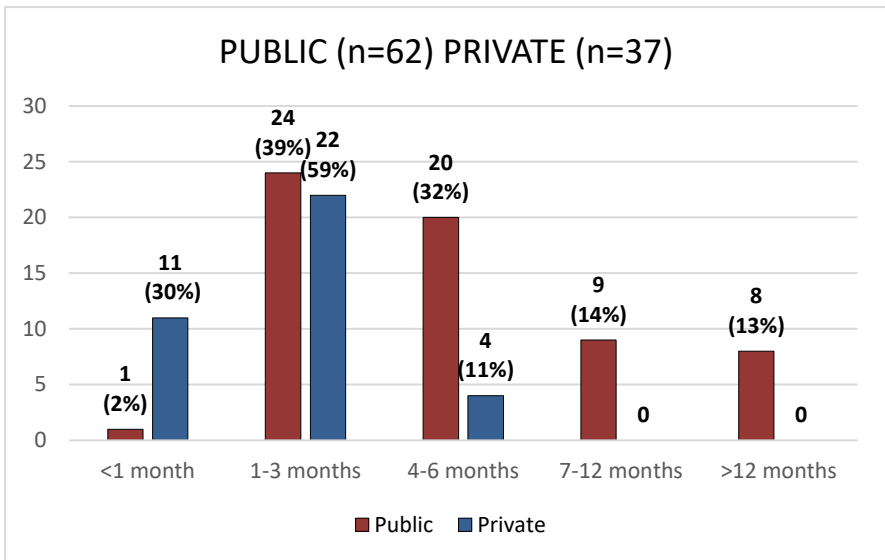
The Australasian Society of Clinical Immunology and Allergy (ASCIA) conducted a workforce survey of Full (Ordinary) members in 2018-2019. A total of 99 clinical immunology/allergy specialists who are Full (Ordinary) ASCIA members completed the survey. The following graphs show data from these responses.



Question: Does your allergy service perform medically supervised food allergen challenges?

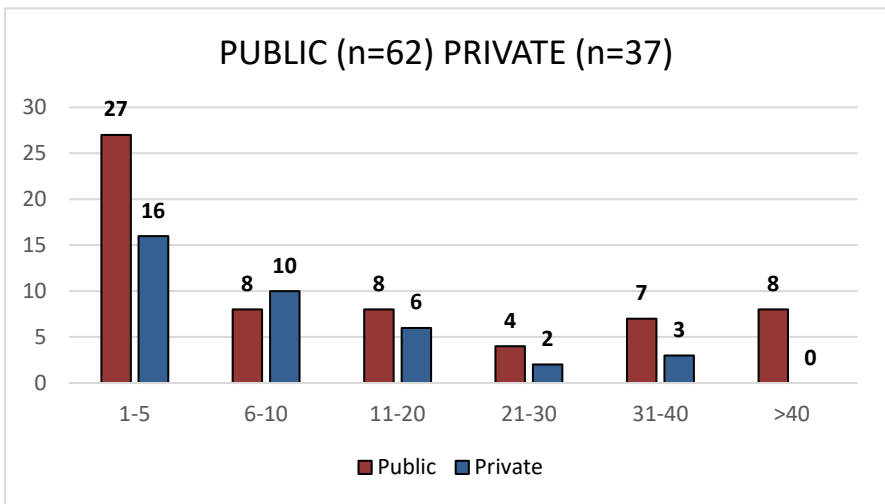
The responses showed that 89% of public allergy clinics conduct food allergen challenges, compared to only 54% of private allergy clinics. This reflects the following:

- Without an item number for food allergen challenges, it is not always feasible to perform food allergen challenges in private clinics.
- Currently private clinics running food allergen challenges often perform these at a loss, due to the absence of a specific item number to rebate the procedure. This is also reflected in the long wait times for food allergen challenges in hospital clinics as shown below.



Question: What is the average wait time (after initial clinic consultation) for a food allergen challenge?

Responses showed that the wait time for food allergen challenges exceeds 4 months in the majority (70%) of cases, and more than 7 months in 27% of cases. Please note that the numbers in this figure are responses to the question, and do not reflect the number of food challenges completed.



Question: On average, how many patients undergo food allergen challenges per month in your service/practice?

The responses in this graph showed that most patients undergo food allergen challenges in public allergy clinics. This is most probably due to the absence of an item number, which makes it less feasible to perform food allergen challenges in private clinics.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

This section is not applicable to this application.

42. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

Summarise clinical claims here

43. Please advise if the overall clinical claim is for:

- Superiority
- Non-inferiority

44. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety Outcomes: List safety outcomes here

Clinical Effectiveness Outcomes: List clinical effectiveness outcomes here

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

From data collected by ASCIA we estimate the maximum total number of annual food allergen challenges conducted across Australia is 9,460 which includes lower probability of allergy challenges, which are not part of the proposed eligibility criteria in this submission. We estimate that one third of these (3,153) will be medium/high probability challenges in children aged five years or less, which is the population of interest and eligibility in this application.

46. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

Most patients will only require one food allergen challenge for a food, but some may require multiple challenges for different foods.

47. How many years would the proposed medical service(s) be required for the patient?

Most patients will only require one food allergen challenge per food. Some patients who have a positive challenge, and are confirmed to be allergic to that may require a future challenge if there is future evidence that tolerance has likely occurred. In that setting the repeat food allergen challenge is likely to be several years or more after the initial challenge.

48. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year: 3,153 (one third of the total of 9,460), being high risk patients, aged five years or less.

49. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

It is estimated that up to 28,380 food allergen challenges would be performed over the next three years. However, it is estimated that of these, one third (9,460) would be food allergen challenges (medically supervised) provided by a specialist (clinical immunology/allergy) for children aged five years or less, including those that require a challenge before they commence school.

PART 8 – COST INFORMATION

50. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

\$1,100: This is based on each challenge (with adequate documentation for at least 4 hours) generating 0.2407 per Weighted Inlier Equivalent Separation (WIES).

\$550: The proposed fee in this application is 50% of the WIES value and should cover some basic costs.

51. Specify how long the proposed medical service typically takes to perform:

The food challenge takes 2-3 hours, and is followed by 2 hours of observation after the challenge or reaction.

52. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Category (insert proposed category number here) – (insert proposed category description here)

Proposed item descriptor: Food allergen challenge (medium/high risk), for children aged five years or less and supervised by a clinical immunology/allergy specialist.

The patient must be being assessed for likely IgE mediated food allergy on the basis of a past history of clinical reaction and sensitisation (either by documented positive results from skin tests or blood tests for allergen specific IgE), and the need to carry an adrenaline (epinephrine) autoinjector.

Fee: \$550 (50% of the WIES value of \$1,100)

This application is for a restricted item number, compared to the previous application that did not specify criteria for a requirement for a medically supervised challenge and did not limit the population to “children aged five years or less”. The previous application included Food Protein Induced Enterocolitis Syndrome (FPIES) and applied to general paediatricians with postgraduate qualification/experience in allergy.

ASCIA requests that this restricted item number is introduced on a trial basis for twelve months, with the following outcomes measured and data reported back to the relevant government departments:

- ‘De-labelling’ of children who no longer have a food allergy, which has significant cost saving, quality of life and developmental implications. For example, children no longer needing to carry an adrenaline autoinjector (e.g. EpiPen) has significant cost savings, particularly when food allergen challenges are performed in children prior to starting school, thus avoiding years of prescriptions and associated health care visits. This includes annual reviews by a clinical immunology/allergy specialist.
- Improved quality of life for children and their families, with children who have “negative” results no longer having to restrict foods. Food restriction has significant developmental and growth implications, particularly in children.
- Confirming the diagnosis of food allergy provides opportunities for reduced morbidity and mortality from accidental exposures, as education and retraining on emergency treatment of anaphylaxis can be undertaken once the diagnosis is confirmed.

PART 9 – FEEDBACK

The Department is interested in your feedback.

53. How long did it take to complete the Application Form?

Several days over a period of 2 years

54. (a) Was the Application Form clear and easy to complete?

Yes except for the table format of part 4

No

(b) If no, provide areas of concern:

Describe areas of concern here

55. (a) Are the associated Guidelines to the Application Form useful?

Yes

No

(b) If no, what areas did you find not to be useful?

Insert feedback here

56. (a) Is there any information that the Department should consider in the future relating to the questions within the Application Form that is not contained in the Application Form?

Yes

No

(b) If yes, please advise:

Insert feedback here