Draft Protocol

for

Epicutaneous patch testing for investigation of allergic dermatitis – Revision of MBS items (12012-12021)

Medical Services Advisory Committee

Application 1390

October 2014

1) Title of Application

Epicutaneous patch testing for investigation of allergic dermatitis – Revision of MBS items (12012-12021).

2) Purpose of application

An application for a review of Medicare funded patch testing items was received in April 2014 from the Australasian College of Dermatologists. The purpose of the application is to amend both the structure and fees of the existing MBS items to better reflect current clinical practice including the time and cost of providing the service. Patch testing currently attracts Medicare rebates through four items (12012 through to 12021).

Epicutaneous patch testing is an established tool to diagnose allergic contact dermatitis. First introduced in the late 19th century, it involves exposing patients, who have a clinical history consistent with contact dermatitis, to likely allergens in order to reproduce their skin reaction in a standardised testing procedure. Patch testing differs from skin sensitivity testing (MBS items 12000/12003), which is used to evaluate immediate hypersensitivity reactions, most commonly used in the investigation of patients with asthma, hay fever and food allergies by allergists.

This document has been put together by the Department of Health on behalf of the applicant.

3) Population targeted by patch testing - allergic contact dermatitis

The target population for patch testing is allergic contact dermatitis which is an itchy skin condition caused by a delayed immune reaction (type IV hypersensitivity) to skin exposure to allergen/s. It begins hours to days after exposure manifesting as an itchy, red and uncomfortable skin rash. A severe reaction causes blistering and skin swelling requiring hospitalisation. With removal of the allergen/s, identified by patch testing, and appropriate medical treatment, it usually settle down over weeks. If the allergen/s go unrecognized, the condition can persist with spreading to other parts of the body. In 10-15% of occupational cases, the condition can persist indefinitely without allergen exposure. The reason for this is unknown and is extremely disabling and severely impacts on quality of life. Diagnosis can be a challenge as there is a delay between allergen exposure and the development of dermatitis. It is necessary for the expert in contact dermatitis with a thorough knowledge of the many sources of allergens (workplace, recreational and domestic) to perform testing to isolate the responsible allergens.

According to the applicant, allergic contact dermatitis represents a subset of 4-16% of patients suffering from eczematous skin conditions. The terms eczema and dermatitis are often used synonymously but are most easily thought of as either coming from outside, from exogenous skin contact with allergens such as allergic contact dermatitis (and also irritant contact dermatitis) or various forms of endogenous eczema coming from an inherited predisposition, such as atopic eczema. Irritant contact dermatitis is an important diagnosis for which there is no test available, and it relies on the exclusion of allergic contact dermatitis. Many patients have a combination of diagnoses, whereby multiple factors contribute to their complex skin condition. Often patients with

eczematous rashes are treated, and referred for patch testing only when their condition fails to respond to treatment, suggesting ongoing exposure to allergens. However, there are some occupational groups and clinical scenarios where allergic contact dermatitis is highly likely: these include hairdressers and those working with epoxy resins.

Generally, the patient populations thought to be at appreciable risk of allergic contact dermatitis and thus benefit most from patch testing include those with:

a. Regional dermatitis: hand, face, eyelid, truncal, anogenital, flexural, airborne exposure sites, sun exposed sites, feet.
b. Occupational dermatitis, improving during time off work
c. Unexplained flare of atopic dermatitis
d. Drug allergy eg fixed drug eruption
e. Noneczematous dermatitis eg erythema multiforme
f. Systemic contact dermatitis with ingestion of allergen producing widespread dermatitis
g. Dermatitis related to medicaments, including medical aids eg tape, antiseptics, stoma reactions, local anaesthetics
h. Leg ulcer patients
i. Exposure to plants
j. Exposure to sunscreens requiring photopatch testing (where the allergens are often photo allergens and need exposure to UV light prior to reaction)
k. Healthcare workers especially with hand dermatitis
l. Patients requiring joint replacement or post joint replacement reactions
m. Oral mucosal dermatitis/lichen planus
n. Those with unresolving dermatitis despite adequate treatment

4) Process of patch testing

After allergen selection has been finalised; pre-prepared allergens are loaded on to small discs attached to hypoallergenic tape in a systematic pattern allowing for easy and reliable identification when the patches are removed. These are usually attached to the patients back and left on for 48 hours. A map of where the allergens were placed is constructed for future reference in the patient's file. At 48 hours the discs are removed and reactions are recorded and graded. A second reading is done from one to five days later.

When a person is sensitized to a test substance, an inflammatory reaction will develop in the exposed area. The intensity of the reaction is scored and recorded according to the rules of the International Contact Dermatitis Research Group (ICDRG) which has laid down the standardization of gradings, methods and nomenclature for patch testing. The reading and interpretation of patch results requires training and some experience. In doubtful cases, verification of the tests in a reference centre may be necessary.

A positive result of a patch test may not always be equivalent with the diagnosis of allergic contact dermatitis. Some persons with positive patch test result will never experience any clinical symptoms after exposure. Therefore, the clinical relevance of positive patch test should be considered in each case.

5) Clinical place of patch testing and choosing the optimal number of allergens

The number of patches and the allergens selected for testing is generally determined based on the patient's age, history, environment and living conditions (eg, region of the country), occupation, and activities. An important concept in patch testing is testing all patients with the 'standard' series of allergens, which is now called 'baseline' series. This series includes all the important allergens in a particular population, as there are regional differences in allergen prevalence. For example, tea tree oil allergy is relatively common in Australia. A number of different countries have developed their own series of allergens used for patch testing. The number of allergens in these series has varied between 30 (European Contact Dermatitis Research Group) and 80 (Mayo Clinic Contact Dermatitis Research Group series). Associate Professor Nixon, Dr Mei Tam and colleagues in Melbourne have recently reviewed the patch test results of over 5000 patients tested at the Skin and Cancer Foundation in Melbourne and used this data to construct the first Australian Baseline Series of 60 allergens. This paper has recently been accepted for publication in the Australasian Journal of Dermatology and is attached to the application. In selecting the 60 allergens, a balance is found between testing the most important allergens in the population, as well as not testing to many allergens, causing additional expense in both the cost of the allergens and the time spent in preparing the tests.

According to the applicant, the optimal number for allergens in Australia most experts would now agree on is the Australian baseline series of 60 allergens. The Australian Baseline Series is now done by some dermatologists in private practice particularly in rural and regional areas where referrals to a tertiary referral centre in the city would require three visits in a week and be very disruptive. That said, in private practice this can be time consuming for many dermatology practices to perform, particularly those outside of tertiary referral centres and for those who do not employ a practice nurse, so testing a smaller numbers of allergens with a convenient pre-packaged kit will pick up many common contact allergies. These are particularly useful where a specific contact allergen is strongly suspected on clinical grounds and the commercialized patch tests most commonly used in this scenario are the T.R.U.E ^{TM} test and SmartPractice^{TM} test which contains 24-36 allergens. Although these pre-packaged panels are convenient to apply, they can be expensive so some practitioners opt to only use the first two panels of 24 allergens (the cost of which is around $40) which provide a very basic screen of only the most common allergens. These are claimed under item 12012 (< 26 allergens). If the results of the prepackaged panels are negative, but allergic contact dermatitis is strongly suspected on clinical grounds, then more extensive testing is indicated at a tertiary referral centre.

For complicated cases (for example occupational exposure) it is then best to send the patient to a tertiary referral centre from the outset so that all the suspected allergens can be tested at once given the testing can be time consuming for the patient in question. Patients are referred predominantly by dermatologists who either do not have expertise in contact dermatitis nor the

facilities and allergens to perform comprehensive patch testing. At tertiary referral centres, patients are routinely tested with the Australian Baseline Series (60 allergens) and where relevant 'additional series' relating to their history of exposure, such as the Cosmetics, Hairdressing and Rubber series. Further some patients may be asked to bring their own samples so they are tested with the actual substances suspected of causing their dermatitis, such as moisturizing creams, fragrances, sunscreens, wet wipes, plants, gloves and work chemicals. These substances will need to be prepared prior to testing, often requiring dilution.

6) Current MBS items for patch testing (the 'comparator')

The current descriptors for items 12012 through to 12021 have been the same since 1st November 1995 (Table 1). These items are located in Category 2 (Diagnostic procedures) of the General Services Medical Table (GMST). For the purpose of this document, the current structure of items will serve as a comparator against the proposed structure for these items outlined later.

Table 1: Current MBS items for patch testing

		Schedule Fee (as of May 2014)	75% Benefit	85% Benefit	Notes
12012	EPICUTANEOUS PATCH TESTING in the investigation of allergic dermatitis using less than the number of allergens included in a standard patch test battery (see D1.16)	$ 20.80	$ 15.60	$ 17.70	< 26 allergens
12015	EPICUTANEOUS PATCH TESTING in the investigation of allergic dermatitis using all of the allergens in a standard patch test battery (see D1.16)	$62.45	$46.85	$53.10	Standard patch test battery of 26 allergens
12018	EPICUTANEOUS PATCH TESTING in the investigation of allergic dermatitis using all of the allergens in a standard patch test battery and additional allergens to a total of up to and including 50 allergens (see D1.16)	$80.35	$60.30	$68.30	<50 allergens
12021	EPICUTANEOUS PATCH TESTING in the investigation of allergic dermatitis, performed by or on behalf of a specialist in the practice of his and her speciality, using more than 50 allergens	$117.85	$88.40	$100.20	More than 50 allergens

Explanatory note D1.16 A standard epicutaneous patch test battery refers to the European Standard Series or the International Contact Research Group Standard Series

Table 2 outlines the 5 years of utilization for items 12012 through to 12021 with MBS items 12000/12003 for skin prick testing as a reference. Compared to items 12000/12003 for skin sensitivity testing, which both exceed 50,000 per year, annual utilization of the patch testing items is relatively modest. Utilization of 12012 has been steady since the 2008/2009 financial year (approx. 250/year) while item 12014 has seen an increase from 965 in the 2008/2009 financial year to 1438 in the 2012/2013 financial year. The vast majority of the items for patch testing are performed out of hospital.

Table 2: Utilization of MBS items Subgroup 9 – Allergy testing

MBS Item/Financial Year	Item provided In Hospital	Item not provided in Hospital	Total

Item 12012			
Financial Year 2008/2009	2	285	287
Financial Year 2009/2010	0	230	230
Financial Year 2010/2011	0	226	226
Financial Year 2011/2012	0	218	218
Financial Year 2012/2013	1	250	251
Item 12015			
Financial Year 2008/2009	1	1,182	1,183
Financial Year 2009/2010	7	1,060	1,067
Financial Year 2010/2011	1	1,177	1,178
Financial Year 2011/2012	1	1,271	1,272
Financial Year 2012/2013	0	1,331	1,331
Item 12018			
Financial Year 2008/2009	1	1,056	1,057
Financial Year 2009/2010	2	907	909
Financial Year 2010/2011	0	874	874
Financial Year 2011/2012	2	983	985
Financial Year 2012/2013	1	1,138	1,139
Item 12021			
Financial Year 2008/2009	0	965	965
Financial Year 2009/2010	0	1,055	1,055
Financial Year 2010/2011	0	1,022	1,022
Financial Year 2011/2012	0	1,126	1,126
Financial Year 2012/2013	1	1,437	1,438
Item 12000			
Financial Year 2008/2009	101	50,944	51,045
Financial Year 2009/2010	121	52,233	52,354
Financial Year 2010/2011	190	54,879	55,069
Financial Year 2011/2012	253	58,889	59,142
Financial Year 2012/2013	312	61,139	61,451
Item 12003			
Financial Year 2008/2009	27	58,524	58,551
Financial Year 2009/2010	34	52,977	53,011
Financial Year 2010/2011	22	52,294	52,316
Financial Year 2011/2012	24	53,748	53,772
Financial Year 2012/2013	53	53,711	53,764

Table 3 outlines which categories of medical professional have claimed against items 12012 -12021 in the 2012/13 financial year. About 60% of the utilization for item 12012 was performed by dermatologists while the remaining 40% was a combination of general practitioners and paediatric specialists while for item 12015, 48% of the utilization was conducted by dermatologists and 31% by immunologists. Dermatologists make up the majority of utilisation for items 12018 and 12021 (75% and 99% respectively in 2012/13)

Table 3 Utilisation by category of health professional: MBS items 12012-12021 (2012/13 financial year)

Item 12012	251
Dermatology Specialist	146
Procedural GP - Non-recognised	33
Paediatric Medicine	30
Immunology	17
Fellow of the College of GPs	12
Item 12015	1,331
Dermatology Specialist	577
Immunology	419
Fellow of the College of GPs	99
Procedural GP - Non-recognised	98
Paediatric Medicine	69
Vocationally Registered GP	21
Item 12018	1,139
Dermatology Specialist	860
Paediatric Medicine	130
Immunology	71
Remote OMP	24
Fellow of the College of GPs	20
Geriatrics	10
Item 12021	1,438
Dermatology Specialist	1,423

To adequately patch test, the patients require a minimum of 3 consultations. Patients are generally charged an initial consultation (MBS Item No. 104) plus an item number of the cost and preparation of patch tests depending on the number of allergens (MBS Item No. 12012, 12015, 12018). This consultation takes longer than a standard dermatology consultation because an extensive history of skin exposures is ascertained. Thirty minutes is scheduled.

On day 2, patients are charged a review consultation (MBS Item No.105) in which the patches are removed and the back is marked with a surgical marker to indicate where the patches were. A preliminary assessment is made. If the patient has developed some reactions, additional enquiries may be directed to the workplace or to manufacturers of skin are products. Additional tests may be applied to clarify the positive reactions.

Finally on day 4 patients are charged a review consultation (MBS Item No. 105) in which the final assessment is made. The consultation on day 4 is usually lengthy as it involves making a final diagnosis of the patient's skin condition and explaining this to the patient. Suitable products and adjustments to normal habits (workplace, recreational, domestic) are recommended. Ironically at this point, if it transpires that the patient's condition is work-related, additional time is involved in

explanation, certification and contacting the workplace, yet the patient's fee through Workcover (at least in Victoria) is currently reimbursed at a lesser rate than if it were a private patient.

7) Issues with current MBS items

As alluded to earlier, the Australian Baseline Series (60 allergens) is becoming the mainstay of patch testing in the Australian dermatological practice. The wording of the current MBS items, which has been the same since 1995, refers to the 'standard' patch test battery defined as the European patch series which has 26 allergens (utilised under item 12015). According to the applicant, the terminology 'standard' and 'baseline' are often used interchangeably and the term standard can be confusing in terms of what number of allergens are regarded standard as this differs across countries. Overtime experts are gaining better appreciation of the epidemiological profile of allergens likely to be most relevant to the Australian health care context hence there are periodic adjustments to number and types of allergens that make up baseline testing. To avoid confusion, the applicant is proposing that the MBS items should simply refer to the number of allergens.

Another issue with the current MBS items raised by the applicant is that the items do not accurately reflect the cost of delivering the service. In addition, detailed and comprehensive patch testing is complicated and time consuming. Its supervision and interpretation is highly specialised and thus is largely limited to dermatologists with a special interest in this field. Its execution requires a nurse and access to the materials required for testing which are expensive. For example, almost all of the patients at a tertiary referral centre in Victoria are tested with a minimum of 70 allergens and the majority are tested with 80-140 allergens. The rebate for 12021 (> 50 allergens) remains the same regardless of whether 70-140 allergens are tested. Therefore both considerable time (in test preparation) and costly allergens are expended to test patients appropriately and comprehensively in order to diagnose their skin problem however there is no increase in the rebate as the number of allergens tested increases. In order to cover expenses, the Skin and Cancer Foundation currently charges $300 for item 12021, however this leaves the patient significantly out of pocket and is a significant deterrent to patients considering testing. As a result, many patients are not patch tested causing their skin allergy to remain undiagnosed according to the applicant.

8) Proposed MBS items by applicant (the 'Intervention')

In light of the issues outlined above, the College of Dermatologists has put forward a new proposal to restructure items 12012-12021 including increased fees for some items. This includes the creation of three new items (Greater than 75 allergens, Greater than 100 allergens and Greater than 125 allergens). The main driver for the fee increases is primarily to do with the price of associated consumables but also to better reflect the professional time of preparing and applying the patches. The time taken to interpreting results is separately covered by the attendance items outlined earlier.

There is no proposal to change the type and number of consultation visits that are conducted in conjunction with the patch testing. The College's original proposal is outlined in Table 4 (taken from Appendix I of the application). The application is proposing that reimbursement for testing these

larger numbers of allergens be restricted to specialists, such as dermatologists and allergists. This will limit abuse of these item numbers.

Table 4 – proposed structure of MBS items for epicutaneous patch testing

Item no	no of allergens	1.00 per allergen	$4 per patch	Nurse time $18 per 30 allergens	Nurses time for patches off half	Misc cups gauze tape	total	Current medicare rebate		
	ITEM NO	**NUMBER OF ALLERGENS**	**CONSUMABLES**			**PATCH PREPARATION TIME**	**TOTAL**	**CURRENT MEDICARE REBATE**	**PROPOSED MEDICARE REBATE**	
			ALLERGENS ($0.85 per allergen)	**PATCHES ($4.00 per patch)**	**SUPPLIES**	**$1.00 per allergen**				
12012 <26 (*TRUE TEST)	12021	24	20.4	9.6	2	24	53	20.8	53	154% increase
12015 26 allergens (^European standard series)	12015	26	22.1	10.4	3	26	60.5	62.45	62.45	Status quo
12018 <50 allergens	12018	38	32.3	15.2	4	38	85.5	80.35	85.5	7% increase
60 allergens(#Australian Baseline Series)	new proposed category	60	51	20.4	5	60	136.4	new proposed category	136.4	
<75 allergens (50-74)	12021	62	52.7	24.8	6	62	139.5	117.85	139.5	18% increase
<100 allergens(75-99)	new proposed category	87	73.95	34.8	7	77	194.05	new proposed category	194.05	
<125 allergens (100-124)	new proposed category	112	95.2	44.8	8	112	248	new proposed category	248	
>125 allergens (125-150)	new proposed category	137	116.45	54.8	8	137	291.25	new proposed category	291.25	

*TRUE TEST - commercially available standard/baseline series of 24 allergens
^European Standard series - standard/baseline series of 26 allergens used in Europe
#Australian Baseline series - standard/baseline series of 60 allergens used in Australia

PROCESS OF MAKING UP PATCHES FOR TESTING

The allergens from the baseline series, other additional relevant series and patient's own items (diluted to appropriate concentration) are applied onto patches and then applied to the patient's back and reinforced with adhesive tape.
After 2 days, the patches are removed. A surgical marking pen is used to mark the area where the patches were and a preliminary assessment is made.
After 4-7 days, the final assessment is made.

Allergens:
Ready made commercially available allergens in correct patch test concentration and vehicle (petrolatum, alcohol, water)

Standard/baseline series:
Series of all the important allergens in a particular population as there are regional differences in the prevalence of each allergen causing reactions

Other series:
Additional series of all the allergens relating to the patient's history of exposure from occupational, domestic and recreational sources eg Hairdressing, Printing series; patient's distribution of dermatitis eg Shoe, Oral series.

Own items:
Patient's personal items eg moisturiser, hand wash. To be prepared for testing by appropriate dilution to the correct patch test concentration and in the correct vehicle.

Patch:
Hypoallergenic tape incorporating ready made chambers to which allergens are applied
One patch houses 10 allergens.

Supplies:
Cups to mix up own items in.
Gauze
Tape
Wooden applicator sticks (orange sticks) to mix up own items

It should be noted that the proposal above from the original application specifically requested an item for the Australian baseline series (60 allergens) as well as a separate item for 50-74 allergens even though 60 allergens falls within the range of proposed 50-74 item. The applicant has subsequently informed the Department that it would be reasonable to just list the item number for 50-74 allergens which will incorporate the Australian "Baseline" series of 60 allergens.

As there are relatively few specialized private tertiary referral centres in each state (mostly clinics affiliated with the' Skin and Cancer Foundation'), this change is expected to have a relatively small impact according to the applicant. In NSW there are two clinics operated by the Skin and Cancer Foundation (a main centre at Westmead and a clinic in Darlinghurst), however much centralized patch testing is also performed at dermatology outpatient clinics of public hospitals where Medicare is often not billed.

In NSW, the main centre for Skin and Cancer Foundation is at Westmead where for the last year:

- 54 patients were patch tested to 75-99 allergens
- 40 patients were patch tested to 100-124 allergens

- 10 patients were patch tested to >125 allergens.

On the other hand, the major centre for Patch Testing in Australia, located in Melbourne Victoria tested 399 patients in 2013 where:

- 23 patients had less than 49 allergens (5.76%)
- 21 had 50-74 allergens (5.26%)
- 89 had 75-99 allergens (22.3%)
- 69 had 100-124 allergens (42.35%)
- 97 had 125 or more allergens (24.31%)

Very little is done in S.A. & W.A. for the larger numbers of allergens.

9) Expected health outcomes relating to the medical service/clinical claim

The applicant has broadly outlined the following health outcomes related to this application:

1. Quality of life is affected by allergic contact dermatitis. In addition, those with chronic or recurrent disease benefit most from the effect of patch testing on their quality of life.
2. Earlier diagnosis and thus prevention of chronicity of allergic contact dermatitis is helpful.
3. Earlier diagnosis of allergic contact dermatitis reduces treatment costs.
4. Non-Caucasians and younger age groups' quality of life in contact dermatitis is particularly impacted.
5. Occupational contact dermatitis affects quality of life significantly.
6. Emotional impact, in the assessment of quality of life, is severely affected.

There is also the issue of the diagnostic accuracy of epicutaneous patch testing. In straightforward terms, if patients are not tested with the allergen they are allergic to, then their patch tests will be falsely negative. It is therefore extremely important to test appropriately and comprehensively. According to the applicant, limiting patch test numbers will be more likely to be associated with failure to identify the culprit allergen. Another potential issue is whether increasing the number of tested substances will inadvertently lead to an increased risk of false positive or “accidentally positive” reactions (truly positive, yet irrelevant for present symptoms). Individualised patch testing is preferred where possible as commercially readily available tests can potentially miss a diagnosis of allergic contact dermatitis if the allergens selected are not closely aligned with the clinical history of the patient. Advice is sought from PASC whether it is necessarily to review the outcomes of individualised vs commercial/pre-packaged testing.

A chief limitation to traditional patch testing is the lack of a suitable reference standard by which it can be evaluated in terms of analytical validity. Patch tests are most effective when the patients are selected on the basis of a clear-cut clinical suspicion of contact allergy, and they are tested with the chemicals relevant to the problem; these conditions satisfy the prerequisites of high pre-test probability. Although the diagnostic accuracy of contactants cannot be compared with other in vivo or in vitro tests, diagnostic concordance between patch test sensitivity and the outcomes of repeated open provocation tests could be potentially demonstrated for some contactants. PASC’s advice is sought as to whether a targeted consideration of this data (if available) is necessary as part of progressing this proposal. Advice is also sought whether evidence demonstrating that increased

testing improves overall diagnostic performance and reduces time to diagnosis is also necessary to review.

10) Regulatory Information

The allergens prepared for patch testing are prepared in accordance with international standards (International Contact Dermatitis Research Group). According to the applicant the therapeutic goods used in the service are exempt from the regulatory requirements of the Therapeutic Goods Act 1989 and has provided the following link which states that patch test allergens are exempt. (www.tga.gov.au/word/devices-guidelines-35.docx)

11) Decision analytic

A decision analytic will be drafted if PASC decides if the relative merits of the proposed structure of MBS items (versus the existing structure of MBS items) requires economic modelling but should be noted that the same service is effectively performed under the two alternative structure of items.

12) Questions for public funding

Given patch testing has gradually evolved overtime in terms of what is regarded as standard/baseline testing and the fact that fundamentally patch testing is not novel (compared to previous iterations of practice), PASC's advice is sought as to the extent to which it is feasible to undertake a comparative health technology assessment relating to safety, clinical effectiveness and cost-effectiveness. The updated practice in terms of the Australian baseline series of 60 allergens is already being conducted under the existing MBS items (12021) so making a sufficient distinction between the intervention and the comparator will be challenging. Specifically advice from PASC is sought as to whether it is feasible to clearly demonstrate incremental improvements in health outcomes (generally expected to arise as a result of the proposal) against what is expected to be a net (but modest) increase in MBS expenditure.

Table 5 Summary of PICO to define research question

PICO	**Comments**
Patients *Allergic contact dermatitis*	
Intervention *Proposed structure of MBS items*	Proposed restructure of MBS items to reflect simply the number of allergens that are used per service. Nominated fees predominantly driven by costs of associated consumables as well as the time it takes to prepare and apply the patches which increases as the number of allergens increase.
Comparator *Existing structure and fees of MBs items*	Current item structure has been in place for nearly 20 years and refers what was previously regarded as 'standard'. Fundamentally nature of how epicutaneous patch testing is performed has not physically changed and the optimal number of allergens required is heavily dependent on the nature of the patient's clinical history. PASC to decide whether there is sufficient distinction between patch testing being conducted under the proposed MBS items versus existing items to warrant a comparative assessment of safety, effectiveness and cost effectiveness.
Outcomes *See Section 9*	
For investigative services	
Prior tests *Largely clinical history and examination, no specific prior tests*	Clinical history informs the pre-test probability
Reference standard *Nil*	Patch testing is regarded as the definitive test in terms of diagnosing allergic contact dermatitis though it is not a perfect test. International standards are in place to minimise variability.