
**Medicare Benefits Schedule Review
Taskforce**

**Report from the Pathology Clinical
Committee – Immunology**

February 2018

Important note

The views and recommendations in this report from the Clinical Committee have been released for the purpose of seeking the views of stakeholders.

This report does not constitute the final position on these items, which is subject to:

△ Stakeholder feedback.

Then

△ Consideration by the MBS Review Taskforce.

Then, *if endorsed*, consideration by

△ The Minister for Health.

△ The Government.

Stakeholders should provide comment on the recommendations via mbsreviews@health.gov.au.

Confidentiality of comments:

If you would like your feedback to remain confidential, please mark it as such. It is important to be aware that confidential feedback may still be subject to access under freedom of information law.

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1. Executive summary

The Medicare Benefits Schedule (MBS) Review Taskforce (the Taskforce) is undertaking a program of work that considers how more than 5,700 items on the MBS can be aligned with contemporary clinical evidence and practice and improve health outcomes for patients. The Taskforce also seeks to identify any services that may be unnecessary, outdated or potentially unsafe.

The Taskforce is committed to providing recommendations to the Minister for Health (the Minister) that will allow the MBS to deliver on each of these four key goals:

- △ Affordable and universal access
- △ Best practice health services
- △ Value for the individual patient
- △ Value for the health system.

The Taskforce has endorsed a methodology whereby the necessary clinical review of MBS items is undertaken by clinical committees and working groups. The Taskforce has asked the clinical committees to undertake the following tasks:

1. Consider whether there are MBS items that are obsolete and should be removed from the MBS.
2. Consider identified priority reviews of selected MBS services.
3. Develop a program of work to consider the balance of MBS services within its remit and items assigned to the committee.
4. Advise the Taskforce on relevant general MBS issues identified by the committee in the course of its deliberations.

The recommendations from the clinical committees are released for stakeholder consultation. The clinical committees will consider feedback from stakeholders then provide recommendations to the Taskforce in review reports. The Taskforce will consider the review reports from clinical committees and stakeholder feedback before making recommendations to the Minister for consideration by Government.

1.1 The Pathology Clinical Committee

The Pathology Clinical Committee (the Committee) was established in 2016 to make recommendations to the Taskforce on the review of MBS items within its remit, based on rapid evidence review and clinical expertise.

Most recommendations relating to these items are included in this report for consultation. The Committee also provided recommendations on items that will be referred to other committees for consultation.

An inclusive set of stakeholders is now engaged in consultation on the recommendations outlined in this report. Following this stakeholder consultation, the recommendations will be finalised and presented to the Taskforce. The Taskforce will consider the report and stakeholder feedback before making recommendations to the Minister for Health for consideration by the Government.

1.2 Recommendations

The Committee was assigned 72 MBS immunology items to review. The Committee's recommendations for stakeholder consultation are that:

- △ four items be deleted from the MBS
- △ five items be added
- △ 21 items should be changed
- △ 40 items should remain unchanged.

These changes focus on encouraging best practice, modernising the MBS to reflect contemporary practice, and ensuring that MBS services provide value for the patient and the healthcare system.

Major changes to items are summarised below and detailed descriptions of all recommendations are found in the body of this report. A plain English summary of all changes can be found in Appendix B – Summary for consumers.

1.2.1 *Antinuclear antibodies*

The Committee recommends limiting the use of item 71097, changing the wording of the descriptor, and educating requesters about optimal use of the item.

The Committee has noted that repeat testing under Medicare is problematic for this item for two main reasons: tests are requested too many times; and lack of understanding by requesters of the intended use of this item. The recommendation for the education program aligns with a separate proposal for antinuclear antibody training to be a requirement for rheumatologists and the as-yet unpublished guidelines on use of antinuclear antibodies.

1.2.2 *Quantitation of complement components*

The Committee recommends changes to the descriptors and tests included in each of the items in this group. The knowledge and utility of more complex testing has advanced in medicine, with many new applications being relevant to the investigation of disease.

The Committee recommends removing properdin and factor B from items 71083–71087, as this test is of limited clinical use. The Committee also recommends deleting item 71087 (testing for three of the preceding items), as this is no longer applicable because the grouping will subsequently only contain two items, that is, testing for C3 and/or C4. The Committee recommends removing the wording specifying breakdown products of complement proteins and replacing the wording with other than C3 or C4 from items 71089–71093.

1.2.3 *Erythrocyte sedimentation rate (ESR) guidelines*

While the Committee considers ESR to have a limited clinical role and that the evidence supporting the various clinical uses of ESR testing are poor, the recommendation is to retain this test on the MBS. This is in part due to the retention of ESR in some prognosis scoring systems and Pharmaceutical Benefits Scheme authority criteria.

1.3 Consumer engagement and impact

The Committee includes experienced and committed health practitioners and consumer representatives. This section summarises the report's key recommendations from a consumer perspective. It aims to make it easier for health consumers and members of the general public to understand the report's recommendations.

A complete list of the recommendations can be found in Appendix B, including a description in plain English of the medical service and the Committee's recommendation, as well as an explanation of why the recommendation has been made.

Consumers rarely engage with MBS item numbers unless they are following up on out-of-pocket expenses. Nevertheless, item descriptions and restrictions are an important part of healthcare accountability. The Committee's recommendations encourage agreed best practice and reflect current clinical evidence.

Both consumers and clinicians are expected to benefit from these recommendations because they address concerns regarding consumer safety and quality of care, and take steps to simplify the MBS and make it easier to use and understand. Consumer access to services was considered for each recommendation. The Committee also considered the impact of each recommendation on requestor and provider groups to ensure that changes were reasonable and fair. However, if the Committee identified evidence of potential item misuse or safety concerns, recommendations were made to encourage best practice, in line with the overarching purpose of the MBS Review.

The Committee expects these recommendations to support better requesting, with the aim of ensuring that patients are provided with clinically indicated, high-quality care that reflects modern best practice.

The consumer representatives used the following framework to assess recommendations:

Safety: None of the recommendations negatively affects the safety of pathology services.

Quality: Many of the recommended changes are intended to improve quality, primarily by aligning the reimbursement system with evidence-based practice.

Access: The recommendations do not negatively affect appropriate access. However, some patient groups have been receiving services they do not need, which can result in either negative health impacts or unnecessary cost. Inappropriate access was restricted where possible.

Effectiveness: None of the recommendations reduces the effectiveness of pathology services.

Cost-effectiveness: The recommendations will have a positive effect on cost-effectiveness because they make it easier to determine which patient groups should have access to specific tests and treatments.

Accountability: Many of the changes include wording that facilitates future auditing for quality purposes.

Data collection: Data collection for research, monitoring and auditing presents a huge opportunity for a revised MBS, and the recommendations should improve the opportunities to use this data for targeted research in the future.

2. About the Medicare Benefits Schedule (MBS) Review

2.1 Medicare and the MBS

2.1.1 What is Medicare?

Medicare is Australia's universal health scheme that enables all Australian residents (and some overseas visitors) to have access to a wide range of health services and medicines at little or no cost.

Introduced in 1984, Medicare has three components:

- △ free public hospital services for public patients
- △ subsidised drugs covered by the Pharmaceutical Benefits Scheme (PBS)
- △ subsidised health professional services listed on the MBS.

2.1.2 What is the MBS?

The MBS is a listing of the health professional services subsidised by the Australian Government. There are more than 5,700 MBS items that provide benefits to patients for a comprehensive range of services, including consultations, diagnostic tests and operations.

2.2 The MBS Review Taskforce

2.2.1 What is the MBS Review Taskforce?

The Government established the MBS Review Taskforce to review all 5,700 MBS items to ensure they are aligned with contemporary clinical evidence and practice and improve health outcomes for patients. The Taskforce will also modernise the MBS by identifying any services that may be unnecessary, outdated or potentially unsafe.

2.2.2 What are the goals of the Taskforce?

The Taskforce is committed to providing recommendations to the Minister that will allow the MBS to deliver on each of these four key goals:

- △ **Affordable and universal access**—the evidence demonstrates that the MBS supports very good access to primary care services for most Australians, particularly in urban Australia. However, despite increases in the specialist workforce over the last decade, access to many specialist services remains problematic, with some rural patients being particularly under-served.
- △ **Best practice health services**—one of the core objectives of the Review is to modernise the MBS, ensuring that individual items and their descriptors are consistent with contemporary best practice and the evidence base when possible. Although the Medical Services Advisory Committee (MSAC) plays a crucial role in thoroughly evaluating new services, the vast majority of existing MBS items predate this process and have never been reviewed.
- △ **Value for the individual patient**—another core objective of the Review is to have an MBS that supports the delivery of services that are appropriate to the patient's needs, provide real clinical value and do not expose the patient to unnecessary risk or expense.
- △ **Value for the health system**—achieving the above elements of the vision will go a long way to achieving improved value for the health system overall. Reducing the volume of services that provide little or no clinical benefit will enable resources to be redirected to new and existing services that have proven benefit and are underused, particularly for patients who cannot readily access those services currently.

2.3 The Taskforce's approach

The Taskforce is reviewing the existing MBS items, with a primary focus on ensuring that individual items and usage meet the definition of best practice. Within the Taskforce's brief there is considerable scope to review and advise on all aspects that would contribute to a modern, transparent and responsive system. This includes not only making recommendations about new items or services being added to the MBS, but also about a MBS structure that could better accommodate changing health service models.

The Taskforce has made a conscious decision to be ambitious in its approach and seize this unique opportunity to recommend changes to modernise the MBS on all levels, from the clinical detail of individual items, through administrative rules and mechanisms, to structural, whole-of-MBS issues.

The Taskforce will also develop a mechanism for the ongoing review of the MBS after the current Review is concluded.

As the MBS Review is to be clinician-led, the Taskforce decided that clinical committees should conduct the detailed review of MBS items. The committees are broad-based in their membership, and members have been appointed in an individual capacity rather than as representatives of any organisation.

The Taskforce asked all committees to review MBS items using a framework based on Appropriate Use Criteria accepted by the Taskforce (Elshaug). [1]

The framework consists of seven steps:

1. Develop an initial fact base for all items under consideration, drawing on the relevant data and literature.
2. Identify items that are obsolete, are of questionable clinical value¹, are misused² and/or pose a risk to patient safety. This step includes prioritising items as 'priority 1,' 'priority 2' or 'priority 3,' using a prioritisation methodology (described in more detail below).
3. Identify any issues, develop hypotheses for recommendations and create a work plan (including establishing working groups, when required) to arrive at recommendations for each item.
4. Gather further data, clinical guidelines and relevant literature to make provisional recommendations and draft accompanying rationales, as per the work plan. This process begins with priority 1 items, continues with priority 2 items and concludes with priority 3 items. This step also involves consultation with relevant stakeholders within the committee, working groups, and relevant colleagues or colleges. For complex cases, full appropriate use criteria were developed for the item's explanatory notes.
5. Review the provisional recommendations and the accompanying rationales, and gather further evidence as required.
6. Finalise the recommendations in preparation for broader stakeholder consultation.

¹ The use of an intervention that evidence suggests confers no or very little benefit on consumers; or where the risk of harm exceeds the likely benefit; or, more broadly, where the added costs of the intervention do not provide proportional added benefits.

² The use of MBS services for purposes other than those intended. This includes a range of behaviours, from failing to adhere to particular item descriptors or rules through to deliberate fraud.

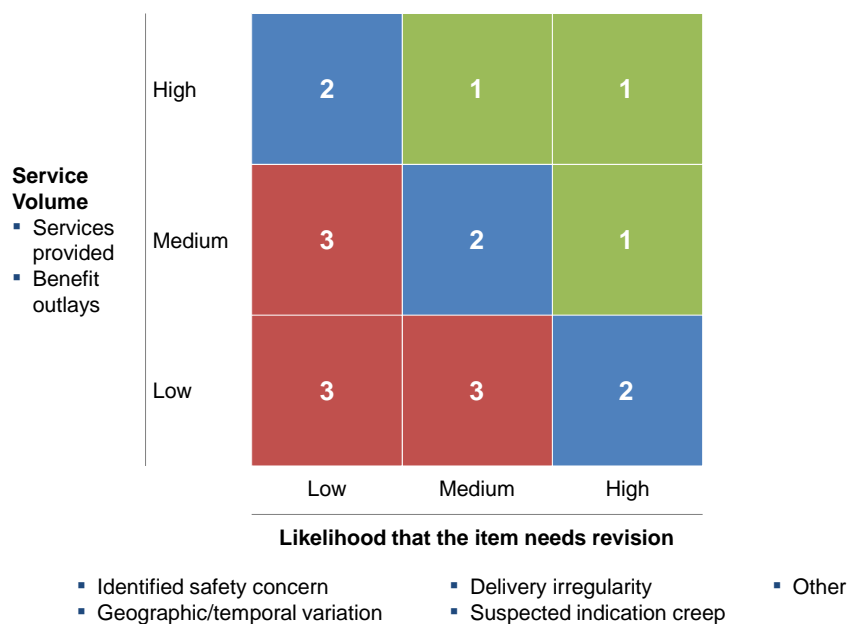
- Incorporate feedback gathered during stakeholder consultation and finalise the Review Report, which provides recommendations for the Taskforce.

All MBS items will be reviewed during the course of the MBS Review. However, given the breadth of, and timeframe for, the Review, each clinical committee had to develop a work plan and assign priorities, keeping in mind the objectives of the Review. Committees used a robust prioritisation methodology to focus their attention and resources on the most important items requiring review. This was determined based on a combination of two standard metrics, derived from the appropriate use criteria (Elshaug): [1]

- △ Service volume.
- △ The likelihood that the item needed to be revised, determined by indicators such as identified safety concerns, geographic or temporal variation, delivery irregularity, the potential misuse of indications or other concerns raised by the Committee (such as inappropriate co-claiming).

For each item, these two metrics were ranked high, medium or low. These rankings were then combined to generate a priority ranking ranging from 1 to 3 (where priority 1 items are the highest priority and priority 3 items are the lowest priority for review), using a prioritisation matrix (Figure 1). The Committee used this priority ranking to organise its review of item numbers and apportion the amount of time spent on each item.

Figure 1. Prioritisation matrix



3. About the Pathology Clinical Committee

The Pathology Clinical Committee (the Committee) is part of the first tranche of clinical committees. It was established in 2016 to make recommendations to the Taskforce on the review of MBS items within its remit, based on rapid evidence review and clinical expertise. The Taskforce has asked the Committee to review pathology services as a priority review.

3.1 Committee members

The Committee consists of 18 members, whose names, positions/organisations and declared conflicts of interest are listed in Table 1. All members of the Taskforce, clinical committees and working groups were asked to declare any conflicts of interest at the start of their involvement and are reminded to update their declarations periodically.

Table 1. Pathology Clinical Committee members

Name	Position/organisation	Declared conflict of interest
Associate Professor Peter Stewart	Royal Prince Alfred Hospital (Public)	None
Professor Rita Horvath	South Eastern Area Laboratory Services (Public)	None
Dr Debra Norris	QML Pathology (Primary)	None
Dr Michael Harrison	Sullivan Nicolaides Pathology (Sonic)	None
Associate Professor Ken Sikaris	Melbourne Pathology (Sonic)	None
Dr Melody Caramins	Specialist Diagnostic Services (Primary)	None
Dr John Rowell	Royal Brisbane & Women's Hospital	None
Professor Dominic Mallon	PathWest	None
Dr Peter Roberts	Ryde Hospital (AESM)	None
Associate Professor Anthony Landgren	Australian Clinical Labs	None
Associate Professor Mary-Jo Waters	St Vincent's Pathology (CHA)	None
Professor Richard Maclsaac	St Vincent's Hospital	None
Dr Emil Djakic	General practitioner	None
Dr Bev Rowbotham	MBS Review Taskforce	None
Dr Jill Thistlethwaite	General practitioner	None
Dr Gary Lum	Department of Health Medical Advisor	None
Ms Valerie Hanrahan	Consumers Health Forum	None

Name	Position/organisation	Declared conflict of interest
Dr Robyn Lindner	National Prescribing Service	None

3.2 Immunology Working Group

The IWG is one of six clinical working groups that have been established to support the work of the Committee. It was established to review immunology pathology items, and make recommendations to the Committee based on rapid evidence review and clinical expertise.

The IWG consists of six members, whose names, positions/organisations and declared conflicts of interest are listed in Table 2 below.

Table 2. Immunology Working Group members

Name	Position/organisation	Declared conflict of interest
Dr Daman Langguth	Sullivan Nicolaides Pathology	None
Dr Theo de Malmanche	NSW Health Pathology	None
Dr Pravin Hissaria	SA Pathology/Royal Adelaide	None
Dr Lucinda Wallman	Laverty Pathology	None
Dr Aniello Iannuzzi	General Practitioner	None
Mr Adam Friederich	Consumer representative	None

3.3 Conflicts of interest

All members of the Taskforce, clinical committees and working groups are asked to declare any conflicts of interest at the start of their involvement and reminded to update their declarations periodically.

It is noted that most Committee members share a common conflict of interest in reviewing items that are a source of revenue for them (i.e. Committee members provide the services under review). This conflict is inherent in a clinician-led process, and having been acknowledged by the Committee and the Taskforce, it was agreed that this should not prevent a clinician from participating in the review.

3.4 Areas of responsibility of the Committee

The Committee was assigned 69 MBS immunology items to review. In the financial year 2014–15 these items accounted for 3,904,839 services (out of a total of 128,786,630 pathology services) and \$137,281,885 in benefits (out of a total of \$2,652,998,768).

A complete list of these items can be found in Appendix A of this report.

3.5 Summary of the Committee's review approach

The Committee completed a review of the 75 items across six meetings, during which it developed the recommendations and rationales outlined in Section 4.

The Review drew on various types of MBS data, including data on:

- △ utilisation of items (services, benefits, patients, providers and growth rates)
- △ service provision (type of provider, geography of service provision)
- △ patients (demographics and services per patient)
- △ co-claiming or episodes of services (same-day claiming and claiming with specific items over time)
- △ additional provider and patient-level data, when required.

The review also drew on data presented in the relevant literature and clinical guidelines, all of which are referenced in the report.

The Committee will consider stakeholder feedback before finalising the recommendations and presenting them to the Taskforce. The Taskforce will consider the report and stakeholder feedback before making recommendations to the Minister for Health for consideration by the Government.

4. Recommendations for immunology-related pathology tests

The Committee reviewed 69 assigned immunology items and made recommendations based on evidence and clinical expertise. The item-level recommendations are described below. A summary list of recommendations can be found in Appendix A and in the summary for consumers in Appendix B.

The Committee's recommendations for stakeholder consultation are that:

- △ six items be deleted from the MBS
- △ five new items be added
- △ 21 items should be changed
- △ 37 items should remain unchanged.

The changes focus on encouraging best practice, modernising the MBS to reflect contemporary practice, and ensuring that MBS services provide value for the patient and the healthcare system. Some of this can be achieved by:

- △ deleting items that are obsolete
- △ consolidating or splitting items to reflect contemporary practice
- △ modernising item descriptors to reflect best practice
- △ providing clinical guidance for appropriate use through explanatory notes.

4.1 Coeliac disease panel: items 71163, 71164

Table 3. Item introduction table for items 71163, 71164

Item	Long item descriptor	Schedule fee	Services FY2014–15	Benefits FY2014–15	Patient count	Services 5-year annual average growth
71163	Detection of one of the following antibodies (of 1 or more class or isotype) in the assessment or diagnosis of coeliac disease or other gluten hypersensitivity syndromes and including a service described in item 71066 (if performed): a) Antibodies to gliadin; or b) Antibodies to endomysium; or c) Antibodies to tissue transglutaminase; - 1 test	24.75	45,768	\$970,209	44,542	-13.0%
71164	Two or more tests described in 71163 and including a service described in 71066 (if performed)	39.90	398,442	\$13,627,707	382,971	13.4%

4.1.1 Recommendation 1

- △ Add explanatory notes to the item descriptor for 71163. The following wording is to be added: 'Serology is not useful in patients shown not to carry the at-risk alleles'. Repeat testing in patients for who antibodies have not been detected is not recommended unless a change in clinical situation has occurred.'
- △ The Department monitor the repeat testing for these tests.

- △ The Department to commission a health technology assessment and/or costing analysis on diagnosing and treating coeliac disease that includes diagnosis of coeliac disease and endoscopy combined with other pathology tests and genetic testing of coeliac disease.

Table 4. Current and proposed item descriptors for items 71163 and 71164

Item	Current item descriptor	Proposed item descriptor
71163	Detection of one of the following antibodies (of 1 or more class or isotype) in the assessment or diagnosis of coeliac disease or other gluten hypersensitivity syndromes and including a service described in item 71066 (if performed): a) Antibodies to gliadin; or b) Antibodies to endomysium; or c) Antibodies to tissue transglutaminase; - 1 test	Detection of one of the following antibodies (of 1 or more class or isotype) in the assessment or diagnosis of coeliac disease or other gluten hypersensitivity syndromes and including a service described in item 71066 (if performed): a) Antibodies to deamidated gliadin; or b) Antibodies to endomysium; or c) Antibodies to tissue transglutaminase. Explanatory notes: Serology is not useful in patients shown not to carry the at-risk alleles. Repeat testing in patients for who antibodies have not been detected is not recommended unless a change in clinical situation has occurred.
71164	Two or more tests described in 71163 and including a service described in 71066 (if performed)	Two or more tests described in 71163 and including a service described in 71066 (if performed) (item is subject to rule 25)

4.1.2 Rationale 1

- △ During the financial year 2010–2011, the total benefits paid for 71163 and 71164 was \$1.7 million and \$8.4 million, respectively; in 2014–2015, the total benefits were \$970,209 and \$13.6 million. The Committee recognises that there has been significant growth in the utilisation of item 71164 for two or more antibodies over the last 5 years, while utilisation of item 71163 has declined.
- △ This increase in utilisation could be due to the increased number of awareness campaigns by certain organisations that may be overstating the prevalence of coeliac disease within the Australian population. The maximum estimated rate of 0.5% of coeliac disease within the Australian population yields 105,000 people and there are approximately 400,000 people being tested per year. An Australian study estimates the prevalence of coeliac disease to be 1.2% in men and 1.9% in women. [2]
- △ During the financial year 2014–2015, women aged 25–34 years were the main users of item 71163 and accounted for 5,155 services compared with 1,825 services for men in the same group. Women aged 25–34 years were the main users of item 71164. This demographic group accounted for 50,000 services compared with men in this age group, who accounted for 20,000 services.
- △ The US Preventive Services Task Force Recommendation Statement says the current evidence is insufficient on the effectiveness of screening for coeliac disease in asymptomatic patients and patients at increased risk for coeliac disease. [3] Diagnosing coeliac disease in symptomatic patients (older than 2 years) comprises test tissue transglutaminase IgA, followed by intestinal biopsy. [2]
- △ The main requesters of items 71163 and 71164 are GPs and gastroenterologists; about 50% of requests from are GPs for item 71163 and 18% from gastroenterologists, while 72% of requests are GPs for item 71164 and 9% are from gastroenterologists. There is a state variation in the utilisation of item 71163, with 49 requests per 100,000 people in SA for the FY 2014–15 compared with 421 and 486 requests per 100,000 people in WA and ACT, respectively.

- △ During the financial year 2014–2015, the number of services received by patients for item 71163 were as follows: 43,009 patients received the service once, 1040 patients received the service twice, 58 patients received the service three times and 11 patients received the service four times. The number of services received by patients for item 71164 were: 370,767 patients received the service once, 13,337 patients received the service twice, 970 patients received the service three times and 126 patients received the service four times.
- △ The Committee recognises that coeliac disease is commonly asymptomatic. However, unrecognised coeliac disease can lead to significant health problems such as iron deficiency and osteoporosis. Coeliac disease can develop at any age and does not have a detectable preclinical state.
- △ The Committee also recognises that two antibody tests increase sensitivity for the diagnosis, especially in patients with low IgA levels (low IgA levels are also associated with a higher rate of coeliac disease). The uncertainties include whether the increased yield in detection justifies the increased cost of testing, increased because:
 - two tests now often done instead of one, and
 - such testing is no longer restricted to patients with symptoms or signs of malabsorption alone (associated iron deficiency and osteoporosis, for example).
- △ A health technology assessment or a review of the literature will be required to provide the prevalence and natural history data for the cost–benefit analysis.
- △ The proposed changes will have no direct effect on patients.

4.2 Genotyping for coeliac disease risk for DQ2 and DQ8: item 71151

Table 5. Item introduction table for item 71151

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71151	Tissue typing for HLA-DR, HLA-DP and HLA-DQ Class II antigens (including any separation of leucocytes) - phenotyping or genotyping of 2 or more antigens	\$118.85	34,208	\$3,589,477	33,365	14.1%

4.2.1 Recommendation 2

- △ Add the following extra wording to the item descriptor for 71151: ‘this item is not to be used for investigation of possible coeliac disease.’
- △ Create a new item with the following item descriptor:
 - Tissue typing in coeliac disease: Determination of tissue types (DQ2/DQ8) associated with coeliac disease. The method used needs to be able to resolve both the DQA1* and DQB1* alleles to the four-digit level of resolution, for all the known at-risk alleles of DQ2 and DQ* and exclude common alternative alleles.

Table 6. Current and proposed item descriptors for item 71151 and new item

Item	Current item descriptor	Proposed item descriptor
71151	Tissue typing for HLA-DR, HLA-DP and HLA-DQ Class II antigens (including any separation of leucocytes) -	Tissue typing for HLA-DR, HLA-DP and HLA-DQ Class II antigens (including any separation of leucocytes) - phenotyping or genotyping of

Item	Current item descriptor	Proposed item descriptor
	phenotyping or genotyping of 2 or more antigens	2 or more antigens. <i>This item is not to be used for investigation of possible coeliac disease.</i>
New item	—	Tissue typing in coeliac disease: Determination of tissue types (DQ2/DQ8) associated with coeliac disease. The method used must be able to resolve both the DQA1* and DQB1* alleles to the four-digit level of resolution, for all the known at-risk alleles of DQ2 and DQ* and exclude common alternative alleles

4.2.2 Rationale 2

- △ Item 71151 is used to detect leucocyte antigens and this testing is important in transplanting organs or tissue. The Committee noted that during 2014–15 there was variation in the utilisation of item 71151 across the states and territories, which can possibly be accounted for by public hospital laboratories in Qld and WA performing tissue typing onsite.
- △ Genetic testing with HLA DQ2/DQ8 is useful in certain circumstances:
 - A negative test result excludes coeliac disease, as more than 99% of patients with coeliac disease carry one or other of the markers.
 - A positive test is not useful to diagnose coeliac disease because HLA DQ2/DQ8 is present in about 50% of the population. [2]
- △ The Committee recognises that testing for coeliac disease-related HLA-DQ typing (i.e. for DQ2 and DQ8) is likely to be included in requests for item 71151 and therefore recommended that a new item be created for this indication.
- △ This has been considered before by the Pathology Service Advisory Committee (PSAC). PSAC advised that item 71151 is at risk of inappropriate use by referrers, by possibly using a positive test result for HLA to imply the presence of possible coeliac disease; PSAC suggested restricting this item to promote appropriate use.
- △ The Committee recognises there may be changes in clinical guidelines that may influence the requesting of this test, which could lead to increased testing.
- △ As these are tests of a person's DNA, the results should not change during their lifetime. However, testing a second time to confirm unexpected results may occasionally be required, or if results from previous testing are not available.
- △ The Committee recognises that the current Schedule does not reflect current clinical practice and proposes that a new item be created for this test to be remunerated within the MBS (at the same fee for item 71151).

4.3 Specific immunoglobulin E antibodies: item 71079

Table 7. Item introduction table for item 71079

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71079	Detection of specific immunoglobulin E (IgE) antibodies to single or multiple potential allergens, 1	\$26.80	201,567	\$4,615,660	191,701	7.3%

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
	test (Item is subject to rule 25)					

4.3.1 Recommendation 3

- △ Create a new item to capture multiple recombinant and purified component allergens.
- △ Amend the item descriptor of item 71079 to add the word ‘extracted’.
- △ The utilisation of the new item is to be monitored by the Department.

The Committee’s proposed changes to item 71079 are presented in the table below.

Table 8. Current and proposed item descriptors for item 71079 and new item

Item	Current item descriptor	Proposed item descriptor
71079	Detection of specific immunoglobulin E antibodies to single or multiple potential allergens, 1 test (Item is subject to rule 25)	Detection of specific immunoglobulin E (IgE) antibodies to single or multiple potential extracted allergens.
New item	—	Detection of specific immunoglobulin E (IgE) antibodies to single or multiple recombinant and purified component allergens for allergens. Explanatory note: This test is to be used in specific patient populations such as those who have food allergies, insect venom allergies and aeroallergies.

4.3.2 Rationale 3

- △ Item 71079 is an allergen-specific IgE antibody test used to screen for an allergy to a specific allergen, for example, the subcomponents of peanut such as Ara h 2. The Committee recognises the importance of allergen testing and considered the literature when making its recommendation for this item.
- △ The clinical utility of recombinant and purified allergen testing was considered when the Committee was proposing recommendations for this item. Recombinant and purified allergen markers are considered to be more predictive of disease than previously available allergen extracts, hence the recommendation for introduction of the new item.
- △ The issues regarding purified and recombinant allergens (sometimes referred to as component resolved diagnostics) are as follows:
 - In about the last 5 years a number of purified or recombinant allergens have been identified that can improve the performance of testing. Examples include Ara h 2, Ara h 8, Ara h 9 (these three for peanut), ‘alpha-gal’ (for meat allergy), and omega-gliadin (for exercise-induced wheat allergy)—the latter two are often used in workup of idiopathic anaphylaxis, a rare but serious consideration.
 - Recombinant allergen testing has greater clinical utility than routine allergy testing, in a small number of patients. The current item 71079 is used for both these newer allergen tests and the older less predictive allergen testing.
- △ There are issues regarding the overuse of allergy testing (including allergen extracts), including:

- The older / more established testing to allergen extracts are noted to be imperfect and inferior to skin prick testing when performed by a specialist allergist.
 - Access to allergist review is limited to metropolitan areas. Blood tests to allergen extracts can therefore be helpful for patients in regional and rural areas, and addresses the access gap.
 - The potential for overuse of blood tests for allergies is high. One solution would be to restrict to specialists. However, there are not enough allergists to review all these patients.
 - Many requests include an excessive number of allergens, with a diminishing yield from such ‘fishing trips’.
- △ The test is difficult to restrict and there would be some patients, including some children, who would benefit from having multiple allergens tested on the one sample, although this is a very small group. This item could be restricted to a specialist only MBS number; nonetheless this would be a great challenge for the laboratory and not a solution for this item. Hence, the proposal to create a new item to capture the population—including patient populations who have food allergies, insect venom allergies and aeroallergies—that would require this test and that this new item be monitored to see requesting patterns.

4.4 Antinuclear antibodies tests: item 71097

Table 9. Item introduction table for item 71097

Item	Long descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71097	Antinuclear antibodies - detection in serum or other body fluids, including quantitation if required	\$24.45	525,936	\$10,964,607	469,294	4.4%

4.4.1 Recommendation 4

The Committee proposes the following:

- △ Change the item descriptor to remove the wording ‘or other body fluids’ from the current item descriptor
- △ Develop a targeted education program on the clinical appropriateness of antinuclear antibodies for GPs and rheumatologists. This education program should inform requesters of the changes and the appropriate guidelines for testing. This recommendation aligns with a separate proposal for antinuclear antibody training to be a requirement for rheumatologists and the as-yet unpublished guidelines on use of antinuclear antibodies.

Table 10. Current and proposed item descriptors for item 71097

Item	Current item descriptor	Proposed item descriptor
71097	Antinuclear antibodies - detection in serum or other body fluids, including quantitation if required	Antinuclear antibodies - detection in serum, including quantitation if required

4.4.2 Rationale 4

- △ Item 71097 is the antinuclear antibody test used to help confirm or exclude the diagnosis of systemic rheumatic disease. Antinuclear antibodies are associated with a number of autoimmune diseases but are used specifically to diagnose and classify disease in patients

presenting with clinical symptoms or other laboratory results suggesting rheumatic disease. Antinuclear antibody tests are rarely used in isolation and often used early in the evaluation of patients to better direct investigations. [4]

- △ During the financial year 2014–2015, the number of services received by patients were as follows: 424,153 patients received the service once, 38,890 patients received the service twice, and 5763 patients received the service three times. The number of patients receiving the service more than three times during 2014–15 was 1881.
- △ When present and associated with disease, these antibodies remain stable for many years. Repeat testing to confirm unexpected results is appropriate, but these antibodies are not validated for monitoring disease activity.
- △ The Committee decided to remove body fluids from the item descriptor because there is no clinical reason to perform an antinuclear antibody test on body fluids. Testing for the presence of antinuclear antibodies in samples other than peripheral blood is not recommended because there are no clinically validate indications for such testing, and reference intervals cannot be established for such samples, which precludes useful interpretation of such results.
- △ When diseases for which these antibodies are associated are present, the antibodies normally precede the disease presentation by months to years. Repeating testing in early stages of a patient’s presentation to see if there are progression of such antibodies therefore is almost always unnecessary.
- △ The proposed changes will have no direct effect on patients.

4.5 Double-stranded DNA antibodies: item 71099

Table 11. Item introduction table for item 71099

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71099	Double-stranded DNA antibodies - quantitation by 1 or more methods other than the Crithidia method	\$26.50	195,681	\$4,419,881	168,350	7.9%

4.5.1 Recommendation 5

The Committee proposes the following:

- △ Remove the wording ‘other than the Crithidia method’ from the item descriptor.

Table 12. Current and proposed item descriptors for item 71099

Item	Current item descriptor	Proposed item descriptor
71099	Double-stranded DNA antibodies - quantitation by 1 or more methods other than the Crithidia method	Double-stranded DNA antibodies - quantitation by 1 or more methods

4.5.2 Rationale 5

- △ Item 71099 is the anti-double stranded DNA test used to help diagnose systemic lupus erythematosus in patients who have a positive result on an antinuclear antibody test and have presenting clinical symptoms. There is an equal utilisation of item 71099 across the states and territories.

- △ The use of Crithidia as a substrate for the detection of antibodies to double stranded DNA is a valid methodology, and not inferior to some of the alternate assay methodologies in current use.
- △ The proposed changes have no direct effect on patients.

4.6 Antibodies to extractable nuclear antigens: items 71101 and 71103

Table 13. Item introduction table for items 71101 and 71103

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71101	Antibodies to 1 or more extractable nuclear antigens - detection in serum or other body fluids	\$17.40	151,483	\$2,235,329	139,029	8.6%
71103	Characterisation of an antibody detected in a service described in item 71101 (including that service)	\$52.05	35,313	\$1,568,130	29,504	13.4%

4.6.1 Recommendation 6

- △ Amend item descriptor of item 71101 to remove the words 'or other body fluids'.
- △ Items 71101 and 71103 to be monitored by the Department. Laboratories who claim a ratio of 71103:71101 greater than one-third should be audited.

4.6.2 Rationale 6

- △ Items 71101 and 71103 are tests used to detect antibodies for extractable nuclear antigens (ENA); these tests are used to help diagnose and distinguish between autoimmune disorders such as mixed connective tissue disease, Sjögren's syndrome and systemic lupus erythematosus. This test has been available for more than 30 years. Autoantibody testing is only necessary when a person presents with symptoms that suggest an autoimmune disorder.
- △ The state variation for items 71101 and 71103 are as follows:
 - NSW has the highest utilisation of item 71101 with 832 per 100,000 compared with 258 per 100,000 people in the NT.
 - Utilisation of item 71103 is 644 per 100,000 in ACT while in Vic the utilisation is 82 per 100,000.
- △ For item 71101, the number of services received by patients during 2014–2015 are as follows: 128,622 patients received the service once, 8989 had the service twice, and 1217 patients received the service three times; 329 patients received the service four or more times. For item 71103, a total of 24,952 patients received the service once, 3735 patients received the service twice, and 672 patients received the service three times; 222 patients received the service four or more times.
- △ The Committee recognises that item 71101 might be used as a monitoring test in clinical practice and is being repeated unnecessarily. Item 71101 should not be repeated until clinical conditions change. Changes in long-lived antibodies are gradual, requiring several months to develop, resolve or alter, and in most cases these antibodies remain unchanged for several years.

- △ The Committee recommended that the Department monitor items 71101 and 71103 and audit laboratories when the ratio of 71103:71101 is greater than one-third. These antibodies are relatively uncommon, so most testing will not detect them. Item 71103 is for the characterisation of antibodies after detection, and so should be required in a minority of samples.
- △ There is no clinical reason to perform an extractable nuclear antibody test on body fluids. Testing for the presence of extractable nuclear antibodies in samples other than peripheral blood is not recommended because there are no clinically validated indications for such testing, and reference intervals cannot be established for such samples, which precludes useful interpretation of such results.
- △ The proposed changes have no direct effect on patients.

4.7 Quantitation of complement components: items 71083, 71085, 71087, 71089, 71091 and 71093

Table 14. Item introduction table for items 71083, 71085, 71087, 71089, 71091 and 71093

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71083	Quantitation of complement components C3 and C4 or properdin factor B – 1 test	\$20.15	4,649	\$79,087	3,382	20.6%
71085	2 tests described in item 71083	\$28.95	95,153	\$2,336,440	77,173	7.6%
71087	3 or more tests described in item 71083	\$37.70	329	\$10,532	271	21.8%
71089	Quantitation of complement components or breakdown products of complement proteins not elsewhere described in an item in this Schedule - 1 test (Item is subject to rule 6)	\$29.15	540	\$13,325	515	3.7%
71091	2 tests described in item 71089 (Item is subject to rule 6)	\$52.85	133	\$5,941	132	36.5%
71093	3 or more tests described in item 71089 (Item is subject to rule 6)	\$76.45	24	\$1,514	26	-36.7%

4.7.1 Recommendation 7

- △ Remove the properdin and factor B from items 71083–71087.
- △ Delete item 71087.
- △ Remove the wording specifying ‘breakdown products of complement proteins’ from the item descriptors for items 71089–71093.
- △ Add the wording ‘other than C3 or C4’ to the item descriptors for items 71089–71093.

The Committee’s proposed changes are summarised in the table below.

Table 15. Current and proposed item descriptors for items 71083, 71085, 71087, 71089, 71091 and 71093

Item no	Current descriptor	New proposed descriptor
71083	Quantitation of complement components C3 and C4 or properdin factor B - 1 test	Quantitation of complement components C3 or C4

Item no	Current descriptor	New proposed descriptor
71085	2 tests described in item 71083	Quantitation of complement components C3 and C4 (2 tests)
71087	3 or more tests described in item 71083	Delete
71089	Quantitation of complement components or breakdown products of complement proteins not elsewhere described in an item in this Schedule - 1 test	Quantitation of complement components other than C3 or C4 (1 test)
71091	2 tests described in item 71089	2 tests described in item 71089
71093	3 or more tests described in item 71089	3 or more tests described in item 71089

4.7.2 Rationale 7

- △ Items 71083–71093 are tests used to determine whether deficiencies or abnormalities in the complement system contribute to a person’s condition. Complement tests are used to monitor people diagnosed with an autoimmune disorder (such as rheumatoid arthritis or lupus) to see if treatment is working; C3 and C4 are the most commonly measured complement components. The main requestors of these tests are rheumatologists and immunologists.
- △ The proposed changes reflect that knowledge and utility of more complex testing has advanced in medicine, with many new applications being relevant to the investigation of disease. The proposed changes remove obsolescence from the tests for quantitation of complement components and bring the tests into line with these advances. For example, properdin and factor B no longer reflect clinical practice, and item 71087 is no longer required with removal of these components.
- △ The combined testing for C3 and C4 results in loss of ability to track the items separately. Therefore the Committee recommends that the descriptors for items 71803 and 71805 be changed to enable tracking of both items.

The proposed changes have no direct effect on patients.

4.8 Antibodies to tissue antigens: items 71119, 71121, 71123 and 71125

Table 16. Item introduction table for items 71119, 71121, 71123 and 71125

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71119	Antibodies to tissue antigens not elsewhere specified in this Table - detection, including quantitation if required, of 1 antibody	\$17.35	146,135	\$2,157,532	135,781	6.3%
71121	Detection of 2 antibodies specified in item 71119	\$20.80	21,047	\$370,277	20,352	5.1%
71123	Detection of 3 antibodies specified in item 71119	\$24.25	14,633	\$300,222	14,312	0.3%
71125	Detection of 4 or more antibodies specified in item 71119	\$27.65	7989	\$187,265	7379	13.0%

4.8.1 Recommendation 8

The Committee proposes the following:

- △ Remove the wording 'or more' from the item descriptor for 71125.
- △ Add a new item for five or more tests for antibodies.

The Committee's proposed changes are summarised in the table below.

Table 17. Current and proposed item descriptors for items 71119, 71121, 71123, 71125

Item	Current item descriptor	Proposed item descriptor
71119	Antibodies to tissue antigens not elsewhere specified in this Table - detection, including quantitation if required, of 1 antibody	Remain unchanged
71121	Detection of 2 antibodies specified in item 71119	Remain unchanged
71123	Detection of 3 antibodies specified in item 71119	Remain unchanged
71125	Detection of 4 or more antibodies specified in item 71119	Detection of 4 antibodies specified in item 71119
71126 (new item)		Detection of 5 or more antibodies specified in item 71119.

4.8.2 Rationale 8

- △ Items 71119, 71121, 71123 and 71125 are tests used to detect antibodies for autoimmune diseases that are not already accounted for by an individual item number within the MBS; these diseases include scleroderma and myositis. Currently, there is no item number to capture the clinical population that requires a test for five or more antibodies to tissue antigens. There is a small but significant clinical population that will require four or more antibodies (see benefits paid).
- △ The Committee recognises that creating a new item will allow for better data collection on this population to find out what proportion of the population requires five or more antibodies. Certain patients have a defined autoimmune disease, and testing for more antibodies allows for profiling of these patients to discover the underlying cause of the disease.
- △ Several antigens are not specified elsewhere in the table, such as myositis- and scleroderma-associated antibodies that would be included under this item and are considered clinically appropriate and valid tests. Extending testing to include five or more antibodies would address the access gap for this small patient cohort, as these tests are expensive but are considered clinically relevant. This Committee recommendation focuses on enabling data collection on the use of the test.

4.9 Antibodies to tissue antigens: item 71165

Table 18. Item introduction table for item 71165

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71165	Antibodies to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, salivary gland, skeletal muscle, skin basement membrane and intercellular substance,	\$34.55	128,207	\$4,391,757	107,564	10.0%

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
	thyroglobulin, thyroid microsome or thyroid stimulating hormone receptor) - detection, including quantitation if required, of 1 antibody (Item is subject to rule 6)					

4.9.1 Recommendation 9

The Committee proposed the following:

- △ Amend the item descriptor for 71165 to remove thyroid antibodies and salivary gland.
- △ Remove salivary gland from the item descriptor.

Table 19. Current and proposed item descriptors for item 71165

Item	Current item descriptor	Proposed item descriptor
71165	Antibodies to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, salivary gland, skeletal muscle, skin basement membrane and intercellular substance, thyroglobulin, thyroid microsome or thyroid stimulating hormone receptor) - detection, including quantitation if required, of 1 antibody (Item is subject to rule 6)	Antibodies to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, skeletal muscle, skin basement membrane and intercellular substance) - detection, including quantitation if required, of 1 antibody (Item is subject to rule 6)

4.9.2 Rationale 9

- △ The Committee recommended removing thyroid antibodies from the item descriptor of 71165, as there is a new item number proposed for thyroid antibodies within the pathology section of the MBS.
- △ The Committee recommended the removal of salivary gland from the item 71165, as this is no longer considered a clinically useful test.
- △ The proposed changes will have no direct effect on patients.

4.10 Quantitation of immunoglobulin E: items 71075 and 71077

Table 20. Item introduction table for item 71075 and 71077

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71075	Quantitation of immunoglobulin E (total), (IgE) 1 test. (Item is subject to rule 25)	\$23.00	133,831	\$2,619,828	127,901	5.5%
71077	Quantitation of immunoglobulin E (total) (IgE) in the follow up of a patient with proven immunoglobulin-E-secreting myeloma, proven congenital immunodeficiency or proven	\$27.05	2	\$43	2	14.9%

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
	allergic bronchopulmonary aspergillosis, 1 test. (Item is subject to rule 25)					

4.10.1 Recommendation 10

- △ Consolidate item 71077 into item 71075.
- △ Change the fee of item 71075 to the same fee as item 71077.

Table 21. Current and proposed item descriptors for items 71075 and 71077

Item	Current item descriptor	Proposed item descriptor
71075	Quantitation of immunoglobulin E (total), (IgE) 1 test. (Item is subject to rule 25)	Quantitation of immunoglobulin E (total), (IgE) 1 test. (Item is subject to rule 25) Explanatory note: Repeat testing of IgE in the monitoring of allergy is of no clinical use.
71077	Quantitation of immunoglobulin E (total) (IgE) in the follow up of a patient with proven immunoglobulin-E-secreting myeloma, proven congenital immunodeficiency or proven allergic bronchopulmonary aspergillosis, 1 test. (Item is subject to rule 25)	Delete

4.10.2 Rationale 10

- △ The Committee noted the low usage of item 71077 is due to the difficulty in the coding, with item 71077 being billed as item 71075. Items 71075 and items 71077 are essentially the same tests but are used for different indications. Deleting item 71077 and consolidating it into item 71075 will simplify the MBS and avoid confusion in terms of claiming.
- △ Monitoring total IgE levels is appropriate for allergic bronchopulmonary aspergillosis and IgE-secreting myeloma (the latter is extremely rare), and such testing should be able to be accommodated with four tests per year. During the financial year 2014–2015, a total of 123,188 patients received service for item 71075 once, 4522 patients received the service twice, 386 patients received the service three times and 97 patients received the service four times. The maximum number of times a patient received a service for item 71075 was 12 during 2014–2015; 77 patients received a service for item 71075 more than four times.
- △ There is no clinical utility in testing more than four times within a 12-month period.
- △ The proposed changes will have no direct effect on patients.

4.11 Quantitation of total immunoglobulin A: item 71066

Table 22. Item introduction table for item 71066

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71066	Quantitation of total immunoglobulin A by any	\$14.55	5150	\$63,549	4867	–5.5%

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
	method in serum, urine or other body fluid – 1 test					

4.11.1 Recommendation 11

△ Remove the words ‘urine or other body fluid’ from item 71066.

Table 23. Current and proposed item descriptors for item 71066

Item	Current item descriptor	Proposed item descriptor
71066	Quantitation of total immunoglobulin A by any method in serum, urine or other body fluid – 1 test	Quantitation of total immunoglobulin A by any method in serum – 1 test

4.11.2 Rationale 11

- △ This test should not be performed in urine or other body fluid.
- △ There is no clinical reason to perform an IgA test on body fluids. Testing for the presence of extractable IgA in samples other than peripheral blood is not recommended because there are no clinically validated indications for such testing, and reference intervals cannot be established for such samples, which precludes useful interpretation of such results.
- △ The proposed change does not have a direct effect on patients.

4.12 Quantitation of total immunoglobulin M: item 71072

Table 24. Item introduction table for item 71072

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71072	Quantitation of total immunoglobulin M by any method in serum, urine or other body fluid - 1 test	\$14.55	1004	\$12,340	708	-17.7%

4.12.1 Recommendation 12

△ Remove the words ‘urine or other body fluid’ from item 71072.

Table 25. Current and proposed item descriptors for item 71072

Item	Current item descriptor	Proposed item descriptor
71072	Quantitation of total immunoglobulin M by any method in serum, urine or other body fluid - 1 test	Quantitation of total immunoglobulin M by any method in serum - 1 test

4.12.2 Rationale 12

- △ This test should not be performed in urine or other body fluid. There is no clinical reason to perform an IgM test on body fluids. Testing for the presence of extractable IgM in samples other than peripheral blood is not recommended because there are no clinically validated

indications for such testing, and reference intervals cannot be established for such samples, which precludes useful interpretation of such results.

- △ The proposed change does not have a direct effect on patients.

4.13 Quantitation of total immunoglobulin D: item 71074

Table 26. Item introduction table for item 71074

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71074	Quantitation of total immunoglobulin D by any method in serum, urine or other body fluid - 1 test	\$14.55	250	\$3,054	226	-0.8%

4.13.1 Recommendation 13

- △ Remove the words 'urine or other body fluid' from item 71074.

Table 27. Current and proposed item descriptors for item 71074

Item	Current item descriptor	Proposed item descriptor
71074	Quantitation of total immunoglobulin D by any method in serum, urine or other body fluid - 1 test	Quantitation of total immunoglobulin D by any method in serum - 1 test

4.13.2 Rationale 13

- △ This test should not be performed in urine or other body fluid. There is no clinical reason to perform an IgD test on body fluids. Testing for the presence of extractable IgD in samples other than peripheral blood is not recommended because there are no clinically validated indications for such testing, and reference intervals cannot be established for such samples, which precludes useful interpretation of such results.
- △ The proposed change does not have a direct effect on patients.

4.14 Cryoglobulins or cryofibrinogen: item 71064

Table 28. Item introduction table for item 71064

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71064	Detection and quantitation of cryoglobulins or cryofibrinogen - 1 or more tests	\$20.75	7302	\$126,810	6579	7.5%

4.14.1 Recommendation 14

- △ Increase the MBS fee for item 71064.
- △ The Committee has referred this recommendation to the Pathology Business Group.

4.14.2 Rationale 14

- △ Item 71064 is a test used to determine whether symptoms such as sensitivity of extremities to cold is due to the presence of abnormal proteins called cryoglobulins. Cryoglobulins tend to clump together when exposed to cold temperatures and dissolve when exposed to warm temperatures; they are present in high levels in abnormal protein production in some autoimmune, infectious and blood diseases.
- △ Currently, the MBS fee does not reflect the costs associated with this test. Cryoglobulins are very expensive to collect and transport; this item is often billed with 71062. When a patient attends a laboratory the 'hot box' equipment is available; this is particularly important issue for remote patients who have to travel to the laboratory.
- △ The analysis includes storage of samples at different temperatures and then determination of proportional precipitation day(s) later. Cryoglobulin testing involves the collection of blood in a pre-warmed tube and keeping the blood sample at body temperature during preparation for testing. If samples are not kept at body temperature after venepuncture until analysis, the results will vary widely.
- △ The complexity of this 'pre-analytical' phase requires significant resources—equipment, staff and education—factors not covered by routine patient episode initiation or the current fee for item 71064. Increasing the fee for item 71064 will allow for correct collection and quality results for patients.
- △ The proposed changes will improve access for patients, reduce rates of unnecessary venepuncture, improve how blood samples are collected and increase accuracy of test results.

4.15 Rheumatoid factor: item 71106

Table 29. Item introduction table for item 71106

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71106	Rheumatoid factor - detection by any technique in serum or other body fluids, including quantitation if required	\$11.30	151,083	\$1,451,776	137,204	1.6%

4.15.1 Recommendation 15

- △ Remove the words 'or other body fluids' from the item descriptor of item 71106.
- △ Develop an education program aimed at rheumatologists on how often to request this test in patients with known rheumatoid disease.

4.15.2 Rationale 15

- △ Item 71106 is a test used to determine the levels of autoantibody rheumatoid factor. Rheumatoid factor is elevated in chronic and acute inflammation and can be used to monitor inflammation in rheumatoid arthritis (RA).
- △ During the financial year 2014–2015, for item 71106, a total of 126,263 patients received the service once, 9214 patients received the service twice, 1359 patients received the service three times and 314 patients received the service four times. The maximum number of services received by a single patient was 14 and approximately 212 patients received the service more than four times in the year.

- △ Other biomarkers are also available which are superior for disease monitoring such as C-reactive protein (CRP) or swollen and/or tender joint count.
- △ The Committee used guidelines for RA to extrapolate from the European League Against Rheumatism management guidelines, which state that ‘monitoring should be frequent in active disease (every 1–3 months); if there is no improvement by at most 3 months after the start of treatment or the target has not been reached by 6 months, therapy should be adjusted.’ [5]
- △ The Committee notes that the guidelines refer to monitoring of biomarkers of disease activity, which includes patient pain, patient function, number of swollen or tender joints, ultrasound assessment of blood flow around joints, and blood tests for inflammation. The tests the Committee has reviewed are not markers of activity but are rather markers of diagnostic utility and prognostic impact. Therefore the antibodies referred to should be tested less than the markers of activity.
- △ The Committee proposed a targeted education program for rheumatologists on utility of the test and alternative biomarkers of disease activity.
- △ The Committee proposes to remove other body fluids from the item descriptor because testing in samples other than peripheral blood is not recommended because there are no clinically validated indications for such testing, and reference intervals cannot be established for such samples, which precludes useful interpretation of such results.
- △ Restricting testing of rheumatoid factor will have no direct impact on patients but may indirectly reduce rates of unnecessary venepuncture, reduce rates of false-positive results and subsequently reduce patient anxiety.

4.16 Antibody to cardiolipin: items 71180, 71183, 71186

Table 30. Item introduction table for items 71180, 71183, 71186

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71180	Antibody to cardiolipin or beta-2 glycoprotein I detection, including quantitation if required; one antibody specificity (IgM or IgG)	\$34.55	12,087	\$354,643	11,239	0.3%
71183	Detection of two antibodies described in item 71180	\$47.45	37,334	\$1,500,999	35,157	3.3%
71186	Detection of three or more antibodies described in item 71180	\$60.30	27,236	\$1,397,535	25,474	6.9%

4.16.1 Recommendation 16

- △ Amend the wording of the item descriptor of 71180 to include IgA.
- △ Limit this item by restricting it to four tests within a 12-month period.

4.16.2 Rationale 16

- △ Items 71180, 71183 and 71186 are tests for beta-2 glycoprotein I and cardiolipin antibodies; testing for these antibodies is used to help diagnose antiphospholipid syndrome. Beta-2 glycoprotein and cardiolipin antibody tests detect the presence of three classes: IgG, IgM and/or IgA. IgA testing for beta-2 glycoprotein I antibody and cardiolipin has superior positive predictive value than IgM testing for the same antigens. IgG antibodies are more prevalent, so

IgG antibodies have a higher overall sensitivity than IgA antibodies. IgM testing is present in 71180, but IgA is not, and should be included in this item.

- △ The clinical utility of IgM cardiolipin antibodies is being debated internationally, but the evidence is not definite, and if published guidelines for antiphospholipid syndrome criteria [6] are followed, this is rarely a problem. IgM testing should remain in the item while it is still being mentioned in international guidelines.

Table 31. Current and proposed item descriptors for item 71180

Item	Current item descriptor	Proposed item descriptor
71180	Antibody to cardiolipin or beta-2 glycoprotein i detection, including quantitation if required; one antibody specificity (IgG or IgM)	Antibody to cardiolipin or beta-2 glycoprotein I detection, including quantitation if required; one antibody specificity (IgG or IgM or IgA) <i>item subject to rule 25</i>

4.17 Free kappa and lambda light chains: item 71200

Table 32. Item introduction table for item 71200

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
71200	Detection and quantitation, if present, of free kappa and lambda light chains in serum for the diagnosis or monitoring of amyloidosis, myeloma or plasma cell dyscrasias.	\$59.60	103,074	\$5,197,217	52,277	27.6%

4.17.1 Recommendation 17

- △ Amend the item descriptor by including the wording: ‘this test is not to be used for the diagnosis or monitoring of lymphoma’.

Table 33. Current and proposed item descriptors for item 71200

Item	Current item descriptor	Proposed item descriptor
71200	Detection and quantitation, if present, of free kappa and lambda light chains in serum for the diagnosis or monitoring of amyloidosis, myeloma or plasma cell dyscrasias.	Detection and quantitation, if present, of free kappa and lambda light chains in serum for the diagnosis or monitoring of amyloidosis, myeloma or plasma cell dyscrasias. This test is not to be used for the diagnosis or monitoring of lymphoma.

4.17.2 Rationale 17

- △ Item 71200 is serum free light-chain testing used to help diagnose plasma cell disorders (dyscrasias) including myeloma and primary amyloidosis. The utilisation of item 71200 appears to be equal across the states and territories. The Committee recognises that the utilisation of item 71200 is increasing. This is a test mainly requested by haematologists. This item cannot be restricted within a 12-month period, as some patients are treated with particular dialysis therapy. Such patients will require this test every time they undergo dialysis.
- △ The Committee recommends a change to the item descriptor wording to specifically exclude the use of this test in lymphoma to reinforce that the clinical utility of these tests are in the assessment of plasma cell disorders only. Lymphoma is specifically excluded from this item, as the diagnosis and management of lymphoma does not require measurement of light chains.

4.18 Items to be deleted

4.18.1 Recommendation 18

The following items are to be deleted from the MBS as the items are obsolete and are no longer used in clinical practice. These items are not supported by current treatment strategies.

Table 34. Items to be deleted

Item	Item descriptor	Schedule fee (\$)	Services (2014–15)
71095	Quantitation of serum or plasma eosinophil cationic protein, or both, to a maximum of 3 assays in 1 year, for monitoring the response to therapy in corticosteroid treated asthma, in a child aged less than 12 years	40.55	83
71096	A test described in item 71095 if rendered by a receiving APP, (Item is subject to rule 18)	40.55	3
71137	Quantitation of cell-mediated immunity by multiple antigen delayed type hypersensitivity intradermal skin testing using a minimum of 7 antigens, 1 of this item to a maximum of 2 in a 12 month period	30.25	0
71203	Determination of hlab5701 status by flow cytometry or cytotoxicity assay prior to the initiation of abacavir therapy including item 73323 if performed.	40.55	0

4.19 No changes

4.19.1 Recommendation 19

The Committee recommends that the MBS items listed in Table 35 do not require amendment, as they are clinically appropriate.

Table 35. MBS items that do not require amendment

Item	Item descriptor	Schedule fee (\$)	Services (2014–15)
71057	Electrophoresis, quantitative and qualitative, of serum, urine or other body fluid all collected within a 28 day period, to demonstrate: (a) protein classes; or (b) presence and amount of paraprotein; including the preliminary quantitation of total protein, albumin and globulin - 1 specimen type	32.90	266,770
71058	Examination as described in item 71057 of 2 or more specimen types	50.50	39,204
71059	Immunofixation or immunoelectrophoresis or isoelectric focusing of:(a) urine for detection of bence jones proteins; or(b) serum, plasma or other body fluid; and characterisation of a paraprotein or cryoglobulin - examination of 1 specimen type (e.g. serum, urine or csf)	35.65	143,431
71060	Examination as described in item 71059 of 2 or more specimen types	44.05	24,043
71062	Electrophoresis and immunofixation or immunoelectrophoresis or isoelectric focussing of CSF for the detection of oligoclonal bands and including if required electrophoresis of the patient's serum for comparison purposes - 1 or more tests	44.05	1,873
71068	Quantitation of total immunoglobulin G by any method in serum, urine or other body fluid - 1 test	14.55	18,765
71069	2 tests described in items 71066, 71068, 71072 or 71074	22.75	9,172
71071	3 or more tests described in items 71066, 71068, 71072 or 71074	30.95	178,803

Item	Item descriptor	Schedule fee (\$)	Services (2014–15)
71073	Quantitation of all 4 immunoglobulin G subclasses	106.15	20,209
71076	A test described in item 71073 if rendered by a receiving APP - 1 test (Item is subject to rule 18)	106.15	2,009
71081	Quantitation of total haemolytic complement	40.55	3,203
71090	A test described in item 71089, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test (Item is subject to rule 6 and 18)	29.15	357
71092	Tests described in item 71089, other than that described in 71090, if rendered by a receiving APP - each test to a maximum of 2 tests (Item is subject to rule 6 and 18)	23.70	1,072
71127	Functional tests for lymphocytes - quantitation other than by microscopy of: (a) proliferation induced by 1 or more mitogens; or (b) proliferation induced by 1 or more antigens; or (c) estimation of 1 or more mixed lymphocyte reactions; including a test described in item 65066 or 65070 (if performed), 1 of this item to a maximum of 2 in a 12 month period	176.35	244
71129	2 tests described in item 71127	217.85	120
71131	3 or more tests described in item 71127	259.35	16
71133	Investigation of recurrent infection by qualitative assessment for the presence of defects in oxidative pathways in neutrophils by the nitroblue tetrazolium (nbt) reduction test	10.40	21
71134	Investigation of recurrent infection by quantitative assessment of oxidative pathways by flow cytometric techniques, including a test described in 71133 (if performed)	104.05	144
71135	Quantitation of neutrophil function, comprising at least 2 of the following: (a) chemotaxis; (b) phagocytosis; (c) oxidative metabolism; (d) bactericidal activity; including any test described in items 65066, 65070, 71133 or 71134 (if performed), 1 of this item to a maximum of 2 in a 12 month period	207.95	983
71139	Characterisation of 3 or more leucocyte surface antigens by immunofluorescence or immunoenzyme techniques to assess lymphoid or myeloid cell populations, including a total lymphocyte count or total leucocyte count by any method, on 1 or more specimens of blood, CSF or serous fluid	\$104.05	53,570
71141	Characterisation of 3 or more leucocyte surface antigens by immunofluorescence or immunoenzyme techniques to assess lymphoid or myeloid cell populations on 1 or more disaggregated tissue specimens	197.35	1,420
71143	Characterisation of 6 or more leucocyte surface antigens by immunofluorescence or immunoenzyme techniques to assess lymphoid or myeloid cell populations for the diagnosis (but not monitoring) of an immunological or haematological malignancy, including a service described in 1 or both of items 71139 and 71141 (if performed), on a specimen of blood, CSF, serous fluid or disaggregated tissue	260.00	66,141
71145	Characterisation of 6 or more leucocyte surface antigens by immunofluorescence or immunoenzyme techniques to assess lymphoid or myeloid cell populations for the diagnosis (but not monitoring) of an immunological or haematological malignancy, including a service described in 1 or more of items 71139, 71141 and 71143 (if performed), on 2 or more specimens of disaggregated tissues or 1 specimen of disaggregated tissue and 1 or more specimens of blood, CSF or serous fluid	424.50	3,705
71146	Enumeration of cd34+ cells, only for the purposes of autologous or directed allogeneic haemopoietic stem cell	104.05	2,768

Item	Item descriptor	Schedule fee (\$)	Services (2014–15)
	transplantation, including a total white cell count on the pheresis collection		
71147	HLA-B27 typing (Item is subject to rule 27)	40.55	52,955
71148	A test described in item 71147 if rendered by a receiving APP. (Item is subject to rule 18 and 27)	40.55	3,420
71149	Complete tissue typing for 4 HLA-A and HLA-B Class I antigens (including any separation of leucocytes), including (if performed) a service described in item 71147	108.25	3,663
71153	Investigations in the assessment or diagnosis of systemic inflammatory disease or vasculitis - antineutrophil cytoplasmic antibody immunofluorescence (anca test), antineutrophil proteinase 3 antibody (pr-3 anca test), antimyeloperoxidase antibody (mpo anca test) or antiglomerular basement membrane antibody (gbm test) - detection of 1 antibody (item is subject to rule 6 and 23)	34.55	89,567
71154	A test described in item 71153, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test.(Item is subject to rule 6, 18 and 23)	34.55	3,035
71155	Detection of 2 antibodies described in item 71153	47.45	6,387
71156	Tests described in item 71153, other than that described in 71154, if rendered by a receiving APP each test to a maximum of 3 tests(Item is subject to rule 6, 18 and 23)	12.85	4,320
71157	Detection of 3 antibodies described in item 71153(item is subject to rule 6 and 23)	60.30	33,610
71159	Detection of 4 or more antibodies described in item 71153 (Item is subject to rule 6 and 23)(item is subject to rule 6 and 23)"	73.15	1,948
71170	Tests described in item 71165, other than that described in 71169, if rendered by a receiving APP – each test to a maximum of 3 tests. (Item is subject to rule 6 and 18.)	12.85	15,399
71189	Detection of specific igg antibodies to 1 or more respiratory disease allergens not elsewhere specified.	15.50	1,872
71192	2 items described in item 71189.	28.35	434
71195	3 or more items described in item 71189.	40.05	457
71198	Estimation of serum tryptase for the evaluation of unexplained acute hypotension or suspected anaphylactic event, assessment of risk in stinging insect anaphylaxis, exclusion of mastocytosis, monitoring of known mastocytosis.	40.55	11,570

Source: Department of Human Services, date of processing

5. Referred items

5.1 Erythrocyte sedimentation rate (ESR)

ESR was a priority item identified for review by the Taskforce following submissions from the Royal College of Pathologists of Australasia (RCPA) and Public Pathology Australia to the Taskforce. The Committee sought input on ESR from both immunology and haematology experts.

Table 36. Item introduction for item 65060

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count	Services 5-year annual average growth
65060	Haemoglobin, erythrocyte sedimentation rate, blood viscosity -1 or more tests	\$7.85	175,678	\$1,153,004	137,360	-3.2%

5.1.1 Recommendation 20

△ The Committee proposes to leave ESR unchanged on the MBS.

5.1.2 Rationale 20

- △ The Committee discussed the ESR literature review and noted its findings and limitations.
- △ The Committee noted that patients may require ESR testing to be eligible to access biological disease modifying anti-rheumatic drugs (bDMARDs) through the PBS. Although CRP testing can also be used for most patients, ESR still plays a role in determining which patients should initiate and/or continue bDMARD therapy.

The Committee noted the following issues with ESR:

- △ ESR is very likely to have inferior performance to that of CRP for detection of inflammation.
- △ Biological variance between individuals is the reason that occasional samples are discordant in favour of ESR over CRP, and not reflective of a higher assay performance.
- △ Every time inflammatory biomarkers are evaluated head-to-head (i.e. each time a new marker becomes available, such as CD64, sCD14, PCT and SOFA), CRP outperforms ESR. Unfortunately historical indications (e.g. osteomyelitis, Hodgkin's disease) are not being revisited in this way, therefore there is an absence of evidence.
- △ On the other hand, for Hodgkin's disease, for example, the European Organisation for Research and Treatment of Cancer (EORTC), National Cancer Institute of Canada (NCIC), and German Study Hodgkin Lymphoma Study Group (GSHG) use ESR (50 mm/hour if no B symptoms, 30 mm/hour with B symptoms), but other scoring systems such as the Hasenclever use WBC instead. Some might consider that this suggests a WBC might be of comparable performance.
- △ In regard to sepsis and infection, these are all disappointing in studies with wider recruitment. Respiratory rate is a very good biomarker for sepsis, and much under-used.
- △ There is low clinical utility for the ESR item and the test is variable.
- △ ESR is considered to have a limited clinical role; however, international clinical guidelines still mention the use of ESR. It would be challenging to remove this test from the MBS without significant clinical 'push back'.

6. Recommendations to the Medical Services Advisory Committee

The Committee has also developed provisional recommendations for the consideration of other committees. The item-level recommendations can found below.

6.1 Neuromyelitis optica (NMO) antibody testing

6.1.1 Recommendation 21

- △ Create a new item for NMO-antibody testing with the following item descriptor wording:
 - To investigate the presence of neuromyelitis optica by the detection of aquaporin 4 antibodies in serum and/or cerebrospinal fluid (CSF).

6.1.2 Rationale 21

- △ The Committee recognises that the current MBS does not reflect current clinical practice and proposes that a new item be created for this test to be remunerated within the MBS.
- △ An NMO test is a test has been in clinical use for 10 years and is used to diagnose a treatable disease known as neuromyelitis optica. This disease is similar to multiple sclerosis and presents with optic neuritis and spinal cord inflammation that can lead to paraplegia and blindness.
- △ The disease can be diagnosed by other methods; however, this test provides a rapid diagnosis in young people. This test is important as it helps with diagnosis of neuromyelitis optica and it leads to specific treatment early in the course of the disease that can have a significant impact on patient outcomes.
- △ Use of this test is supported by the International consensus diagnostic criteria for neuromyelitis optica spectrum disorder. [7] It is also supported by the European Federation of Neurological Societies guidelines on diagnosis and management of neuromyelitis optica. [8] This test is mainly used by neurologists to diagnose this disease.
- △ The Committee recommends an education campaign on the utility and frequency of test.
- △ In most samples, testing will be for diagnosis only. Patients will often require repeat testing to see whether they have had a relapse. Significant changes in antibody levels will not occur more often than every 3 months. Over-testing for antibody levels does not add clinical value. The Committee estimates the utilisation of this test to be 5000 per year based on the prevalence of NMO in a study that was reported as 0.33 per 100,000. [9]

6.2 Antibodies to citrullinated peptide antigens

These antibodies are also referred to as cyclic citrullinated peptide antibodies (CCP).

6.2.1 Recommendation 22

- △ Create a new item for cyclic citrullinated peptide antibodies with the following wording:
 - Investigation for rheumatoid arthritis: citrullinated peptide antibodies.
- △ Add rule 25 to restrict this item to three tests within a 12-month period.

Table 37. Proposed new item descriptor for antibodies to citrullinated peptide antigens

Item	Item descriptor
New item	Investigation for rheumatoid arthritis: citrullinated peptide antibodies, excludes item 71119. (Item is subject to rule 25)

6.2.2 Rationale 22

- △ The Committee recognises that this test has been in clinical practice for about 15 years; however, this test has not been on the MBS. Currently there is no item specifically for this test and it is being billed under item 71119. This is a high-utility test that impacts greatly on treatment and disease classification. It is a robust test that produces quality results when there is an increase in antibodies. It is the standard of care in rheumatoid arthritis to have this test done and it has high clinical utility in the monitoring of drugs but not in monitoring of disease.
- △ The Committee recognises that the current schedule does not reflect current clinical practice and proposes that a new item be created for this test to be remunerated (at a higher rate than item 71119, which is currently being used to capture this test) within the MBS. The Committee estimates the utilisation to be approximately 150,000 services per annum.
- △ The Committee has proposed that this item also be limited to three tests in a 12-month period, as there is no clinical need to test more often than this. Other biomarkers are available that are superior for disease monitoring, such as CRP or swollen and/or tender joint count.

7. References

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8. Glossary

Term	Description
CAGR	Compound annual growth rate, or the average annual growth rate over a specified time period.
Change	Describes when the item and/or its services will be affected by the recommendations. This could result from a range of recommendations, such as: (i) specific recommendations that affect the services provided by changing item descriptors or explanatory notes, (ii) the consolidation of item numbers, and (iii) splitting item numbers (e.g. splitting the current services provided across two or more items).
CRP	C-reactive protein
Delete	Describes when an item is recommended for removal from the MBS and its services will no longer be provided under the MBS.
FY	Financial year
GP	General practitioner
High-value care	Services of proven efficacy reflecting current best medical practice, or for which the potential benefit to consumers exceeds the risk and costs.
Ig	Immunoglobulin
Inappropriate use/misuse	Use of MBS services for purposes other than those intended. This includes a range of behaviours, from failing to adhere to particular item descriptors or rules through to deliberate fraud.
Low-value care	Use of an intervention that evidence suggests confers little benefit or no benefit to patients; or when the risk of harm from the intervention exceeds the likely benefit; or, more broadly, when the added costs of the intervention do not provide proportional added benefits.
MBS	Medicare Benefits Schedule
MBS item	An administrative object listed in the MBS and used for the purposes of claiming and paying Medicare benefits, consisting of an item number, service descriptor and supporting information, schedule fee and Medicare benefits.
MBS service	The actual medical consultation, procedure or test to which the relevant MBS item refers.
MSAC	Medical Services Advisory Committee
Multiple services rules	A set of rules governing the amount of Medicare benefit payable for multiple services provided to a patient at the same attendance (same day).
New service	Describes when a new service has been recommended, with a new item number. In most circumstances these will need to go through MSAC. It is worth noting that implementation of the recommendation may result in more or fewer item numbers than specifically stated.
No change or unchanged	Describes when the services provided under these items will not be changed or affected by the recommendations. This does not rule out small changes in item descriptors (e.g. references to other items, which may have changed as a result of the MBS Review or prior reviews).
Obsolete services/items	Services that should no longer be performed, as they do not represent current clinical best practice and have been superseded by superior tests or procedures.
PEI	Patient episode initiation
PBS	Pharmaceutical Benefits Scheme
PCC	Pathology Clinical Committee
PSAC	Pathology Services Advisory Committee
RA	Rheumatoid arthritis
RACGP	Royal Australian College of General Practitioners
Rule 25	For any particular patient, this item is applicable not more than once in a 12-month period
The Taskforce	MBS Review Taskforce

Appendix A – Immunology-related pathology test items – recommendations list

Table A1. MBS items considered by the committee

Item	Current descriptor	Recommendation	Section reference
71163	Detection of one of the following antibodies (of 1 or more class or isotype) in the assessment or diagnosis of coeliac disease or other gluten hypersensitivity syndromes and including a service described in item 71066 (if performed): a) Antibodies to gliadin; or b) Antibodies to endomysium; or c) Antibodies to tissue transglutaminase; - 1 test	Change	4.1.1
71164	Two or more tests described in 71163 and including a service described in 71066 (if performed)	No change	4.1.1
71151	Tissue typing for HLA-DR, HLA-DP and HLA-DQ Class II antigens (including any separation of leucocytes) - phenotyping or genotyping of 2 or more antigens	Change	4.2.1
71079	Detection of specific immunoglobulin E (IgE) antibodies to single or multiple potential allergens, 1 test (Item is subject to rule 25)	Change	4.3.1
71097	Antinuclear antibodies - detection in serum or other body fluids, including quantitation if required	Change	4.4.1
71099	Double-stranded DNA antibodies - quantitation by 1 or more methods other than the Crithidia method	Change	4.5.1
71101	Antibodies to 1 or more extractable nuclear antigens - detection in serum or other body fluids	Change	4.6.1
71103	Characterisation of an antibody detected in a service described in item 71101 (including that service)	Change	4.6.1
71083	Quantitation of complement components C3 and C4 or properdin factor B – 1 test	Change	4.7.1
71085	2 tests described in item 71083	Change	4.7.1
71087	3 or more tests described in item 71083	Delete	4.7.1
71089	Quantitation of complement components or breakdown products of complement proteins not elsewhere described in an item in this Schedule - 1 test (Item is subject to rule 6)	Change	4.7.1
71091	2 tests described in item 71089 (Item is subject to rule 6)	Change	4.7.1
71093	3 or more tests described in item 71089 (Item is subject to rule 6)	Change	4.7.1
71119	Antibodies to tissue antigens not elsewhere specified in this Table - detection, including quantitation if required, of 1 antibody	No change	4.8.1
71121	Detection of 2 antibodies specified in item 71119	No change	4.8.1
71123	Detection of 3 antibodies specified in item 71119	No change	4.8.1
71125	Detection of 4 or more antibodies specified in item 71119	Change	4.8.1
71165	Antibodies to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet,	Change	4.9.1

Item	Current descriptor	Recommendation	Section reference
	salivary gland, skeletal muscle, skin basement membrane and intercellular substance, thyroglobulin, thyroid microsome or thyroid stimulating hormone receptor) - detection, including quantitation if required, of 1 antibody (Item is subject to rule 6)		
71075	Quantitation of immunoglobulin E (total), (IgE) 1 test. (Item is subject to rule 25)	Change	4.10.1
71077	Quantitation of immunoglobulin E (total) (IgE) in the follow up of a patient with proven immunoglobulin-E-secreting myeloma, proven congenital immunodeficiency or proven allergic bronchopulmonary aspergillosis, 1 test. (Item is subject to rule 25)	Delete	4.10.1
71066	Quantitation of total immunoglobulin a by any method in serum, urine or other body fluid – 1 test	Change	4.11.1
71072	Quantitation of total immunoglobulin m by any method in serum, urine or other body fluid - 1 test	Change	4.12.1
71074	Quantitation of total immunoglobulin d by any method in serum, urine or other body fluid - 1 test	Change	4.13.1
71064	Detection and quantitation of cryoglobulins or cryofibrinogen - 1 or more tests	Change	4.14.1
71106	Rheumatoid factor - detection by any technique in serum or other body fluids, including quantitation if required	Change	4.15.1
71180	Antibody to cardiolipin or beta-2 glycoprotein I detection, including quantitation if required; one antibody specificity (IgM or IgG)	Change	4.16.1
71183	Detection of two antibodies described in item 71180	No change	4.16.1
71186	Detection of three or more antibodies described in item 71180	No change	4.16.1
71200	Detection and quantitation, if present, of free kappa and lambda light chains in serum for the diagnosis or monitoring of amyloidosis, myeloma or plasma cell dyscrasias.	Change	4.17.1
71095	Quantitation of serum or plasma eosinophil cationic protein, or both, to a maximum of 3 assays in 1 year, for monitoring the response to therapy in corticosteroid treated asthma, in a child aged less than 12 years	Delete	4.18.1
71096	A test described in item 71095 if rendered by a receiving APP, (Item is subject to rule 18)	Delete	4.18.1
71137	Quantitation of cell-mediated immunity by multiple antigen delayed type hypersensitivity intradermal skin testing using a minimum of 7 antigens, 1 of this item to a maximum of 2 in a 12 month period	Delete	4.18.1
71203	Determination of hlab5701 status by flow cytometry or cytotoxicity assay prior to the initiation of abacavir therapy including item 73323 if performed.	Delete	4.18.1
71170	Tests described in item 71165, other than that described in 71169, if rendered by a receiving APP – each test to a maximum of 3 tests. (Item is subject to rule 6 and 18.)	No change	4.19.1
71057	Electrophoresis, quantitative and qualitative, of serum, urine or other body fluid all collected within a 28 day period, to demonstrate: (a) protein classes; or (b) presence and amount	No change	4.19.1

Item	Current descriptor	Recommendation	Section reference
	of paraprotein; including the preliminary quantitation of total protein, albumin and globulin - 1 specimen type		
71058	Examination as described in item 71057 of 2 or more specimen types	No change	4.19.1
71059	Immunofixation or immunoelectrophoresis or isoelectric focusing of:(a) urine for detection of bence jones proteins; or(b) serum, plasma or other body fluid; and characterisation of a paraprotein or cryoglobulin -examination of 1 specimen type (e.g. serum, urine or csf)	No change	4.19.1
71060	Examination as described in item 71059 of 2 or more specimen types	No change	4.19.1
71062	Electrophoresis and immunofixation or immunoelectrophoresis or isoelectric focussing of CSF for the detection of oligoclonal bands and including if required electrophoresis of the patient's serum for comparison purposes - 1 or more tests	No change	4.19.1
71068	Quantitation of total immunoglobulin g by any method in serum, urine or other body fluid - 1 test	No change	4.19.1
71069	2 tests described in items 71066, 71068, 71072 or 71074	No change	4.19.1
71071	3 or more tests described in items 71066, 71068, 71072 or 71074	No change	4.19.1
71073	Quantitation of all 4 immunoglobulin G subclasses	No change	4.19.1
71076	A test described in item 71073 if rendered by a receiving APP - 1 test(Item is subject to rule 18)	No change	4.19.1
71081	Quantitation of total haemolytic complement	No change	4.19.1
71090	A test described in item 71089, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test(Item is subject to rule 6 and 18)	No change	4.19.1
71092	Tests described in item 71089, other than that described in 71090, if rendered by a receiving APP - each test to a maximum of 2 tests(Item is subject to rule 6 and 18)	No change	4.19.1
71127	Functional tests for lymphocytes - quantitation other than by microscopy of: (a) proliferation induced by 1 or more mitogens; or (b) proliferation induced by 1 or more antigens; or (c) estimation of 1 or more mixed lymphocyte reactions; including a test described in item 65066 or 65070 (if performed), 1 of this item to a maximum of 2 in a 12 month period	No change	4.19.1
71129	2 tests described in item 71127	No change	4.19.1
71131	3 or more tests described in item 71127	No change	4.19.1
71133	Investigation of recurrent infection by qualitative assessment for the presence of defects in oxidative pathways in neutrophils by the nitroblue tetrazolium (nbt) reduction test	No change	4.19.1
71134	Investigation of recurrent infection by quantitative assessment of oxidative pathways by flow cytometric techniques, including a test described in 71133 (if performed)	No change	4.19.1
71135	Quantitation of neutrophil function, comprising at least 2 of the following: (a) chemotaxis; (b) phagocytosis; (c) oxidative metabolism; (d) bactericidal activity; including any test	No change	4.19.1

Item	Current descriptor	Recommendation	Section reference
	described in items 65066, 65070, 71133 or 71134 (if performed), 1 of this item to a maximum of 2 in a 12 month period		
71139	Characterisation of 3 or more leucocyte surface antigens by immunofluorescence or immunoenzyme techniques to assess lymphoid or myeloid cell populations, including a total lymphocyte count or total leucocyte count by any method, on 1 or more specimens of blood, CSF or serous fluid	No change	4.19.1
71141	Characterisation of 3 or more leucocyte surface antigens by immunofluorescence or immunoenzyme techniques to assess lymphoid or myeloid cell populations on 1 or more disaggregated tissue specimens	No change	4.19.1
71143	Characterisation of 6 or more leucocyte surface antigens by immunofluorescence or immunoenzyme techniques to assess lymphoid or myeloid cell populations for the diagnosis (but not monitoring) of an immunological or haematological malignancy, including a service described in 1 or both of items 71139 and 71141 (if performed), on a specimen of blood, CSF, serous fluid or disaggregated tissue	No change	4.19.1
71145	Characterisation of 6 or more leucocyte surface antigens by immunofluorescence or immunoenzyme techniques to assess lymphoid or myeloid cell populations for the diagnosis (but not monitoring) of an immunological or haematological malignancy, including a service described in 1 or more of items 71139, 71141 and 71143 (if performed), on 2 or more specimens of disaggregated tissues or 1 specimen of disaggregated tissue and 1 or more specimens of blood, CSF or serous fluid	No change	4.19.1
71146	Enumeration of cd34+ cells, only for the purposes of autologous or directed allogeneic haemopoietic stem cell transplantation, including a total white cell count on the pheresis collection	No change	4.19.1
71147	HLA-B27 typing (Item is subject to rule 27)	No change	4.19.1
71148	A test described in item 71147 if rendered by a receiving APP. (Item is subject to rule 18 and 27)	No change	4.19.1
71149	Complete tissue typing for 4 HLA-A and HLA-B Class I antigens (including any separation of leucocytes), including (if performed) a service described in item 71147	No change	4.19.1
71153	Investigations in the assessment or diagnosis of systemic inflammatory disease or vasculitis - antineutrophil cytoplasmic antibody immunofluorescence (anca test), antineutrophil proteinase 3 antibody (pr-3 anca test), antimyeloperoxidase antibody (mpo anca test) or antiglomerular basement membrane antibody (gbm test) - detection of 1 antibody (item is subject to rule 6 and 23)	No change	4.19.1
71154	A test described in item 71153, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test.(Item is subject to rule 6, 18 and 23)	No change	4.19.1
71155	Detection of 2 antibodies described in item 71153	No change	4.19.1
71156	Tests described in item 71153, other than that described in 71154, if rendered by a receiving APP each test to a maximum of 3 tests(Item is subject to rule 6, 18 and 23)	No change	4.19.1
71157	Detection of 3 antibodies described in item 71153 (item is subject to rule 6 and 23)	No change	4.19.1

Item	Current descriptor	Recommendation	Section reference
71159	Detection of 4 or more antibodies described in item 71153 (Item is subject to rule 6 and 23)	No change	4.19.1
71189	Detection of specific IgG antibodies to 1 or more respiratory disease allergens not elsewhere specified.	No change	4.19.1
71192	2 items described in item 71189.	No change	4.19.1
71195	3 or more items described in item 71189.	No change	4.19.1
71198	Estimation of serum tryptase for the evaluation of unexplained acute hypotension or suspected anaphylactic event, assessment of risk in stinging insect anaphylaxis, exclusion of mastocytosis, monitoring of known mastocytosis.	No change	4.19.1
65060	Haemoglobin, erythrocyte sedimentation rate, blood viscosity - 1 or more tests	No change	5.1.1

Appendix B – Summary for consumers

This summary describes the medical service, the recommendations of the clinical experts and why the recommendation(s) has been made.

Recommendation 1: Coeliac disease tests				
Items	What it does	Committee recommendation	What would be different	Why
71163, 71164	These tests detect one (71163) or more (71164) immune-responses to gluten. They are used to diagnose coeliac disease or gluten-hypersensitivity syndromes.	Advise health professionals on the appropriate use of these tests. Limit testing to four times a year per patient	The description of the test would be changed to reflect the Committee's recommendations, so that only at-risk people qualify for testing	Many more people are being tested than end up having the condition, possibly because increased awareness campaigns about gluten intolerance have overstated how common coeliac disease is.

Recommendation 2: Genotyping for coeliac disease risk for DQ2 and DQ8				
Item	What it does	Committee recommendation	What would be different	Why
71151 and new item	This item provides rebates for 'tissue typing' tests, which are needed when transplanting organs and tissues. This item can currently be used to test for the 'DQ2' and 'DQ8' genes, which can indicate whether a person has coeliac disease.	Change the description of the existing item to prevent it from being used to check for coeliac disease. Create a new item to use specifically for checking for coeliac disease and limit it to twice a year per patient.	Only the new test would be used to check for the possibility coeliac disease	It is likely that requests for testing tissue types in possible coeliac disease are being included under existing item 71151, which includes other tests not related to coeliac disease.

Recommendation 3: Specific immunoglobulin E antibodies

Item	What it does	Committee recommendation	What would be different	Why
71079	This test is used to detect allergic responses to specific allergens, by detecting and measuring immunoglobulin E (a type of antibody associated with allergic reactions).	Create a new item for the newer, more accurate (but more expensive) tests that have been developed for measuring IgE. Keep only the older, more established tests in the current item. Limit testing with the new test to four times a year per patient.	Overuse of the newer techniques would be reduced, and a separate test would enable monitoring of how many people require the newer techniques and who requests them.	To enable more accurate diagnosis and greater monitoring.

Recommendation 4: Antinuclear antibodies tests

Item	What it does	Committee recommendation	What would be different	Why
71097	An antinuclear antibody is an antibody that targets the “normal” proteins where the DNA is stored inside cells. The presence of large amount of antinuclear antibodies can indicate a person has an autoimmune disease. This test is used to measure the amount of antinuclear antibodies a person has.	Educate health professionals about correct use of this test.	Health professionals would better understand the intended use of repeat testing for this item, reducing incorrect use of the test	In some patients, this test is being ordered too frequently without any clinical benefit to the patient.

Recommendation 5: Double-stranded DNA antibodies

Item	What it does	Committee recommendation	What would be different	Why
71099	<p>A double stranded DNA antibody is an antibody that targets DNA within a person's own body.</p> <p>The presence of large amount of this antibody can indicate a person has an autoimmune disease.</p> <p>This test determines if a person has any double stranded DNA antibodies.</p>	<p>Change the description so that the 'Crithidia method' is not excluded</p>	<p>The test would no longer exclude this method of testing for an immune response against the body's own DNA</p>	<p>The Crithidia method is considered to be a valid test and there is no reason to exclude it</p>

Recommendation 6: Antibodies to extractable nuclear antigens

Items	What it does	Committee recommendation	What would be different	Why
71101, 71103	<p>Extracts (71101) and identifies (71103) inappropriate immune responses to various proteins from the cell nucleus (central portion of the cell containing DNA/genes)</p>	<p>Change item 71101 to ensure that the test is performed using serum.</p> <p>Monitor items 71101 and 71103.</p> <p>Audit laboratories where the ratio of item 71103: 71101 is more than one third.</p>	<p>Testing would only be possible four times a year for individual patients</p>	<p>Test 71101 may be being repeated unnecessarily for monitoring (it should only be repeated if the patient's condition changes)</p>

Recommendation 7: Quantitation of complement components

Item	What it does	Committee recommendation	What would be different	Why
71083, 71085, 71087, 71089, 71091, 71093	<p>Tests for chemicals produced by the body in an immune response, which complement the response by immune cells</p>	<p>Delete item 71087 and update the descriptions for the other items to reflect advances in testing and remove outdated information</p>	<p>Item 71087 would no longer be available, while the descriptions for the remaining items would be brought into line with advances in testing</p>	<p>Item 71087 is now outdated. Knowledge and use of the more advanced testing has increased, so the available tests need to reflect this</p>

Recommendation 8: Antibodies to tissue antigens

Item	What it does	Committee recommendation	What would be different	Why
71119, 71121, 71123, 71125	Identifies inappropriate immune responses to specific body tissues not included in the next Recommendation	Create a new item to capture how many people have 5 or more such immune responses	We could know how many patients need 4 tests and how many needed 5 or more (we can't do this currently)	Some patients need a test for 4 specific immune responses, others for 5 or more to identify the cause of their disease Patients with one abnormal immune response have a tendency to produce more than one immune response

Recommendation 9: Antibodies to tissue antigens

Item	What it does	Committee recommendation	What would be different	Why
71165	Identifies inappropriate immune responses to specific body tissues	Remove the references to thyroid gland and salivary gland	The item description would not refer to testing for immune responses to these two glands	The salivary gland test is no longer considered useful, and a new thyroid test is proposed in the pathology section of the MBS

Recommendation 10: Quantitation of Immunoglobulin E

Item	What it does	Committee recommendation	What would be different	Why
71075, 71077	Measures the extent of an immune response handled by 'IgE' (one of the body's main immune molecules), either at an initial consultation (item 71077) or when following up certain conditions (71077)	Merge these two items into one and limit testing to four times a year per patient	Item 71077 would be merged into item 71075, with the lower cost of 71077 applied to 71075, then item 71077 would be deleted	Item 71077 is under-used because of difficulty with the description and higher cost. The changes will simplify the MBS.

Recommendation 11: Quantitation of total Immunoglobulin A

Item	What it does	Committee recommendation	What would be different	Why
71072	Measures the extent of an immune response handled by 'IgM' (one of the body's main immune molecules)	Remove the words 'urine or other body fluid' from the description	The test would refer only to blood serum, not to urine or other body fluids	This test should not be performed using urine or other body fluids as it is of no medical value

Recommendation 12: Quantitation of total Immunoglobulin M

Item	What it does	Committee recommendation	What would be different	Why
71072	Measures the extent of an immune response handled by 'IgM' (one of the body's main immune molecules)	Remove the words 'urine or other body fluid' from the description	The test would refer only to blood serum, not to urine or other body fluids	This test should not be performed using urine or other body fluids as it is of no medical value
71072	Measures the extent of an immune response handled by 'IgM' (one of the body's main immune molecules)	Remove the words 'urine or other body fluid' from the description	The test would refer only to blood serum, not to urine or other body fluids	This test should not be performed using urine or other body fluids as it is of no medical value

Recommendation 13: Quantitation of total Immunoglobulin D

Item	What it does	Committee recommendation	What would be different	Why
71074	Measures the extent of an immune response handled by 'IgD' (one of the body's main immune molecules)	Remove the words 'urine or other body fluid' from the description	The test would refer only to blood serum, not to urine or other body fluids	This test should not be performed using urine or other body fluids as it is of no medical value

Recommendation 14: Cryoglobulins or cryofibrinogen

Item	What it does	Committee recommendation	What would be different	Why
71064	Checks for abnormal forms of these molecules in the blood which are sensitive to cold	Increase the Schedule fee for this item	The new cost would cover the test's actual cost including specialised collection and transport	The current Schedule fee does not reflect the associated costs because cryoglobulins are very expensive to collect and transport

Recommendation 15: Rheumatoid factor

Item	What it does	Committee recommendation	What would be different	Why
71106	Detects a specific inappropriate immune response against IgG (one of the body's main immune molecules) seen in rheumatoid arthritis	Limit testing to four times a year per patient, and educate rheumatologists on appropriate use	The current overuse of the test would be reduced	Testing more than 4 times a year is inappropriate because it is of no medical value. Education needs to address testing by rheumatologists

Recommendation 16: Antibody to cardiolipin

Item	What it does	Committee recommendation	What would be different	Why
71180, 71183, 71186	Detects an inappropriate immune response against cardiolipin, seen in a range of diseases	Change the description of item 71180 to include immunoglobulin A (IgA [another of the body's main immune molecules]). Limit testing to four times a year per patient	IgA testing would be included with IgG and IgM testing. Overuse of the test would be prevented.	IgA testing is also of value together with IgG and IgM testing for detecting this immune response.

Recommendation 17: Free kappa and lambda light chains

Item	What it does	Committee recommendation	What would be different	Why
71200	Measures the amounts of these components, which are elevated in certain types of blood cancers (myeloma)	Change the description to prevent the test being used to diagnose/monitor lymphoma	Requesters (mainly haematologists) would not be able to use to this test for diagnosing/monitoring lymphoma	Use of this test is increasing more than it should. Others test should be used to diagnose/monitor lymphoma

Recommendation 21: NMO testing

Item	What it does	Committee recommendation	What would be different	Why
New item	Provides rapid diagnosis of this newly-described condition to 3 times a year per patient	Create a new item for this test	The new test would provide access that wasn't available before	Use of this test is supported by expert international guidelines and consensus

Recommendation 22: Antibodies to citrullinated peptide antigens

Item	What it does	Committee recommendation	What would be different	Why
New item	Tests for this inappropriate immune response seen in rheumatoid arthritis	Create a new item for this test and limit it to 4 times a year per patient	A new item would be available to test specifically for this inappropriate immune response, and overuse prevented	Requesters have been using this test for about 15 years but it has not been on the MBS. It is included with other tests in item 71119 so requesters have been using that instead
