
**Medicare Benefits Schedule Review
Taskforce**

**Report from the Pathology Clinical
Committee-Haematology**

October 2017 v1

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 The Taskforce will also seek to identify any services that may be unnecessary, outdated or potentially unsafe.

The Taskforce is committed to providing recommendations to the Minister for Health 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 a Review Report. The Taskforce will consider the Review Report from clinical committees and stakeholder feedback before making recommendations to the Minister for Health, 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 MBS Review Taskforce on the review of MBS items within its remit, based on rapid evidence review and clinical expertise.

The majority of 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 period of 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 Key recommendations

The Committee has highlighted its most important recommendations below. The complete recommendations (and the accompanying rationales) for all items can be found in Section 4. Recommendations developed for referral to other committees are presented in Section 5.ⁱ A complete list of items, including the nature of the recommendations and the page number for each recommendation, can be found in Appendices A and B (in table summary form).

1.2.1 Recommendations for consultation

The Committee's recommendations for stakeholder consultation are:

- five items should be deletedⁱⁱ from the MBS;
- 12 items should be changedⁱⁱⁱ;
- 34 items should remain unchanged.

The Committee has proposed seven new items; with three expected to be referred to the Medicare Services Advisory Committee (MSAC).

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.

Significant recommendations are summarised below.

△ Blood group and blood group antibody item

Split the current item 65096 into two items—an initial test that includes screening for antibodies; and a second item that includes the identification and measurement only if antibodies are detected.

△ Compatibility testing items

Combine the existing four items 65099, 65102, 65105 and 65108 into two items, based on the detection of antibodies. One item will be for the screening and release of blood if no antibodies are detected; and the other for further testing and release of blood when antibodies are detected.

△ Coagulation test items (65120, 65123, 65126 and 65129)

Limit the number of tests funded through the MBS to a maximum of three different types of tests rather than four tests.

△ D-dimer test

ⁱ Recommendations that are eventually made for consideration by the Government will not necessarily reflect the final recommendations made to the Taskforce by the Committee after consultation. As stated, the Taskforce will consider these recommendations, and it may alter recommendations to bring items in line with broader changes that are being made. Additionally, the wording or structuring of item descriptors and explanatory notes may be changed to ensure consistency with the language and structure of the MBS. It should also be noted that the recommendations focus on the services provided by the items. Specific item numbers may be altered during implementation of the eventual recommendations proposed by the Minister for Health. For example, where the Committee has requested that services for item A be consolidated under item B, the actual item number for item B may be changed in some circumstances.

ⁱⁱ Describes when an item is recommended for removal from the MBS and its services will no longer be provided under the MBS.

ⁱⁱⁱ Describes when the item and/or its services will be affected by the recommendations. This could result from a range of recommendations, such as: (a) specific recommendations that affect the services provided by changing item descriptors or explanatory notes, (b) the consolidation of item numbers, and (c) splitting item numbers (e.g., splitting the current services provided across two or more items).

Split D-dimer from item 65120 into a separate item with clinical restrictors to ensure its appropriate use.

△ Platelet function tests

Split the existing item 65144 into two separate items—initial platelet function tests involving a limited panel of tests, and platelet aggregation tests involving an expanded panel of tests. The second item should only be requested by, or in communication with, a specialist to ensure its appropriate use.

△ Assessment of haemolysis or metabolic enzymes

Remove several obsolete tests no longer used from item 65075, and include a new test—eosin-5-maleimide (E5M) by flow cytometry, which is now the gold standard for diagnosing a common cause of haemolysis.

1.2.2 Recommendations for referral to other committees

The Committee's recommendations to be referred to MSAC for their consideration:

△ Release of immunoglobulin – new service

The Committee recommends the introduction a new MBS item for the release of immunoglobulin to reimburse laboratories for the work involved in managing the increasing demand and administrative requirements associated with immunoglobulin.

△ Alpha thalassaemia genetic testing – new service

The Committee recommends the introduction a new MBS item for the genetic testing of alpha thalassaemia. This test would enable at-risk populations to have this test funded by Medicare.

△ Warfarin care programs – new service

The Committee recommends the introduction of a new MBS item for the management of patients on warfarin, which was recommended in the 2012 *Sansom Review of Anticoagulation Therapies in Atrial Fibrillation*. This would to allow patients on warfarin to have the option of having their warfarin therapy managed through a formal program offered by pathology laboratories.

The Committee's recommendation for referral to the General Practice Primary Care Clinical Committee (GPPCCC) and the Diagnostic Medicine Clinical Committee (DMCC):

△ Opportunities for practice improvement around ordering tests

The Committee recommends ensuring that guidelines are up to date, education is provided, MBS item descriptors are integrated into clinical practice software and decision support tools are developed for the high priority areas.

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 C, 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

What is Medicare?

Medicare is Australia's universal health scheme, which 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 Medicare Benefits Schedule (MBS).

What is the Medicare Benefits Schedule (MBS)?

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

2.2 What is the MBS Review Taskforce?

The Government established the MBS Review Taskforce (the Taskforce) as an advisory body to review all 5,700 MBS items to ensure that they align 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.

What are the goals of the Taskforce?

The Taskforce is committed to providing recommendations to the Minister for Health that will allow the MBS to deliver on each of these four 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 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, where possible. Although the MSAC plays a crucial role in thoroughly evaluating new services, the vast majority of existing MBS items pre-date this process and have never been reviewed.
- △ **Value for the individual patient** – another core objective of the Review is to maintain 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 will go a long way towards 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 benefits but are underused, particularly for patients who cannot readily access these services.

2.3 The Taskforce's approach

The Taskforce is reviewing 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 provide advice on all aspects that would contribute to a modern, transparent and responsive system. This includes not only making recommendations about adding new items or services to the MBS, but also about an MBS structure that could better accommodate changing health service models.

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

The Taskforce will also develop a mechanism for an ongoing review of the MBS once the current Review has 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. [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 value^{iv}, are misused^v 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 in order 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 item. 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.

^{iv} The use of an intervention that evidence suggests confers no benefit or very little benefit on patients; 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.

^v The use of MBS services for purposes other than those intended. This includes a range of behaviours ranging 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: [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) was established in April 2016 to make recommendations to the Taskforce on MBS items within its remit, based on rapid evidence review and clinical expertise. The Taskforce asked the Committee to review haematology-related MBS items.

3.1 Pathology Clinical Committee members

The Committee consists of 19 members, whose names, positions/organisations and declared conflicts of interest are listed in Section 3.1. 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	Pathology Queensland	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 Djacic	General practitioner	None
Dr Bev Rowbotham	MBS Taskforce	None
Dr Jill Thistlethwaite	General practitioner	None
Ms Valerie Hanrahan	Consumers Health Forum	None
Dr Robyn Lindner	National Prescribing Service	None
Professor Hans Schneider	Alfred Pathology Service (Melbourne)	None
Associate Professor Adrienne Morey	ACT Pathology	None

It is noted that most committee and working group 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 and is not noted in the table above.

3.2 Haematology Working Group

The Haematology Working Group is one of six clinical working groups supporting the work of the Pathology Clinical Committee. It was established to review haematology pathology items and make recommendations to the Pathology Clinical Committee based on rapid evidence review and clinical expertise. Their recommendations were endorsed by the Pathology Clinical Committee to go out for targeted consultation before MBS Taskforce consideration.

The Haematology Working Group consists of 8 members, whose names, positions/organisations and declared conflicts of interest are listed in Table 2 below.

Table 2: Haematology Working Group members

Name	Position/Organisation	Declared conflict of interest
Dr John Rowell (Chair)	Pathology Queensland	None
Dr James Daly	QML Pathology (Primary)	None
Professor Mark Hertzberg	Prince of Wales Hospital	None
Professor Parker Magin	University of Newcastle	None
Dr Ellen Maxwell	Melbourne Pathology (Sonic Healthcare)	None
Ms Ingrid Ozols	Consumer	None
Dr Lesley Survela	Pathology North – Northern Sydney	None
Dr Jeannie Yoo	NPS MedicineWise	None

3.3 Areas of responsibility of the Committee

The Committee was assigned 48 MBS haematology items and three referred items to review. [2] A complete list of these items can be found in [Appendix A](#).

3.4 Summary of the Committee's review approach

The Committee completed a review of 48 haematology items and three referred items across eight meetings, during which it developed the recommendations and rationales outlined in [Section 4](#). Recommendations were also developed for referral to other committees. These are outlined in [Section 5](#).

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); and
- △ 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 report will be released for public consultation, giving all Australians, including health professionals, an opportunity to have their say on the draft recommendations. Following this period of consultation, 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 consultation

Introduction

The Committee reviewed 48 haematology items and three referred items and made recommendations based on evidence and clinical expertise, in consultation with relevant stakeholders. The item-level recommendations are described below. A summary list of recommendations can be found in Appendices [A](#) and [B](#), and in the consumer summary table in [Appendix C](#).

The Committee's recommendations for public consultation are that five items should be deleted (and their services no longer be provided under the MBS), 12 items should be changed, and 34 items should remain unchanged. The Committee has proposed seven new items and referred three of these to other committees.

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 not supported by evidence or 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.

The recommendations are presented in item groups below, with higher priority groups presented first.

When the Committee would have preferred to recommend a change but for various reasons has elected not to, the full discussion has been included for the record.

4.1 Blood grouping and blood group antibodies: items 65090, 65093, 65096 and 65111

Table 3: Item introduction table for items 65090, 65093, 65096 and 65111

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
65090	Blood grouping (including back-grouping if performed) - ABO and Rh (D antigen)	\$11.15	83,316	\$808,468	78,721	-5.1%
65093	Blood grouping - Rh phenotypes, Kell system, Duffy system, M and N factors or any other blood group system - 1 or more systems, including item 65090 (if performed)	\$22.00	4,742	\$85,611	4,248	-6.3%
65096	Blood grouping (including back-grouping if performed),	\$41.00	814,844	\$27,973,826	633,205	5.2%

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
	and examination of serum for Rh and other blood group antibodies, including: (a) identification and quantitation of any antibodies detected; and (b) (if performed) any test described in item 65060 or 65070					
65111	Examination of serum for blood group antibodies (including identification and, if necessary, quantitation of any antibodies detected)	\$23.20	119,718	\$2,377,048	99,957	-0.4%

4.1.1 Recommendation 1

- △ Amend the item descriptor of 65096 based on the detection of positive antibodies.
- △ Create a new initial test item for blood group and antibody screening as follows:
 - revised item 65096: blood group, examination of serum for Rh and other blood group antibodies and antibody identification and quantitation of positive antibodies (including 65090, 650XX and 65111)
 - new item 650XX: blood group and examination of serum for Rh and other blood group antibodies using 2- or 3-cell panel (including 65090).
- △ Redistribute the funding across these two items to reflect the greater complexity associated with positive antibody testing and the technology-driven efficiencies associated with negative antibody samples.
- △ Add explanatory notes to 650XX, 65096 and 65111 to indicate when use of these items is appropriate.
- △ No changes to items 65090 and 65093.
- △ The proposed changes to the item descriptors are as follows:

Table 4: Proposed changes to item 65096

Item	Current descriptor	Proposed change to descriptor
65090	Blood grouping (including back-grouping if performed) - ABO and Rh (D antigen)	No change
65093	Blood grouping - Rh phenotypes, Kell system, Duffy system, M and N factors or any other blood group system - 1 or more systems, including item 65090 (if performed)	No change
New 650XX		Blood grouping (including back-grouping if performed), and examination of serum for Rh and other blood group antibodies using a 2- or 3-cell panel, including (if performed) item 65090 Explanatory note: applicable when examination for antibodies is negative

Item	Current descriptor	Proposed change to descriptor
65096 and Revised 65096	Blood grouping (including back-grouping if performed), and examination of serum for Rh and other blood group antibodies, including: (a) identification and quantitation of any antibodies detected; and (b) (if performed) any test described in item 65060 or 65070	Blood grouping (including back-grouping if performed), and examination of serum for Rh and other blood group antibodies using a 2- or 3-cell panel, including: (a) identification and quantitation of any antibodies detected; and (b) (if performed) any test described in items 65090, 650XX and 65111. Explanatory note: applicable when examination for antibodies is positive
65111	Examination of serum for blood group antibodies (including identification and, if necessary, quantitation of any antibodies detected)	Examination of serum for blood group antibodies (including identification and, if necessary, quantitation of any antibodies detected) Explanatory note: applicable when repeat blood grouping is not required.

4.1.2 *Rationale 1*

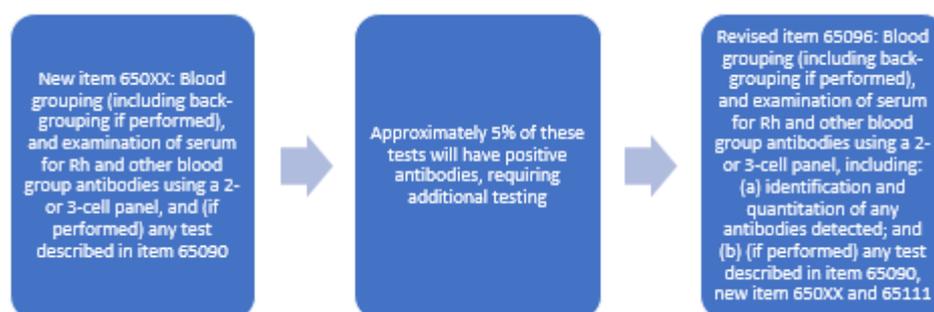
The recommendations focus on modernising the MBS and are based on the following observations:

- △ Splitting item 65096, based on a positive antibody screen, better reflects the clinical workload and follows the logical sequence of laboratory processes. The split provides an opportunity to simplify this section of the schedule, review relevant costings and provide better MBS data to monitor practice changes and inform future reviews.
- △ Several items in the schedule cover blood grouping, screening for antibodies and, if detected, subsequent identification and quantitation of these antibodies (items 65090, 65093, 65096, 65111). The complexity of testing increases with the detection of positive antibodies and a series of additional steps is required to identify and quantitate the antibodies. The Committee estimates that 5 per cent of antibody screens are positive. Currently the identification and quantitation component is embedded into the descriptors of items 65096 and 65111.
- △ The recommendation relates to item 65096, which is used to identify and or quantify the antibodies detected. The key change is the separation of the blood group and antibody screening test into a new item that will be the initial test performed. In 95 per cent of cases no significant antibodies will be detected and no further testing will be required (see Figure 2). Positive antibodies will be detected in 5 per cent of cases and the test will then be upgraded to item 65096, which includes the additional steps to identify and quantify the antibodies detected.
- △ Antibody identification and quantitation involves the use of additional or an extended panel of at least 11 cells, including when indicated, parallel testing of previous samples. It may additionally involve using specific techniques of adsorption and elution to separate the antibodies. These tests require staff with higher expertise and experience. They are time consuming and non-automated, involving increased labour, time and reagent costs.
- △ The Committee recommends that the new item for positive antibody testing be appropriately costed to recognise the additional time and materials required to perform this test and agreed that the change across these items should be cost neutral.
- △ The current descriptor for item 65096 includes the provision of any test described in item 65060 or 65070. The test common in these two items is for haemoglobin. The Committee

consider that this test is independent of the purpose of both the current and revised item 65096 and have therefore removed this from the revised descriptor.

- △ The Committee recommends no change to items 65090 and 65093, as these blood grouping and phenotyping tests are still required and are appropriate. They also recommended no change to item 65111, which is used only to confirm the antibody status of blood where the blood group is already known and does not need to be repeated.

Figure 1. Sequence of the proposed changes to item 65096.



The revised item 65096 will be used for an estimated 5 per cent of positive antibody screens detected via the new item 650XX.

- △ The Committee agreed that the changes to these items will require modelling and costing revision to ensure that the changes recommended remain cost neutral. They recommended that the distribution of funding should shift, with weighting towards the more complex processes associated with positive antibody testing. It is not expected that these changes will impact on other items in the schedule.

- △ The Committee noted that the Obstetrics Clinical Committee has made a recommendation to standardise antenatal pathology screening, and have recommended a panel of tests that pregnant women should have done in the first trimester. [3] These are:

- 65070 – Full blood examination
- 65096 – Blood grouping and examination of serum for Rh and other blood group antibodies
- 69333 – Urinalysis with midstream urine (MSU) microscopy, culture and sensitivities
- 69415 – Hepatitis B, hepatitis C, HIV, rubella, syphilis (item is for testing all five).

If the recommendation to change the existing item 65096 is accepted, this will need to be translated to the proposed antenatal panel.

4.2 Compatibility testing: items 65099, 65102, 65105 and 65108

Table 5: Item introduction table for items 65099, 65102, 65105 and 65108

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
65099	Compatibility tests by crossmatch - all tests performed on any one day for up to 6 units, including:	\$108.90	43,467	\$3,791,057	23,480	–8%

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
	(a) all grouping checks of the patient and donor; and (b) examination for antibodies, and if necessary identification of any antibodies detected; and (c) (if performed) any tests described in item 65060, 65070, 65090 or 65096 (item is subject to rule 5)					
65102	Compatibility tests by crossmatch - all tests performed on any one day in excess of 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies, and if necessary identification of any antibodies detected; and (c) (if performed) any tests described in item 65060, 65070, 65090, 65096, 65099 or 65105 (Item is subject rule 5)	\$164.60	343	\$43,511	282	-0.5%
65105	Compatibility testing using at least a 3-cell panel and issue of red cells for transfusion - all tests performed on any one day for up to 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies and, if necessary, identification of any antibodies detected; and (c) (if performed) any tests described in item 65060, 65070, 65090 or 65096 (item is subject to rule 5)	\$108.90	121,637	\$10,457,370	63,600	6.7%
65108	Compatibility testing using at least a 3-cell panel and issue of red cells for transfusion - all tests performed on any one day in excess of 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies and, if necessary, identification of any antibodies detected; and(c) (if performed) any tests described in item 65060, 65070, 65090,	\$164.60	2,039	\$257,323	1,840	7.0%

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
	65096, 65099 or 65105 (Item is subject to rule 5)					

4.2.1 Recommendation 2

- △ Amend the compatibility items 65099, 65102, 65105 and 65108 based on the detection and testing for positive antibodies.
- △ Amend the item descriptor of 65099 to specifically cover the testing of blood for transfusion, based on the detection of positive antibodies. The revised item will include the compatibility testing and release of compatible blood in any one day, regardless of volume.
- △ Create a new item number for the release of antibody-negative red blood cells for transfusion. This will include the release in any one day regardless of volume.
- △ Redistribute the funding across these items to reflect the complexity of positive antibody testing and technology-driven efficiencies associated with negative antibody screens and electronic issue (e-issue) in a cost-neutral manner.
- △ Delete items 65102, 651205 and 65108.

Table 6: Proposed changes to compatibility items

Item	Current descriptor	Proposed change to descriptor
65099 Revised 65099 (new # required)	Compatibility tests by crossmatch - all tests performed on any one day for up to 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies, and if necessary identification of any antibodies detected; and (c) (if performed) any tests described in item 65060, 65070, 65090 or 65096 (item is subject to rule 5)	Compatibility testing (including crossmatch and phenotype) of the patient and donor and release of red cells for transfusion – all tests performed and units released on any one day regardless of volume. Explanatory note: This item must be in association with revised item 65096 (i.e. performed based on a positive antibody screen, or a negative screen if a documented past history of red cell antibodies)
New 650YY		Release of red cells for transfusion by e-issue or after immediate spin, regardless of volume on any one day. Explanatory note: This item must be in association with new item 650XX (i.e. performed based on the absence of current or documented history of red cell antibodies)
65102	Compatibility tests by crossmatch - all tests performed on any one day in excess of 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies, and if necessary identification of any antibodies detected; and (c) (if performed) any tests described in item 65060, 65070, 65090, 65096, 65099 or 65105 (Item is subject rule 5)	Delete
65105	Compatibility testing using at least a 3-cell panel and issue of red cells for transfusion - all	Delete

Item	Current descriptor	Proposed change to descriptor
	tests performed on any one day for up to 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies and, if necessary, identification of any antibodies detected; and (c) (if performed) any tests described in item 65060, 65070, 65090 or 65096 (item is subject to rule 5)	
65108	Compatibility testing using at least a 3-cell panel and issue of red cells for transfusion - all tests performed on any one day in excess of 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies and, if necessary, identification of any antibodies detected; and(c) (if performed) any tests described in item 65060, 65070, 65090, 65096, 65099 or 65105 (Item is subject to rule 5)	Delete

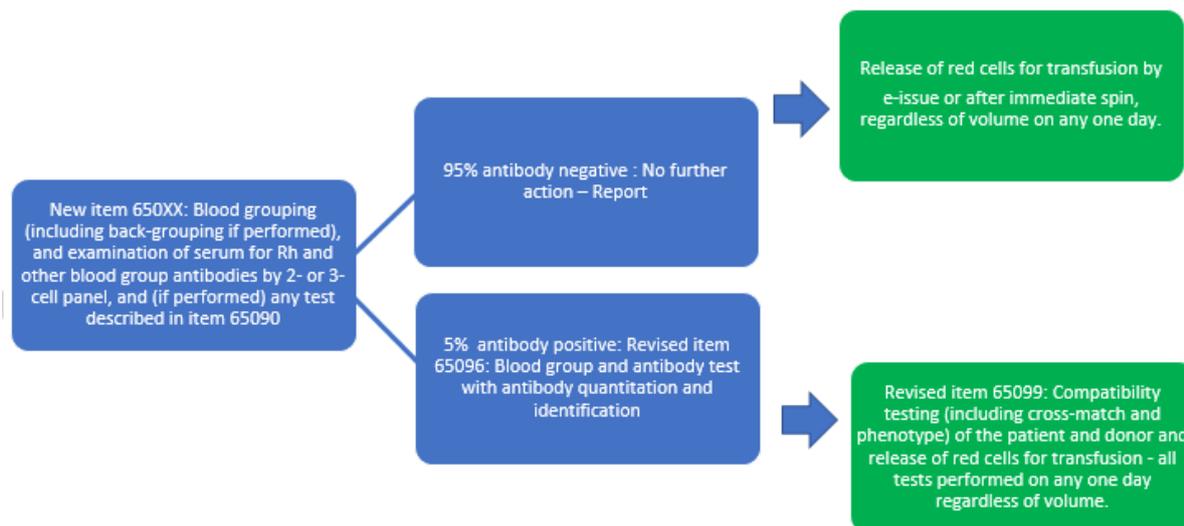
4.2.2 *Rationale 2*

The recommendations focus on modernising and simplifying the MBS and are based on the following observations.

- △ When blood is requested for transfusion, testing is required to confirm the compatibility between the patient’s blood and the donor red blood cells to prevent a haemolytic transfusion reaction. If the patient does not have clinically significant antibodies or a history of antibodies, i.e. is antibody negative, the compatibility is checked using the laboratory information system and is known as electronic or computer cross-matching, also referred to as ‘e-issue’. Electronic issue of negative antibody units is now generally regarded as standard practice. An immediate spin is an alternative test sometimes used to check blood group compatibility, and involves mixing a patient’s plasma and donor red cells together. It is rarely done now, in preference for the more efficient e-issue.
- △ If antibodies are detected in a patient’s blood, i.e. their blood is antibody positive, specific cross-match testing of the donor and patient’s blood is required. Cross-matching units of blood are currently covered by items 65099, or item 65102 for quantities greater than 6 units per day.
- △ In line with the recommendations proposed for blood group and antibody testing (as discussed in Section 4.1), splitting and rearranging the items based on a positive antibody screen better reflects the clinical workload and follows the logical sequence of laboratory processes. The split provides an opportunity to simplify this section of the schedule, review relevant costings and to provide better MBS data to monitor practice changes and inform future reviews.
- △ The Committee proposed a tiered structure for these items (Figure 3) and recommended a change in the funding distribution between them to reflect the time and materials associated with positive antibody screens and the subsequent compatibility testing then required. The Committee agreed that the changes across this group of items should be cost neutral.
- △ The compatibility items currently ‘bundle’ the process of releasing blood to a patient for transfusion. In practice the process within the laboratory involves allocation—the selection and labelling of units with patient details—and when requested, the physical release—recording the issue and providing the product to a ward or patient. The release of antibody-positive units has been left in the proposed descriptor, therefore requiring a new item number for the release of antibody-negative red cells. As previously mentioned, electronic issue of negative antibody units is now standard practice.

- △ Current MBS data and member feedback indicate that the issue of more than 6 units is rare, and the Committee agreed that it would be feasible to delete items 65102 and 65108 on this basis. It is the expectation that the fee for the release of units of antibody-negative blood would be for a one-day supply, regardless of the volume.

Figure 2. Proposed sequence of compatibility testing and release of red cells for transfusion.



4.3 Coagulation studies: items 65120, 65123, 65126 and 65129

Table 7: Item introduction table for items 65120, 65123, 65126 and 65129

Item	Long item descriptor	Schedule fee	Services FY2014–15	Benefits FY2014–15	Patient count 2014–15	5-year service change(CAGR)
65120	Prothrombin time (including INR where appropriate), activated partial thromboplastin time, thrombin time (including test for the presence of heparin), test for factor XIII deficiency (qualitative), Echis test, Stypven test, reptilase time, fibrinogen, or 1 of fibrinogen degradation products, fibrin monomer or D-dimer - 1 test	\$13.70	3,128,308	\$36,033,617	313,373	-4.1%
65123	2 tests described in item 65120	\$20.35	391,044	\$6,260,831	196,296	3.4%
65126	3 tests described in item 65120	\$27.85	271,767	\$6,024,580	165,852	8.9%
65129	4 or more tests described in item 65120	\$35.50	341,961	\$9,848,751	232,787	12.5%

4.3.1 Recommendation 3

- △ Amend the item descriptor of 65120 to remove services that are either obsolete or recommended to be separated (D-dimer) into another item number or currently covered elsewhere in the schedule (factor XIII).
- △ Amend the item descriptor of 65126 to limit the number of tests that can be charged to the MBS and review the fee.
- △ Delete item 65129.
- △ The proposed changes to item descriptors are as follows:
 - Item 65120: Prothrombin time (including INR where appropriate), activated partial thromboplastin time, thrombin time (including test for the presence of heparin), Echis test, reptilase time, fibrinogen – 1 test.
 - Item 65126: 3 or more tests described in 65120.
- △ No change to item 65123.

Table 8: Proposed changed to items 65120–65129

Item	Current descriptor	Proposed change to descriptor
65120	Prothrombin time (including INR where appropriate), activated partial thromboplastin time, thrombin time (including test for the presence of heparin), test for factor XIII deficiency (qualitative), Echis test, Stypven test, reptilase time, fibrinogen, or 1 of fibrinogen degradation products, fibrin monomer or D-dimer - 1 test	Prothrombin time (including INR when appropriate), activated partial thromboplastin time, thrombin time (including test for the presence of heparin), Echis test, reptilase time, fibrinogen – 1 test
65123	2 tests described in item 65120	No change
65126	3 tests described in item 65120	3 or more tests described in item 65120
65129	4 or more tests described in item 65120	Delete

4.3.2 Rationale

The recommendations focus on ensuring appropriate use and value for the healthcare system and are based on the following observations.

- △ The Committee noted different claiming patterns between states, where the number of tests ordered range from one test through to four or more tests. The Committee reviewed the data trends, co-claiming patterns, state variation and requester patterns and discussed which tests are relevant in different clinical contexts and settings. The Committee agreed that while the patterns were variable, it is difficult to use the high-level MBS data to interpret with any certainty the clinical appropriateness or otherwise of the testing patterns.
- △ The Committee acknowledged that over the past 5 years, changes in coagulation testing have been influenced by the introduction of new anticoagulants. The Committee noted however that existing guidelines for requesters about which coagulation tests to request and when are limited, and often requesters will request ‘coagulation screen’, leaving the specific tests to be determined by the laboratories. Unfortunately, in many circumstances limited clinical information is provided with the requests for this to be an efficient process and it is possible

that this is leading to the shift to more tests being performed rather than appropriately targeted tests.

- △ The Committee agreed that it is difficult to use the MBS to control or influence the requesting of specific tests for specific contexts and supported the development and promotion of educational programs, guidelines, and decision support and practice software integrated with the Schedule to support requesters to order the most appropriate tests.
- △ The Committee recommended that the following tests included in the current descriptor for item 65120 be removed, as they are obsolete—Stypven test, 1 of fibrinogen degradation products and fibrin monomer. The Committee agreed that D-dimer, a test to help rule out the presence of an inappropriate blood clot, for example, a deep vein thrombosis or a pulmonary embolism, has the potential to be inappropriately ordered and should be separated into a new item number with qualifiers to ensure its appropriate clinical utility (see recommendation 4.4). It also recommended that the test for factor XIII deficiency (qualitative) be removed from this item. It is currently and more appropriately covered under item 65150.
- △ The Committee reviewed the remaining coagulation tests available—prothrombin time (including INR where appropriate), activated partial thromboplastin time, thrombin time (including test for the presence of heparin), Echis test, reptilase time and fibrinogen. It agreed that there are some circumstances in which three coagulation tests could be justified, but felt it was difficult to justify four tests routinely for a standard ‘coagulation screen’.
- △ The Committee recommended limiting the number of coagulation tests to (a) one test, (b) two tests and (c) three or more tests. This will mean that the maximum number of tests reimbursed will be three, and any additional tests can be performed by laboratories, but there will not be additional remuneration. This will provide laboratories the incentive to perform only the most clinically relevant tests rather than a ‘screen’ of up to four or more tests.
- △ The Committee strongly recommended that educational resources and software support should be developed to guide requesters to select the most appropriate tests for specific clinical contexts rather than order a generic ‘screen’. The concept of standardised panels of coagulation tests being ordered for the appropriate indications was briefly discussed and, if supported by appropriate education and decision-support tools, may be a practical consideration.
- △ The Committee believes that the limitation on the number of tests remunerated will not adversely affect consumers. Currently the risk of having too many tests puts patients at risk of over-diagnosis, triggering further unnecessary investigations and costs.

4.4 D-dimer Item descriptor to be split

4.4.1 *Recommendation 4*

- △ Create a new item (split from coagulation item 65120) for D-dimer with qualifiers based on appropriate clinical use.
- △ The proposed descriptor would contain the following elements:
 - diagnosis of venous thromboembolism (VTE) or pulmonary embolism (PE) to exclude the need for further imaging in a patient with a low pre-test clinical probability of VTE or PE as defined by local algorithms,
 - follow-up to support decision to cease anticoagulation, or
 - diagnosis and monitoring of disseminated intravascular coagulopathy (DIC).

Table 9: Proposed descriptor for new item for D-dimer.

Item	Current descriptor	Proposed descriptor
New item		<p>D-dimer on whole blood to (a) exclude the need for further imaging in patients with a low pre-test clinical probability of venous thromboembolism (VTE) or pulmonary embolism (PE), (b) support clinical decisions regarding duration of anticoagulation, or (c) diagnose and/or monitor disseminated intravascular coagulopathy (DIC).</p> <p>Explanatory note for (a): The sensitivity and specificity of the D-dimer is dependent on both patient and technical factors. It has no useful positive predictive value for confirmation of thrombosis. The utility of a negative predictive value for DVT/PE is most valid when the test is used in conjunction with clinical assessment by standard algorithm of a patient determined to be at low to moderate risk for thrombosis.</p>

4.4.2 *Rationale 4*

The recommendation is focused on improving patient care and encouraging best practice. It is based on the following observations.

- △ D-dimer is currently included as one of the tests in the coagulation item 65120. The MBS data do not provide information on the number of D-dimer requests and this is one of the limitations of ‘bundling’ it with the other coagulation studies.
- △ D-dimer has specific clinical utility and should only be used in certain circumstances. It is a sensitive test but has a poor specificity and should only be used to rule out deep vein thrombosis (DVT) or PE, not to confirm a diagnosis. It is most valid and useful when the test is done for people who are considered to be at low to moderate risk for thrombosis.
- △ D-dimer is relevant in the following circumstances:
 - A negative result for whole-blood D-dimer to exclude PE in low-risk patients instead of imaging (supported by the Royal Australian and New Zealand College of Radiologists [RANZCR] Choosing Wisely recommendation— ‘*Don’t request any diagnostic testing for suspected pulmonary embolism (PE) unless indicated by Wells Score (or Charlotte Rule) followed by PE Rule-out Criteria (in patients not pregnant). Low risk patients in whom diagnostic testing is indicated should have PE excluded by a negative D dimer, not imaging*’). [4]
 - A negative result for D-dimer assay in ambulatory outpatients with suspected lower-limb DVT and a DVT risk assessment score (Wells Score) of less than 2, which can exclude a DVT and prevent the need for diagnostic imaging (supported by RANZCR Choosing Wisely recommendation— ‘*Don’t request duplex compression ultrasound for suspected lower limb deep venous thrombosis in ambulatory outpatients unless the Wells Score (DVT risk assessment score is greater than 2, OR if less than 2, D-dimer assay is positive*’). [4]
 - When used to monitor DIC treatment, decreasing levels indicate that treatment is effective while increasing levels may indicate that treatment is not working.
 - To guide the duration of anticoagulation in patients with a VTE.
- △ The Committee agreed that creating a separate item number for D-dimer provides the opportunity to restrict the test to the most appropriate clinical contexts and minimise

inappropriate use and cost. It will improve patient care and safety by reducing the number of potentially misleading test results. As a separate item number, decision support can be developed to guide the appropriate use of this test and utilisation patterns can be better monitored.

- △ D-dimer has been identified as an area where there is need for education to ensure appropriate ordering and interpretation of results both in the acute care setting such as Emergency Departments, but particularly for GPs. Any changes will require communication with both providers and requesters.

4.5 Platelet assessment and platelet aggregation tests: item 65144 and new split item

Table 10: Item introduction table for item 65144

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
65144	Platelet aggregation in response to ADP, collagen, 5HT, ristocetin or other substances; or heparin, low molecular weight heparins, heparinoid or other drugs - 1 or more tests	\$56.55	15,901	\$760,474	13,930	1.8%

4.5.1 Recommendation 5

- △ Amend the item descriptor for 65144 to include a limited panel of tests for the initial assessment of platelet function.
- △ Include an explanatory note that the test is not indicated for monitoring patients on antiplatelet therapy. This will require a cost analysis and evidence to support this.
- △ Create a new (split) item to include an expanded panel of tests for the diagnostic assessment of platelet aggregation. This test should only be performed when requested by, or in communication with, a consultant physician or specialist haematologist. This will require a cost analysis and evidence to support this.

Table 11: Proposed changes to item 65144

Item	Current descriptor	Proposed change to descriptor
65144	Platelet aggregation in response to ADP, collagen, 5HT, ristocetin or other substances; or heparin, low molecular weight heparins, heparinoid or other drugs - 1 or more tests	Platelet aggregation in response to ADP, collagen, heparins, heparinoid or other drugs, to a maximum of 3 agonists, for the initial assessment of platelet function – 1 or more tests Explanatory note: not indicated for monitoring patients on antiplatelet therapy
New 651XX		Platelet aggregation in response to up to 6 agonists for the diagnosis or confirmation of platelet function disorders.

Item	Current descriptor	Proposed change to descriptor
		Explanatory note or rule: only requested by, or in communication with, a consultant physician or specialist pathologist

4.5.2 *Rationale 5*

The recommendations are focused on improving patient care and encouraging best practice. They are based on the following observations.

- △ The current item 65144 is being used to fund initial platelet assessment tests, as well as more formal platelet aggregometry tests. While both types of platelet tests are required on the MBS, they are indicated for different clinical indications and involve different methods with very different costs.
- △ The current descriptor for item 65144 is platelet aggregometry, which measures platelet aggregation in response to a panel of agonists including ADP, collagen, 5HT and ristocetin, and drugs including heparin, low molecular weight heparins and heparinoid. The Committee noted the literature review and cost review of platelet function tests prepared for the Department. [5], [6]. The review focused on formal platelet aggregometry and identified that light transmission platelet aggregation (LTA) is the most widely used method and is considered the ‘gold standard’ test for measuring platelet function.
- △ The review identified that platelet aggregation testing using LTA has diagnostic utility in patients with suspected bleeding disorders, and possible clinical utility in guiding antiplatelet therapy. The literature does not support its use in screening for bleeding tendency. Currently there are no clinical restrictors on the use of this item and the Committee agreed that this test is complex and could be ordered inappropriately. They recommended restricting the item to consultant physicians or specialist pathologists only.
- △ In practice, item 65144 is also being used to fund initial or first-tier platelet assessment tests. These tests are used to identify and help diagnose platelet dysfunction in those with a history of excessive bleeding, to help diagnose inherited and acquired platelet dysfunctions. Several commercial tests are available, including PFA-100.
- △ The Committee agreed that the clinical value of routine platelet testing is limited and the current item has the potential to be over-ordered. Despite lack of evidence, these tests are sometimes used to estimate a patient’s risk of bleeding postoperatively. Currently most antiplatelet therapies cannot be routinely monitored with platelet function testing. The Committee agreed that a note should be added to the item indicating that the test is not indicated for patients on antiplatelet therapy.
- △ Splitting the current item provides the opportunity to include restrictors in either rules or explanatory notes to improve the ordering of both platelet aggregometry tests and initial assessment tests and provide better data to inform future reviews and interventions.
- △ The current remuneration does not accurately reflect the costs of either of the proposed items, and splitting them will require a cost analysis. The cost review proposed a revised costing for LTA ranging from \$153.96 to \$200.80. [6]
- △ The Committee also discussed the increasing availability of ‘point of care’ methods for testing platelet function. Two examples are TEG (thromboelastography) and ROTEM (rotational thromboelastometry), both acronyms being registered trademarks. These are tools for assessing whole blood clotting and are used at the bedside, in outpatient and ambulatory settings and in operating theatres.

There is increasing evidence that use of TEG/ROTEM is associated with reduced blood use in management of massive haemorrhage. This is outside the scope of this review, but is a trend worth noting for the future.

- △ These changes are not expected to impact utilisation, although it is possible that the number of requests for formal platelet aggregation could decrease with tighter parameters ensuring appropriate use.

4.6 Assessment of haemolysis or metabolic enzymes: Item 65075

Table 12: Item introduction table for item 65075

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
65075	Haemolysis or metabolic enzymes - assessment by: (a) erythrocyte autohaemolysis test; or (b) erythrocyte osmotic fragility test; or (c) sugar water test; or (d) G-6-P D (qualitative or quantitative) test; or (e) pyruvate kinase (qualitative or quantitative) test; or (f) acid haemolysis test; or (g) quantitation of muramidase in serum or urine; or (h) Donath Landsteiner antibody test; or (i) other erythrocyte metabolic enzyme tests - 1 or more tests	\$51.95	\$373,388	8,422	8,099	-2.2%

4.6.1 Recommendation 6

- △ Amend the item descriptor for 65075 to delete several obsolete methods (erythrocyte autohaemolysis test, erythrocyte osmotic fragility test, sugar water test, acid haemolysis test, quantitation of muramidase in serum or urine) and add eosin-5-maleimide (E5M) by flow cytometry, which has replaced the osmotic fragility test in practice.

Table 13: Proposed changes to item 65075

Item	Item descriptor	Proposed amendment
65075	Haemolysis or metabolic enzymes - assessment by: (a) erythrocyte autohaemolysis test; or (b) erythrocyte osmotic fragility test; or (c) sugar water test; or (d) G-6-PD (qualitative or quantitative) test; or (e) pyruvate kinase (qualitative or quantitative) test; or (f) acid haemolysis test; or (g) quantitation of muramidase in serum or urine; or (h) Donath Landsteiner antibody test; or (i) other erythrocyte metabolic enzyme tests - 1 or more tests	Haemolysis or metabolic enzymes - assessment by (a) G-6-PD (qualitative or quantitative) test; or (b) pyruvate kinase (qualitative or quantitative) test; or (c) Donath Landsteiner antibody test; (d) E5M by flow cytometry or (e) other erythrocyte metabolic enzyme tests - 1 or more tests

4.6.2 Rationale 6

The recommendation focuses on modernising the MBS and is based on the following observations.

- △ The Committee identified several redundant methods no longer used to assess haemolysis and recommended they be removed from the descriptor of this item. They included erythrocyte autohaemolysis test, erythrocyte osmotic fragility test, sugar water test, acid haemolysis test quantitation of muramidase in serum or urine.
- △ Eosin-5-maleimide (E5M) by flow cytometry is a relatively new test for the diagnosis of hereditary spherocytosis (HS), a common cause of haemolysis. E5M is a fluorescent dye that reacts by binding to the red cell membrane. Analysis by flow cytometry measures the fluorescent intensity of labelled intact red cells.
This method is now accepted as the gold standard for the diagnosis of HS. [7] Previously, osmotic fragility was the test most commonly used. This required a large volume of blood and an incubation period of 24 hours and was not specific for HS, resulting in a proportion of false-positive test results. [8]
- △ E5M is currently not funded by the MBS, but the Committee agreed that it is the current technology being used instead of osmotic fragility and therefore it should be included within this MBS item. E5M is a very specific test ordered for the investigation of haemolysis and would usually only be ordered by, or on the advice of, a specialist.

4.7 Full blood examination: item 65070

Table 14: Item introduction table for item 65070

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
65070	Erythrocyte count, haematocrit, haemoglobin, calculation or measurement of red cell index or indices, platelet count, leucocyte count and manual or instrument generated differential count - not being a service where haemoglobin only is requested - one or more instrument generated set of results from a single sample; and (if performed) (a) a morphological assessment of a blood film; (b) any service in item 65060 or 65072	\$16.95	11,363,746	\$160,594,803	5,188,994	4.4

4.7.1 Recommendation 7

- △ No change to item 65070.

4.7.2 Rationale 7

The Committee discussed this item at length before resolving to recommend no change.

- △ The Committee’s preferred option focused on modernising the MBS by splitting the current item into two items: (a) a full blood count—quantitative, and (b) a blood film examination—for qualitative abnormalities. For reasons outlined below, this was not progressed to a

recommendation because of the complex processes that would be required to ensure appropriate use, without which there could be a risk of increased utilisation.

- △ The current item covers two separate processes—a count of blood components (erythrocyte count, haematocrit, haemoglobin, calculation or measurement of red cell index or indices, platelet count, leucocyte count and manual or instrument-generated differential count) and, if required, a morphological assessment (also known as a blood film). A blood film is not required for every sample and it is estimated from members' data that about 10–12 per cent of general practice requests will require a blood film. The rate is about 25 per cent in laboratories servicing haematology and oncology practices, where higher rates of abnormal counts are to be expected.
- △ In practice, most blood counts are now automated. However, if the presence of abnormal cells is identified or suspected, a blood film examined by a trained professional is required to definitively evaluate and identify immature and abnormal cells. This is a manual process involving the preparation of slides and examination by staff ranging from scientists to consultant haematologists.
- △ The Committee agreed that the fee attached to the current item 65070 does not reflect the skill, time and cost of reagents required to perform a blood film, and that splitting the item would provide the opportunity to review the costs associated with both processes. Film review rates will possibly decrease over time as machine technology improves, but the complexity of those requiring assessment will likely increase. Splitting the items would provide better data to inform future reviews.
- △ To support the recommendation to split the item, it would be necessary to define the criteria for when a blood film is appropriate, to avoid unintended or inappropriate growth. In practice, appropriate indications include:
 - automated machine flags for quantitative and qualitative parameters, for example, cytopenias, blasts, nucleated red cells, immature granulocytes
 - automated delta checks that flag significant changes compared with results obtained on previous samples from the same patient
 - co-requested tests, when a film review will add value to the clinical question, for example, lymphocytes markers, bone marrow investigations, haemoglobinopathy
 - clinical notes accompanying the request that may indicate that a film review will add value to the clinical question.
- △ While consensus guidelines are available, [9] the Committee agreed that it would be difficult to specifically define the haematological parameters within an MBS item descriptor. Haematological parameters are influenced by various factors, including age, ethnicity, diet, genetic and gender differences and it would require an extensive set of rules to define the specific reference values. There are also differences in the equipment used, which would make standardising tests between laboratories an issue. The Committee recognised that this change would need to be auditable to ensure appropriate use, and currently this would be impractical to implement.
- △ The Committee considered the option of limiting the review of films to senior staff only, i.e. haematologists or pathologists, to limit potential 'creep' in the number of blood films reviewed. In theory, this would be more easily audited, but in practice would be impractical.
- △ The Committee considered some initial cost models, with the understanding that any funding changes should remain cost neutral. Initial indications were that a review of costs of the

proposed new items could have enabled a funding shift to recognise the more complex film review component.

After much discussion, the Committee resolved that in consideration of the systems changes required to implement the change and the audit capability needed to ensure the appropriate use of these items, that this option was not a practical recommendation.

4.8 Thrombophilia tests: items 65171, 65175, 65176, 65177, 65178, 65179, 65180 and 65181

Table 15: Item introduction table for items 65171, 65175, 65176, 65177, 65178, 65179, 65180 and 65181

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
65171	Test for the presence of antithrombin III deficiency, protein C deficiency, protein S deficiency or activated protein C resistance in a first degree relative of a person who has a proven defect of any of the above - 1 or more tests	\$25.35	807	\$17,453	797	-5.6%
65175	Test for the presence of antithrombin III deficiency, protein C deficiency, protein S deficiency, lupus anticoagulant, activated protein C resistance - where the request for the test(s) specifically identifies that the patient has a history of venous thromboembolism - quantitation by 1 or more techniques - 1 test (Item is subject to Rule 6)	\$25.35	5,778	\$123,337	5,128	1.3%
65176	2 tests described in item 65175 (Item is subject to rule 6)	\$48.65	4,724	\$193,671	4,297	4.8%
65177	3 tests described in item 65175 (Item is subject to rule 6)	\$71.95	3,949	\$239,052	3,801	0.3%
65178	4 tests described in item 65175 (Item is subject to rule 6)	\$95.20	7,237	\$581,565	7,119	0.2%
65179	5 tests described in item 65175 (Item is subject to rule 6)	\$118.50	10,254	\$1,039,842	10,079	12.4%
65180	A test described in item 65175, if rendered by a receiving APA, where no	\$25.35	1,293	\$27,684	1,233	6.3%

Item	Long item descriptor	Schedule fee	Services FY 2014–15	Benefits FY 2014–15	Patient count 2014–15	5-year service change (CAGR)
	tests in the item have been rendered by the referring APA - 1 test (Item is subject to rule 6 and 18)					
65181	Tests described in item 65175, other than that described in 65180, if rendered by a receiving APA - each test to a maximum of 4 tests (Item is subject to rule 6 and 18)	\$23.30	2,725	\$53,694	1,017	-1.3%

4.8.1 *Recommendation 8*

- △ No change to items 65171, 65176, 65177, 65178, 65179, 65180 and 65181.
- △ Amend the item descriptor for 65175 to include an explanatory note describing the appropriate indications for use. The proposed explanatory note is as follows:
 - For use in patients with a history of unprovoked venous thromboembolism (VTE), life-threatening VTE, VTE in unusual sites, VTE in pregnancy or a strong family history of VTE (more than one relative VTE or VTE at young age in first-degree relative).

4.8.2 *Rationale 8*

The Committee discussed these items at length before resolving to only amend item 65175. The recommendations made focus on encouraging appropriate use and are based on the following observations.

- △ The Committee reviewed the MBS data and noted state variation in testing patterns in terms of the number of tests requested. They agreed that this is a very complicated area of practice, with potential for tests to be over-ordered and incorrectly used. They noted that general practice guidelines are limited and many GP requesters do not know which specific thrombophilia tests to order and often order a ‘thrombophilia screen’. In these circumstances, the laboratory would determine which tests are performed based on the clinical information provided with the request. This is challenging, as adequate clinical information is often not provided, potentially resulting in more tests being performed than clinically required. In complicated investigations, the laboratory would determine which tests need to be performed and these would legitimately account for some of ordering of four and five tests.
- △ The concept of standardised panels of coagulation tests being ordered for the appropriate indications was briefly discussed, and if supported by appropriate education/decision support tools, may be a practical consideration.
- △ The Committee discussed restricting the ordering of these tests to specialists but agreed that it is necessary for GPs to order these tests, particularly on behalf of specialists and in regional areas where access to specialists is limited. They agreed that there needs to be a review of guidelines to ensure evidence-based recommendations are available to guide requesters to order the most appropriate tests for specific clinical circumstances. The Committee suggested a Position Statement from the RCPA, co-badged with Australian Society of Thrombosis and Haemostasis (ASTH) would be

advantageous. The Committee strongly recommended that VTE diagnosis and management requires education and decision support to guide the appropriate ordering of tests.

- △ The Committee considered changing the descriptor of item 65175, limiting the contexts in which these tests should be ordered to: ‘a personal history of unprovoked VTE, a life-threatening VTE, VTE in unusual sites, VTE in pregnancy, a strong family history of VTE (more than one relative with a VTE or VTE at a young age in one first-degree relative)’. It was agreed that the aim of this information was to guide requesters, and in the absence of decision support links to the MBS items, the information at this stage would be better placed in an explanatory note rather than the descriptor.
- △ The Committee discussed the tests that should be included in item 65175 and recommended that the test panel include antithrombin (AT), protein C (PC), protein S (PS) and activated protein C resistance (APCR). They noted that lupus anticoagulant is also currently listed under a separate MBS item number 65137. They discussed removing lupus from the thrombophilia item, as technically it is not a thrombophilia test. In practice, however, it is performed with the thrombophilia tests and changing this may lead to confusion and the risk that the test not be performed when it is appropriate.

4.9 Erythrocyte sedimentation rate (ESR): item 65060

Table 16: Item introduction table for item 65060

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

4.9.1 Recommendation 9

- △ Remove blood viscosity from the descriptor.
- △ No change to erythrocyte sedimentation rate (ESR) test within the descriptor.
- △ Develop education programs for requesters to highlight the issues with ESR and promote appropriate testing.
- △ Review ESR again in 5 years.

4.9.2 Rationale 9

The recommendations are based on several external factors currently beyond the control of the Committee, and the following observations.

- △ Blood viscosity is an obsolete test infrequently used and its removal will not impact patient care.
- △ The Committee agreed that there is significant over-ordering of ESR and a lack of understanding of the limitations of the test. ESR has doubtful utility and in most cases C-reactive protein (CRP) is more appropriate. Evidence, however, does support a small number of indications in which ESR may have value, for example, Hodgkin’s lymphoma, polymyalgia rheumatica and systemic lupus erythematosus. Reference to ESR remains in many clinical guidelines. [10], [11] ESR is also linked to the

eligibility and maintenance criteria for biological disease-modifying anti-rheumatic drugs (DMARDs) on the Pharmaceutical Benefits Scheme. Removal would have a substantial impact on PBS processes and would require a submission to PBAC, as clinical trials for many of these drugs have used ESR as a measure of response.

- △ The Committee noted that ESR is usually bundled as part of other tests such as a blood count or haemoglobin, and removing the ESR items will have little impact on costs to the MBS, as the ESR test would be coned out and the cost borne by the laboratory.
- △ The Committee agreed that education about rational test ordering is challenging but very important, particularly in practice for junior and registrar medical staff.

4.10 Minor changes

The Committee has made recommendations for minor changes to the items in the following table. The changes relate to removing redundant methods, simplifying wording and updating terminology, or adding an explanatory note. The proposed changes are underlined.

Table 17: Minor changes recommended

Item	Item descriptor	Proposed amendment
65066	Examination of: (a) a blood film by special stains to demonstrate Heinz bodies, parasites or iron; or (b) <u>a blood film by enzyme cytochemistry for neutrophil alkaline phosphatase, alphanaphthyl acetate esterase or chloroacetate esterase</u> ; or (c) <u>a blood film using any other special staining methods including periodic acid Schiff and Sudan Black</u> ; or (d) a urinary sediment for haemosiderin including a service described in item 65072	Examination of: (a) a blood film by special stains to demonstrate Heinz bodies, parasites or iron; or (b) <u>use of cytochemical stains to aid the diagnosis of leukaemias</u> or (c) a urinary sediment for haemosiderin, including a service described in item 65072
65081	Tests for the investigation of haemoglobinopathy <u>consisting</u> of haemoglobin electrophoresis or chromatography and at least 1 of: (a) <u>heat denaturation test</u> ; or (b) <u>isopropanol precipitation test</u> ; or (c) tests for the presence of haemoglobin S; or (d) quantitation of any haemoglobin fraction (including S, C, D, E) including (if performed) any service described in item <u>65060</u> , 65070 or 65078	Tests for haemoglobinopathy disorders by electrophoresis or chromatography and at least 1 of: (a) tests for the presence of haemoglobin S; or (b) quantitation of any haemoglobin fraction (including S, C, D, E) including (if performed) any service described in item 65070 or 65078
65147	Quantitation of anti-Xa activity when monitoring is required for a patient <u>receiving a low molecular weight heparin or heparinoid</u> - 1 test	Quantitation of anti-Xa activity when monitoring is required for a patient <u>receiving relevant anticoagulation with known anti-Xa effect</u> - 1 test <u>Explanatory note: Include the name of the relevant anticoagulant medication in the request</u>
65175	Test for the presence of antithrombin III deficiency, protein C deficiency, protein S deficiency, lupus anticoagulant, activated protein C resistance - where the request for the test(s) specifically identifies that the patient has a history of venous thromboembolism - quantitation by 1 or more techniques - 1 test (Item is subject to Rule 6)	Test for the presence of antithrombin III deficiency, protein C deficiency, protein S deficiency, lupus anticoagulant, activated protein C resistance - <u>when</u> the request for the test(s) specifically identifies that the patient has a history of venous thromboembolism – quantitation by 1 or more techniques – 1 test (Item is subject to Rule 6) <u>Explanatory note: For use in patients with a history of unprovoked venous thromboembolism (VTE), life-threatening VTE, VTE in unusual sites, VTE in pregnancy or a</u>

Item	Item descriptor	Proposed amendment
		<u>strong family history of VTE (more than one relative VTE or VTE at young age in first-degree relative).</u>

4.11 Items to be deleted

The Committee recommends that the MBS items listed in Table 18 should be removed from the schedule.

- △ Item 65117 is a test no longer relevant due to the availability of alternative methods.
- △ Items 65102, 65105 and 65108 have been made redundant following the recommendation to revise the compatibility items (see section 4.2).
- △ Item 65129 is redundant following the recommendation to limit the number of coagulation tests funded (see section 4.3).

Table 18: Items recommended for removal from the MBS

Item	Item descriptor	Schedule fee	Services (FY 2014–15)
65117	1 or more of the following tests: (a) spectroscopic examination of blood for chemically altered haemoglobins; (b) detection of methaemalbumin (Schumm's test)	\$20.25	4,598
65102	Compatibility tests by crossmatch - all tests performed on any one day in excess of 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies, and if necessary identification of any antibodies detected; and (c) (if performed) any tests described in item 65060, 65070, 65090, 65096, 65099 or 65105 (Item is subject rule 5)	\$164.60	343
65105	Compatibility testing using at least a 3-cell panel and issue of red cells for transfusion - all tests performed on any one day for up to 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies and, if necessary, identification of any antibodies detected; and (c) (if performed) any tests described in item 65060, 65070, 65090 or 65096 (item is subject to rule 5)	\$108.90	121,637
65108	Compatibility testing using at least a 3-cell panel and issue of red cells for transfusion - all tests performed on any one day in excess of 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies and, if necessary, identification of any antibodies detected; and(c) (if performed) any tests described in item 65060, 65070, 65090, 65096, 65099 or 65105 (Item is subject to rule 5)	\$164.60	2,039
65129	4 or more tests described in item 65120	\$35.50	341,961

4.12 No changes

The Committee recommends that the MBS items listed in Table 19 do not require amendment, as they are clinically appropriate.

Table 19: MBS items that do not require change

Item	Item descriptor	Schedule fee	Services FY 2014–15
65070	Erythrocyte count, haematocrit, haemoglobin, calculation or measurement of red cell index or indices, platelet count, leucocyte count and manual or instrument generated differential count - not being a service where haemoglobin only is requested - one or more instrument generated set of results from a single sample; and (if performed) (a) a morphological assessment of a blood film; (b) any service in item 65060 or 65072	\$16.95	11,363,746
65072	Examination for reticulocytes including a reticulocyte count by any method – 1 or more tests	\$10.20	4,458
65078	Tests for the diagnosis of thalassaemia consisting of haemoglobin electrophoresis or chromatography and at least 2 of: (a) examination for HbH; or (b) quantitation of HbA ₂ ; or (c) quantitation of HbF; including (if performed) any service described in item 65060 or 65070	\$90.20	88,000
65079	Tests described in item 65078 if rendered by a receiving APP – 1 or more tests (Item is subject to rule 18)	\$90.20	1,817
65082	Tests described in item 65081 if rendered by a receiving APP – 1 or more tests (Item is subject to rule 18)	\$96.60	570
65084	Bone marrow trephine biopsy – histopathological examination of sections of bone marrow and examination of aspirated material (including clot sections where necessary), including (if performed): any test described in item 65060, 65066 or 65070	\$165.85	15,455
65087	Bone marrow – examination of aspirated material (including clot sections when necessary), including (if performed): any test described in item 65060, 65066 or 65070	\$83.10	2,315
65090	Blood grouping (including back-grouping if performed) – ABO and Rh (D antigen)	\$11.15	83,316
65093	Blood grouping – Rh phenotypes, Kell system, Duffy system, M and N factors or any other blood group system – 1 or more systems, including item 65090 (if performed)	\$22.00	4,742
65109	Release of fresh frozen plasma or cryoprecipitate for the use in a patient for the correction of a coagulopathy – 1 release	\$12.90	17,359
65110	Release of compatible fresh platelets for the use in a patient for platelet support as prophylaxis to minimise bleeding or during active bleeding – 1 release	\$12.90	22,748
65114	1 or more of the following tests: (a) direct Coombs (antiglobulin) test; (b) qualitative or quantitative test for cold agglutinins or heterophil antibodies	\$9.10	58,390
65123	2 tests described in item 65120	\$20.35	391,044
65137	Test for the presence of lupus anticoagulant not being a service associated with any service to which items 65175, 65176, 65177, 65178 and 65179 apply	\$25.35	32,907

Item	Item descriptor	Schedule fee	Services FY 2014–15
65142	Confirmation or clarification of an abnormal or indeterminate result from a test described in item 65175, by testing a specimen collected on a different day – 1 or more tests	\$25.35	339
65150	Quantitation of von Willebrand factor antigen, von Willebrand factor activity (ristocetin cofactor assay), von Willebrand factor collagen binding activity, factor II, factor V, factor VII, factor VIII, factor IX, factor X, factor XI, factor XII, factor XIII, Fletcher factor, Fitzgerald factor, circulating coagulation factor inhibitors other than by Bethesda assay – 1 test (Item is subject to rule 6)	\$70.90	4,322
65153	2 tests described in item 65150 (Item is subject to rule 6)	\$141.85	1,299
65156	3 or more tests described in item 65150 (Item is subject to rule 6)	\$212.75	15,582
65157	A test described in item 65150, 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 rules 6 and 18)	\$70.90	1,174
65158	Tests described in item 65150, other than that described in 65157, if rendered by a receiving APP – each test to a maximum of 2 tests (Item is subject to rules 6 and 18)	\$70.90	3,107
65159	Quantitation of circulating coagulation factor inhibitors by Bethesda assay – 1 test	\$70.90	636
65162	Examination of a maternal blood film for the presence of foetal red blood cells (Kleihauer test)	\$10.45	5,891
65165	Detection and quantitation of foetal red blood cells in the maternal circulation by detection of red cell antigens using flow cytometric methods including (if performed) any test described in item <u>65070</u> or 65162	\$34.45	3,884
65166	A test described in item 65165 if rendered by a receiving APP – 1 or more tests (Item is subject to rule 18)	\$34.45	113
65171	Test for the presence of antithrombin III deficiency, protein C deficiency, protein S deficiency or activated protein C resistance in a first-degree relative of a person who has a proven defect of any of the above – 1 or more tests	\$25.35	807
65176	2 tests described in item 65175 (Item is subject to rule 6)	\$48.65	4,724
65177	3 tests described in item 65175 (Item is subject to rule 6)	\$71.95	3,949
65178	4 tests described in item 65175 (Item is subject to rule 6)	\$95.20	7,237
65179	5 tests described in item 65175 (Item is subject to rule 6)	\$118.50	10,254
65180	A test described in item 65175, if rendered by a receiving APA, where no tests in the item have been rendered by the referring APA – 1 test (Item is subject to rule 6 and 18)	\$25.35	1,293
65181	Tests described in item 65175, other than that described in 65180, if rendered by a receiving APA – each test to a maximum of 4 tests (Item is subject to rule 6 and 18)	\$23.30	2,725
73829 Referred item	Leucocyte count, erythrocyte sedimentation rate, examination of blood film (including differential leucocyte count), haemoglobin, haematocrit or erythrocyte count by a participating nurse practitioner – 1 test	\$4.55	120 (2015–16 data)

Item	Item descriptor	Schedule fee	Services FY 2014–15
73830 Referred item	2 tests described in item 73829 by a participating nurse practitioner	\$6.35	9 (2015–16 data)
73831 Referred item	3 or more tests described in item 73829 by a participating nurse practitioner	\$8.15	36 (2015–16 data)

5. Recommendations to other committees

The Committee has also developed provisional recommendations for the consideration of other committees. These recommendations concern issues that were raised as clinically relevant throughout the course of the Review. These recommendations will be submitted to the relevant committees for consideration as they formulate their own recommendations to the Taskforce. The recommendations will be included in this Committee's final report and may be considered directly by the Taskforce.

The recommendations can be found below in Sections 5.1–5.2, and a summary recommendation table can be found in [Appendix B](#). Recommendations are grouped by the relevant committee.

5.1 Recommendations for referral to MSAC

5.1.1 *Release of immunoglobulin (new item)—Recommendation 10*

- △ Create a new item for the release of intravenous immunoglobulin (IV Ig) or subcutaneous immunoglobulin (SC Ig) to meet the required protocols set by the National Blood Authority (NBA). Limit of one release per day regardless of volume.
- △ The proposed descriptor is as follows:
 - Release of intravenous immunoglobulin (IV Ig) or subcutaneous immunoglobulin (SC Ig) for use in a patient for an approved indication as defined by the National Blood Authority.

Rationale 10

The recommendation is focused on providing fair recompense for services provided to meet the regulatory requirements set by the National Blood Authority. [12] It is based on the following observations.

- △ The MBS currently provides funding for the release of other blood products such as fresh frozen plasma (item 65109) and platelets (item 65110).
The Committee noted that the release of immunoglobulin has become a significant workload for blood bank laboratories. Use of these products has increased by about 10 per cent per year over the past 10 years, [13] yet there is currently no MBS item to reimburse laboratories for the work involved in managing these products.
The release of IV Ig has been an unfunded service provided by local blood banks acting as a conduit between the Australian Red Cross Blood Service and hospitals.
- △ Recent requirements introduced by the NBA have significantly increased the clinical governance and management responsibility of local blood banks and introduced the prospect of financial penalties if protocols are not adhered to. [12]
The NBA protocols outline the roles, responsibilities and expectations of laboratories handling

these products. The Committee considered these changes and the increase in demand for these products, and recommended a new MBS item number with appropriate remuneration.

Expected effects of this recommendation on the item and related-item service volume

- △ The Committee agreed that this item will require modelling and costing. This is a new item for a currently unfunded service and this will result in an increase in expenditure. This change will not have an impact on other items in the schedule.

5.1.2 *Alpha thalassaemia genetic testing recommendation (new item)— Recommendation 11*

- △ Create a new item for genetic testing for the alpha-globin gene. This will require a sponsor to progress this outside of the MBS Review.

Rationale 11

The recommendation is focused on improving patient care and encouraging best practice. It is based on the following observations.

- △ The Committee discussed the gap in the schedule for testing for alpha thalassaemia. Item 65078 tests for the diagnosis of thalassaemia consisting of haemoglobin electrophoresis or chromatography and at least two of: (a) examination for HbH; or (b) quantitation of HbA₂; or (c) quantitation of HbF, including (if performed) any service described in item 65060 or 65070) is a serological test for beta thalassaemia.
Alpha thalassaemia is caused by reduced or absent synthesis of alpha-globin chains. Imbalances of globin chains cause haemolysis and impair erythropoiesis. Silent carriers of alpha thalassaemia and people with alpha thalassaemia trait are asymptomatic and require no treatment.
Alpha thalassaemia intermedia, or haemoglobin H disease, causes haemolytic anaemia. Severe reduction in alpha-globin production results in Hb Barts hydrops, which is usually fatal at birth and can be associated with significant maternal morbidity. It is also possible to be a genetic carrier for beta thalassaemia, known as beta thalassaemia trait or beta thalassaemia minor.
- △ A genetic test for alpha thalassaemia is available but patients must pay privately. Some states do fund testing for target populations but this is variable and inconsistent. The concern is that if patients are required to pay for the test (currently estimated to be \$250 privately), it may deter them from having it. The Committee strongly agreed that a new genetic item is required in the MBS schedule. There is a clearly defined population requiring this test, which would be a one-off testing per partnership as a follow-on test from Item 65078.
- △ The Committee agreed that current testing for thalassaemia is underutilised in many areas and growth in item 65078 is to be expected. They supported the promotion of guidelines and education for requesters and consumers, particularly with the growing migrant population in Australia.
- △ Developing this recommendation further is beyond the scope of the MBS review, but the Committee strongly recommend that this should be considered via an expedited MSAC application at the earliest opportunity. The Committee noted there are very few guidelines describing testing for alpha thalassaemia and those that are available are vague and not directive. There is a need for national guidelines to be developed to ensure best practice can be provided to the relevant populations.
- △ The Committee discussed the relevant population who could be eligible for this test and agreed that the following criteria could be used to define the population for testing:

- Women of childbearing potential and appropriately abnormal red cell indices (mean corpuscular volume (MCV) < 80fL and/or MCV < 28fL):
 - without concurrent iron deficiency
 - with iron deficiency if pregnant and no historical normal red cell indices
 - with concurrent beta-globin gene abnormalities that are microcytic, e.g. beta thalassaemia (10 per cent also carry concurrent alpha thalassaemia, commonly co-inherited with HbE).
- Partners of women of childbearing potential with proven alpha thalassaemia (reasonable to refer but not necessarily test males when the partner is under investigation and alpha thalassaemia status is yet to be defined).

5.1.3 **Warfarin care programs (new item)—Recommendation 12**

- △ Refer to MSAC, the *Sansom Review of Anticoagulation Therapies in Atrial Fibrillation 2012* [14] *Recommendation 12*— which recommended that MSAC consider pathology laboratory warfarin programs.

Recommendation 12 from the Sansom Review (2012) for pathology laboratory warfarin programs

Sansom Review Recommendation 12—pathology laboratory warfarin programs

Consideration should be given to the development of a formalised structure of anticoagulation programs offered by pathology laboratories throughout Australia and to the funding of such a structure.

This would need to involve accreditation of such programs as part of a model of shared responsibility, and the development and endorsement of standard operating procedures (including validation of decision algorithms, patient-management protocols and a quality assurance framework).

The Medical Services Advisory Committee should be asked to consider this matter. Introduction of a ‘patient warfarin-management fee’, or an incentive payment linked to the proportion of patients within a certain INR range, rather than an additional Medicare Benefits Schedule fee per INR test, would address concerns regarding potential over-servicing of INR testing.

Rationale 12

- △ Warfarin is a high-risk medication associated with significant health implications if not managed appropriately. Under-dosing, overdosing and non-compliance can result in significant implications for patients and the healthcare system, and models of care with evidence to support better management have been well documented. The MBS schedule provides an opportunity for pathology laboratories to actively engage in providing such programs.
- △ The Sansom Review acknowledged a range of models and strategies to improve warfarin management, including point of care testing (PoCT) in GP clinics, anticoagulation clinics, pathology laboratory services and pharmacy-led anticoagulation services. It made several specific recommendations related to warfarin management, including *Recommendation 12*, recommending MSAC consider the development of formal anticoagulation programs through pathology laboratories. The Report noted that this model is currently provided through some pathology laboratories in Victoria and Queensland.
- △ Other recommendations in the Review (*Recommendations 10 and 11*) related to warfarin management included government consideration of PoCT models and shared-care models.

Sansom Review Recommendation 10 — point-of-care testing

The use of point-of-care testing (PoCT) for the measurement of INR values should be considered as an option for warfarin management, particularly in the community setting. Such testing could be conducted at a medical practice or could involve a collaborative shared-care arrangement between a patient's medical practitioner and other health professionals with whom the patient has regular and convenient contact (e.g. domiciliary and residential care qualified staff, pharmacists).

Uptake of PoCT in Australia, as a component of a warfarin management program, should be considered for government support.

Sansom Review Recommendation 11 — shared-care model

A nationally endorsed shared-care model for warfarin monitoring and management between health practitioners should be developed. This will require the development of standard protocols and quality assurance systems and consideration of relevant legislation. Such a model has the potential to significantly improve both health outcomes and patient satisfaction.

- △ The Committee recommended that the Sansom Review recommendations be considered in the context of the MBS Review, and recognised that while a number of other models may also be considered for funding options in the future, the pathology laboratory model is a current and realistic option that could be implemented relatively easily through the MBS.

5.2 Recommendations to General Practice Primary Care Clinical Committee (GPPCCC) and the Diagnostic Medicine Clinical Committee (DMCC)

The Committee identified many opportunities where practice could be improved by ensuring that guidelines are up to date, education is provided, MBS item descriptors are integrated into practice software and, for high-priority areas, decision support tools are developed. The integration of the MBS item descriptors into practice software may provide requesters a better understanding of the components of specific tests to help ensure the most appropriate tests are ordered to enhance patient care.

The following areas were identified as high priority for intervention:

- △ Coagulation tests:
 - Promote guidelines and education to encourage requesters to order specific tests rather than a 'coagulation screen'.
 - Consider the concept of standardised panels of coagulation tests being ordered for the appropriate indications, supported by appropriate education/decision support tools.
- △ D-dimer:
 - Promote guidelines and education to ensure appropriate test ordering and interpretation of results.
- △ Thrombophilia tests:
 - Promote up-to-date guidelines and education to support requesters to order appropriate tests. This is an area where decision support would be beneficial.
 - Consider the concept of standardised panels of coagulation tests being ordered for the appropriate indications, supported by appropriate education/decision support tools.
- △ Erythrocyte sedimentation rate:

- Promote up-to-date guidelines and education regarding the limitations of the test in most clinical settings.

6. References

- [1] Elshaug, AG, AM Watt, L Mundy and CD Willis. Over 150 potentially low-value health care practices: an Australian study. *Med J Aust* 2012;197(10):556-60.
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Appendix A—Assigned items: recommendations list

Item	Current descriptor	Recommendation	Section reference
65060	Haemoglobin, erythrocyte sedimentation rate, blood viscosity - 1 or more tests	Change	4.9
65066	Examination of: (a) a blood film by special stains to demonstrate Heinz bodies, parasites or iron; or (b) a blood film by enzyme cytochemistry for neutrophil alkaline phosphatase, alphanaphthyl acetate esterase or chloroacetate esterase; or (c) a blood film using any other special staining methods including periodic acid Schiff and Sudan Black; or (d) a urinary sediment for haemosiderin including a service described in item 65072	Change	4.10
65070	Erythrocyte count, haematocrit, haemoglobin, calculation or measurement of red cell index or indices, platelet count, leucocyte count and manual or instrument generated differential count - not being a service where haemoglobin only is requested - one or more instrument generated set of results from a single sample; and (if performed) (a) a morphological assessment of a blood film; (b) any service in item 65060 or 65072	No change	4.7
65072	Examination for reticulocytes including a reticulocyte count by any method - 1 or more tests	No change	4.12
65075	Haemolysis or metabolic enzymes - assessment by: (a) erythrocyte autohaemolysis test; or (b) erythrocyte osmotic fragility test; or (c) sugar water test; or (d) G-6-P D (qualitative or quantitative) test; or (e) pyruvate kinase (qualitative or quantitative) test; or (f) acid haemolysis test; or (g) quantitation of muramidase in serum or urine; or (h) Donath Landsteiner antibody test; or (i) other erythrocyte metabolic enzyme tests - 1 or more tests	Change	4.6
65078	Tests for the diagnosis of thalassaemia consisting of haemoglobin electrophoresis or chromatography and at least 2 of: (a) examination for HbH; or (b) quantitation of HbA ₂ ; or (c) quantitation of HbF; including (if performed) any service described in item 65060 or 65070	No change	4.12
65079	Tests described in item 65078 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	No change	4.12
65081	Tests for the investigation of haemoglobinopathy consisting of haemoglobin electrophoresis or chromatography and at least 1 of: (a) heat denaturation test; or (b) isopropanol precipitation test; or (c) tests for the presence of haemoglobin S; or (d) quantitation of any haemoglobin fraction (including S, C, D, E) including (if performed) any service described in item 65060, 65070 or 65078	Change	4.10
65082	Tests described in item 65081 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	No change	4.12
65084	Bone marrow trephine biopsy - histopathological examination of sections of bone marrow and examination of aspirated material (including clot sections where necessary), including (if performed): any test described in item 65060, 65066 or 65070	No change	4.12
65087	Bone marrow - examination of aspirated material (including clot sections where necessary), including (if performed): any test described in item 65060, 65066 or 65070	No change	4.12
65090	Blood grouping (including back-grouping if performed) - ABO and Rh (D antigen)	No change	4.12

Item	Current descriptor	Recommendation	Section reference
65093	Blood grouping - Rh phenotypes, Kell system, Duffy system, M and N factors or any other blood group system - 1 or more systems, including item 65090 (if performed)	No change	4.12
65096	Blood grouping (including back-grouping if performed), and examination of serum for Rh and other blood group antibodies, including: (a) identification and quantitation of any antibodies detected; and (b) (if performed) any test described in item 65060 or 65070	Change	4.1
65099	Compatibility tests by crossmatch - all tests performed on any one day for up to 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies, and if necessary identification of any antibodies detected; and (c) (if performed) any tests described in item 65060, 65070, 65090 or 65096 (item is subject to rule 5)	Change	4.2
65102	Compatibility tests by crossmatch - all tests performed on any one day in excess of 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies, and if necessary identification of any antibodies detected; and (c) (if performed) any tests described in item 65060, 65070, 65090, 65096, 65099 or 65105 (Item is subject rule 5)	Delete	4.2, 4.11
65105	Compatibility testing using at least a 3-cell panel and issue of red cells for transfusion - all tests performed on any one day for up to 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies and, if necessary, identification of any antibodies detected; and (c) (if performed) any tests described in item 65060, 65070, 65090 or 65096 (item is subject to rule 5)	Delete	4.2, 4.11
65108	Compatibility testing using at least a 3-cell panel and issue of red cells for transfusion - all tests performed on any one day in excess of 6 units, including: (a) all grouping checks of the patient and donor; and (b) examination for antibodies and, if necessary, identification of any antibodies detected; and (c) (if performed) any tests described in item 65060, 65070, 65090, 65096, 65099 or 65105 (Item is subject to rule 5)	Delete	4.2, 4.11
65109	Release of fresh frozen plasma or cryoprecipitate for the use in a patient for the correction of a coagulopathy - 1 release.	No change	4.12
65110	Release of compatible fresh platelets for the use in a patient for platelet support as prophylaxis to minimise bleeding or during active bleeding - 1 release.	No change	4.12
65111	Examination of serum for blood group antibodies (including identification and, if necessary, quantitation of any antibodies detected)	Change	4.1
65114	1 or more of the following tests: (a) direct Coombs (antiglobulin) test; (b) qualitative or quantitative test for cold agglutinins or heterophil antibodies	No change	4.12
65117	1 or more of the following tests: (a) spectroscopic examination of blood for chemically altered haemoglobins; (b) detection of methaemalbumin (Schumm's test)	Delete	4.11
65120	Prothrombin time (including INR where appropriate), activated partial thromboplastin time, thrombin time (including test for the presence of heparin), test for factor XIII deficiency (qualitative), Echis test, Stypven test, reptilase time, fibrinogen, or 1 of fibrinogen degradation products, fibrin monomer or D-dimer - 1 test	Change	4.3
65123	2 tests described in item 65120	No change	4.3, 4.12

Item	Current descriptor	Recommendation	Section reference
65126	3 tests described in item 65120	Change	4.3
65129	4 or more tests described in item 65120	Delete	4.3, 4.11
65137	Test for the presence of lupus anticoagulant not being a service associated with any service to which items 65175, 65176, 65177, 65178 and 65179 apply	No change	4.12
65142	Confirmation or clarification of an abnormal or indeterminate result from a test described in item 65175, by testing a specimen collected on a different day - 1 or more tests	No change	4.12
65144	Platelet aggregation in response to ADP, collagen, 5HT, ristocetin or other substances; or heparin, low molecular weight heparins, heparinoid or other drugs - 1 or more tests	Change	4.5
65147	Quantitation of anti-Xa activity when monitoring is required for a patient receiving a low molecular weight heparin or heparinoid - 1 test	Change	4.10
65150	Quantitation of von Willebrand factor antigen, von Willebrand factor activity (ristocetin cofactor assay), von Willebrand factor collagen binding activity, factor II, factor V, factor VII, factor VIII, factor IX, factor X, factor XI, factor XII, factor XIII, Fletcher factor, Fitzgerald factor, circulating coagulation factor inhibitors other than by Bethesda assay - 1 test (Item is subject to rule 6)	No change	4.12
65153	2 tests described in item 65150 (Item is subject to rule 6)	No change	4.12
65156	3 or more tests described in item 65150 (Item is subject to rule 6)	No change	4.12
65157	A test described in item 65150, 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	4.12
65158	Tests described in item 65150, other than that described in 65157, if rendered by a receiving APP - each test to a maximum of 2 tests (Item is subject to rule 6 and 18)	No change	4.12
65159	Quantitation of circulating coagulation factor inhibitors by Bethesda assay - 1 test	No change	4.12
65162	Examination of a maternal blood film for the presence of foetal red blood cells (Kleihauer test)	No change	4.12
65165	Detection and quantitation of foetal red blood cells in the maternal circulation by detection of red cell antigens using flow cytometric methods including (if performed) any test described in item 65070 or 65162	No change	4.12
65166	A test described in item 65165 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	No change	4.12
65171	Test for the presence of antithrombin III deficiency, protein C deficiency, protein S deficiency or activated protein C resistance in a first degree relative of a person who has a proven defect of any of the above - 1 or more tests	No change	4.8, 4.12
65175	Test for the presence of antithrombin III deficiency, protein C deficiency, protein S deficiency, lupus anticoagulant, activated protein C resistance - where the request for the test(s) specifically identifies that the patient has a history of venous thromboembolism - quantitation by 1 or more techniques - 1 test (Item is subject to Rule 6)	Change	4.8, 4.10
65176	2 tests described in item 65175 (Item is subject to rule 6)	No change	4.8, 4.12
65177	3 tests described in item 65175 (Item is subject to rule 6)	No change	4.8, 4.12

Item	Current descriptor	Recommendation	Section reference
65178	4 tests described in item 65175 (Item is subject to rule 6)	No change	4.8, 4.12
65179	5 tests described in item 65175 (Item is subject to rule 6)	No change	4.8, 4.12
65180	A test described in item 65175, if rendered by a receiving APA, where no tests in the item have been rendered by the referring APA - 1 test (Item is subject to rule 6 and 18)	No change	4.8, 4.12
65181	Tests described in item 65175, other than that described in 65180, if rendered by a receiving APA - each test to a maximum of 4 tests (Item is subject to rule 6 and 18)	No change	4.8, 4.12
73829 (referred item)	Leucocyte count, erythrocyte sedimentation rate, examination of blood film (including differential leucocyte count), haemoglobin, haematocrit or erythrocyte count by a participating nurse practitioner - 1 test	No change	4.12
73830 (referred item)	2 tests described in item 73829 by a participating nurse practitioner	No change	4.12
73831 (referred item)	3 or more tests described in item 73829 by a participating nurse practitioner	No change	4.12

Appendix B—New or split items

Item	Proposed descriptor	Recommendation	Section reference
New split 650XX	Blood group and examination of serum for Rh and other blood group antibodies using 2- or 3-cell panel (including 65090)	Split the current item into two items—an initial test that includes screening for antibodies (650XX), and a second item that includes the identification and measurement only if antibodies are detected.	4.1
New split 650YY	Release of red cells for transfusion by e-issue or after immediate spin, regardless of volume on any one day. Explanatory note: This item must be in association with new item 650XX (i.e. performed based on the absence of current or documented history of red cell antibodies)	Combine the existing four compatibility items into two items, based on whether positive antibodies are detected. One item will be for the screening and release of antibody-negative blood (650YY), and the other for further testing and release of antibody-positive blood. Most cases do not require more than 6 units to be released in any one day.	4.2
New split	D-dimer The proposed descriptor would contain the following elements: — diagnosis of VTE or PE to exclude the need for further imaging in a patient with a low pre-test clinical probability of VTE or PE as defined by local algorithms; — follow-up to support decision to cease anticoagulation; or — diagnosis and monitoring of disseminated intravascular coagulopathy (DIC).	Split D-dimer from item 65120 into a separate item with clinical restrictors to ensure its appropriate use.	4.4
New split 651XX	Platelet aggregation in response to up to 6 agonists for the diagnosis or confirmation of platelet function disorders. Explanatory note or rule: only requested by, or in communication with, a consultant physician or specialist pathologist.	Split the existing item 65144 into two separate items—initial platelet function tests involving simpler methods, and platelet aggregation tests involving more complex and expensive methods (651XX). This second item should only be ordered by, or in communication with, a specialist to ensure its appropriate use.	4.5
New	Release of intravenous immunoglobulin (IV Ig) or subcutaneous immunoglobulin (SC Ig) for use in a patient for an approved indication as defined by the National Blood Authority.	Introduce a new MBS item for the release of immunoglobulin (see section 5.1.1 of the full report for detail).	5.1.1
New	Alpha thalassaemia genetic testing	Introduce a new MBS item to test for alpha thalassaemia (see section 5.1.2 of the full report for detail)	5.1.2
New	Warfarin care programs	MSAC consider Recommendation 12 of the <i>Sansom Review of Anticoagulation Therapies in Atrial Fibrillation</i> (see section 5.1.3 of the full report for detail).	5.1.3

Appendix C—Summary for consumers

This table describes the pathology service, the recommendation(s) of the clinical experts and why the recommendation(s) has been made.

Recommendation 1: Blood group and blood group antibody items

Item	What it does	Committee recommendation	What would be different	Why
65096 and 650XX	Every individual has one of many blood groups on their blood cells and may develop antibodies to 'foreign' blood groups that may cause transfusion reactions when transfused. When being transfused it is important to transfuse the same blood group to prevent reactions. Blood group and blood group antibody tests are used to determine a patient's blood group, screen for any antibodies, and if antibodies are detected (i.e. they are antibody positive), then to identify and measure them.	Split the current item into two items—an initial test that includes screening for antibodies, and a second item that includes the identification and measurement only if the initial test is positive for antibodies.	Instead of one item that includes all aspects of the testing, there would be one item for the initial screening for antibodies and a second item that would only be used if the antibody screen was positive (antibodies detected in the blood). There will be no impact on patients.	About 95 per cent of tests do not detect any antibodies (they are antibody negative). Only five per cent of tests are antibody positive and need further investigation. The work required to perform the second part of this test is significantly higher and more complex. Splitting the item will allow each part to be costed separately and more fairly. This also follows the practical steps in the laboratory processes.

Recommendation 2: Compatibility testing items 65099, 65102, 65105 and 65108

Item	What it does	Committee recommendation	What would be different	Why
65099 and 650YY	Compatibility testing is used in blood transfusions to check that patient and donor blood is compatible to ensure there is no reaction. This requires screening for antibodies. If antibodies are detected, further tests including cross-matching are required. Once checked, the blood is released for use. Often many units of blood may need to be released.	Combine the existing four items into two items, based on whether positive antibodies are detected. One item will be for the screening and release of antibody-negative blood, and the other for further testing and release of antibody-positive blood. Most cases do not require more than 6 units to be released in any 1 day. There will be no difference for patients.	There would be 2 items instead of 4 items. The 2 items will be based on whether antibodies are detected. If antibodies are not detected the process is simpler. If antibodies are detected, further testing is required. There will be no impact on patients.	About 10 per cent of patients requiring a transfusion are antibody positive or have had a history of antibodies. This requires cross-match testing that is more complex and more expensive to perform. About 90 per cent of patients will be antibody negative and no further testing will be required. Basing the items on whether or not antibodies are detected will mean that the 2 items can be more appropriately costed. This also follows the practical steps in the laboratory processes.

Recommendation 3: Coagulation test items 65120, 65123, 65126 and 65129

Item	What it does	Committee recommendation	What would be different	Why
65120—65129	Coagulation tests are used to assess how a patient's blood is clotting. Several different types of tests are used, depending on the clinical circumstances for each patient.	Limit the number of tests funded through the MBS to a maximum of 3 different types of tests rather than 4 tests.	<p>Doctors can still order more tests, and more tests can be performed by the pathologist, but the maximum fee payable will be for '3 or more tests'. The Committee believes that in most cases a maximum of 3 tests is sufficient.</p> <p>There will be no difference to patients in terms of having blood samples taken, but only clinically relevant coagulation tests would be performed on the blood sample.</p>	Requesters should order the specific tests that they need, but often this does not happen and more tests may be performed than clinically required. By limiting the number of tests to '3 or more', there is an incentive for laboratories to only perform the necessary tests. Very occasionally more than 3 tests will be required, but this is the not common.

Recommendation 4: D-dimer

Item	What it does	Committee recommendation	What would be different	Why
Split item from 65120	D-dimer is a test used to rule out blood clotting in the veins of the leg or arm (deep venous thrombosis—DVT) or clotting in the lung (pulmonary embolus—PE).	Split D-dimer into a separate item with clinical restrictors to ensure its appropriate use.	<p>D-dimer would be ordered separately. The descriptor would include the clinical situations in which the test is appropriate, to help guide requesters to order the test only when necessary. It will be possible to monitor how this test is being used if it has a separate item number.</p> <p>Patients will benefit if requesters have clear guidance on when this test is appropriate to order.</p>	D-dimer is a useful test when it is used in the appropriate situations. It has very specific use, and the results need to be carefully interpreted. Guidelines are available but it is important that the requesters understand that they should only order the test for certain clinical situations. At the moment, it is not possible to know how often the test is being used, and splitting it out will make monitoring and education programs in the future easier to implement.

Recommendation 5: Platelet function tests

Item	What it does	Committee recommendation	What would be different	Why
65144 and 651XX	<p>Platelets are circulating particles in the blood that are an important part of the clotting mechanism in the body. Abnormalities of platelets may cause easy bleeding. Platelet tests are used to identify and diagnose bleeding disorders related to abnormalities of platelets.</p> <p>There are two broad types of tests—one for initial assessment of platelet function using simpler methods, and another for formally assessing platelet aggregation (clumping) that uses more complex methods.</p>	<p>Split the existing item into two separate items—initial platelet function tests involving simpler methods, and—platelet aggregation tests involving more complex and expensive methods. The second item should only be ordered by, or in communication with, a specialist to ensure its appropriate use.</p>	<p>Basic platelet function tests will still be available to be ordered by current requesters. More formal platelet aggregation tests will require a patient to see a specialist, because these tests are complex and expensive and should only be ordered for specific investigations. Splitting the item will enable both types of tests to be costed appropriately. The current item is being used for both types of tests, which was not the intention of this item when introduced on the Schedule.</p> <p>Patients requiring formal platelet aggregation studies will need to see a specialist, which may mean an additional consultation. This is required to ensure that the test is clinically appropriate.</p>	<p>The current item is being used to fund initial platelet function testing as well as the formal platelet aggregation studies. Splitting the item will enable restrictions to be introduced to platelet aggregation tests to ensure the test is only ordered when clinically appropriate. It will also enable more appropriate costing of both types of tests.</p>

Recommendation 6: Assessment of haemolysis or metabolic enzymes item 65075

Item	What it does	Committee recommendation	What would be different	Why
65075	<p>Red blood cells carry haemoglobin and transport oxygen to tissues. Several tests are available to help assess and diagnose causes of red cells breaking down (haemolysis) or red blood cell damage. Some of these tests are no longer used, and newer tests have become the gold standard.</p>	<p>Remove several obsolete tests no longer used, and add a new test (E5M) which is now the best way of diagnosing a common cause of haemolysis.</p>	<p>The best test would be available for diagnosing haemolysis. The item would be modernised by removing obsolete tests no longer recommended.</p> <p>Patients will have access to the most relevant tests.</p>	<p>The current item includes tests that are no longer used. Adding new tests such as E5M that are now routinely used and considered to be the most appropriate, will update the item descriptor and enable funding of the most appropriate tests.</p>

Recommendation 7: Full Blood Examination item 65070

Item	What it does	Committee recommendation	What would be different	Why
65070	A full blood examination provides a count of the various components in blood, and if abnormalities are detected, assessment of the blood is performed by microscope to further describe these.	No change to the tests, but add an explanatory note to guide requesters to order the tests for the most appropriate patients.	Not applicable.	Not applicable.

Recommendation 8: Thrombophilia items 65171—65181

Item	What it does	Committee recommendation	What would be different	Why
65171—65181	Thrombophilia tests are used to investigate and diagnose clotting disorders.	Minor change.	Not applicable.	Not applicable.

Recommendation 9: Erythrocyte sedimentation rate and blood viscosity

Item	What it does	Committee recommendation	What would be different	Why
65060	Erythrocyte sedimentation rate (ESR) is a test used to help diagnose some diseases. It is also used to assess inflammation, although its usefulness is limited. Blood viscosity is a test used to determine the thickness or stickiness of an individual's blood.	No change to the ESR part of the tests, but remove blood viscosity from this item.	This is a test that is no longer used and is now obsolete. Removing it will not impact patient care.	This test is no longer relevant.

Recommendation 10: Release of immunoglobulin

Item	What it does	Committee recommendation	What would be different	Why
New item	<p>This item will provide funding for the provision of immunoglobulin to approved patients. Immunoglobulin replacement therapy is one of the most important and successful therapies for people with primary immunodeficiency diseases. Approval for the use of immunoglobulin and its supply is overseen by the National Blood Authority. It has protocols outlining ordering, dispensing and reporting requirements that must be met by laboratories.</p> <p>There is currently no funding for this service under the MBS.</p>	Introduce a new MBS item for the release of immunoglobulin (see section 5.1.1 of the full report for detail).	<p>The proposed MBS item number would be used to reimburse laboratories for the work involved in managing immunoglobulin.</p> <p>There are existing items in the Schedule for the release of platelets and fresh frozen plasma.</p> <p>There would be no impact on patients.</p>	At present these services have been provided without funding. The demand for immunoglobulins has increased by 10 per cent per year over the past decade. The NBA has recently introduced protocols governing the ordering, dispensing and reporting that all laboratories involved must adhere to. This has significantly increased the administrative burden for these laboratories.

Recommendation 11: Alpha thalassaemia genetic testing

Item	What it does	Committee recommendation	What would be different	Why
New item	This item will provide a genetic test for the testing of alpha thalassaemia (a blood disorder that reduces the production of haemoglobin), which is not currently covered under the MBS.	Introduce a new MBS item to test for alpha thalassaemia (see section 5.1.2 of the full report for detail).	This test would be funded under the MBS, enabling clinically relevant people to have this test without cost.	This is a significant gap in the Schedule. It is a significant risk in specific populations and the lack of funding may mean some people do not have this test, as they do not have the resources to pay for it privately. The consequences are significant, with neonatal death and significant maternal morbidity.

Recommendation 12: Warfarin care programs

Item	What it does	Committee recommendation	What would be different	Why
New item	Warfarin prevents inappropriate blood clotting. This item would provide funding for pathology laboratory warfarin programs that manage warfarin monitoring and dosing for individual patients.	The Medical Services Advisory Committee (MSAC) consider Recommendation 12 of the <i>Sansom Review of Anticoagulation Therapies in Atrial Fibrillation</i> (see section 5.1.3 of the full report for detail).	Patients on warfarin could have the option of having their warfarin therapy managed through a formal program offered by pathology laboratories providing this service.	Evidence supports that pathology laboratories can effectively provide these services and this could provide an alternative model to GP managed care for warfarin dosing.

Appendix D—Glossary

Term	Description
ABS	Australian Bureau of Statistics
APCR	Activated protein C resistance – a test used in the investigation of tendency to venous thromboembolism
CAGR	Compound annual growth rate, or the average annual growth rate over a specified time period.
Change	When referring to an item, 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 2 or more items).
Coning, or episode coning	Episode coning is an arrangement that places an upper limit on the number of services in an episode for which Medicare benefits are payable, and was introduced to prevent over-servicing by doctors. Generally, when more than three items are requested in an episode by a GP for an out-of-hospital service, Medicare only pays for the three most expensive items. Pathology services requested for hospital in-patients, or ordered by specialists, are not subject to these coning arrangements.
Department, The	Australian Government Department of Health
Delete	Describes when an item is recommended for removal from the MBS and its services will no longer be provided under the MBS.
DIC	Disseminated intravascular coagulation
DMCC	Diagnostic Medicine Clinical Committee
DMARDs	Disease-modifying anti-rheumatic drugs
E5M	Eosin-5-maleimide
ESR	Erythrocyte sedimentation rate
FY	Financial year
GP	General practitioner
GPPCCC	General Practice and Primary Care Clinical Committee
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.
HS	hereditary spherocytosis
Inappropriate use / misuse	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.
INR	International normalised ratio – a test used in monitoring warfarin therapy and part of broader testing of anticoagulation.
IVIg	Intravenous immunoglobulin
LTA	Light transmission aggregometry
Low-value care	Services that evidence suggests confer no, or very little, benefit to consumers; or for which the risk of harm exceeds the likely benefit; or, more broadly, where the added costs of services 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.

Term	Description
MBS service	The actual medical consultation, procedure or test to which the relevant MBS item refers.
Misuse (of MBS item)	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.
MSAC	Medical Services Advisory Committee
NBA	National Blood Authority
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 provided, as they do not represent current clinical best practice and have been superseded by superior tests or procedures.
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PE	Pulmonary embolism
PoCT	Point of care testing
RANZCR	Royal Australian and New Zealand College of Radiologists
RCPA	The Royal College of Pathologists of Australia
SCIg	Subcutaneous immunoglobulin
Services average annual growth	The average growth per year, over 5 years to FY 2014–15, in utilisation of services. Also known as the compound annual growth rate (CAGR).
Split items	Where an item contains more than 1 test or more than 1 process, a recommendation to split the item means that that part of the test would become a separate item number.
The Committee	The Pathology Clinical Committee
The Taskforce	The MBS Review Taskforce
Total benefits	Total benefits paid in 2014–15 unless otherwise specified.
VTE	Venous thromboembolism