Medicare Benefits Schedule Review Taskforce

Second report from the Pathology Clinical Committee on Chemical Pathology

September 2017

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 5700 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 The Taskforce will also seek to identify any services that may be unnecessary, outdated or potentially unsafe.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 MBS Review process

The Taskforce has endorsed a process whereby the necessary clinical review of MBS items is undertaken by Clinical Committees and Working Groups. The Taskforce asked all committees in the second tranche of the Review process to review MBS items using a framework based on Appropriate Use Criteria accepted by the Taskforce (Elshaug). This framework includes the following steps:

- Review data and literature relevant to the items under consideration.
- Identify MBS items that are potentially obsolete, are of questionable clinical value, are misused and/or pose a risk to patient safety.
- Develop and refine recommendations for these items, based on the literature and relevant data, in consultation with relevant stakeholders.

In complex cases, full appropriate use criteria were developed for an item's descriptor and explanatory notes. All second-tranche committees involved in this Review adopted this framework, which is outlined in more detail in Section 2.3.

The recommendations from the Clinical Committees will be released for stakeholder consultation. The Clinical Committees will consider feedback from stakeholders and then provide recommendations to the Taskforce in Review reports. The Taskforce will consider the Review reports from Clinical Committees, along with stakeholder feedback, before making recommendations to the Minister for Health for consideration by the Government.

1.2 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. This the second report on Chemical Pathology items. In the 2014–15 financial year chemical items accounted for 47 million services and $1 billion in benefits. Over the four years to 2016 chemical testing has grown by nearly 20%. 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.

1.3 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 for consultation

The Committee's recommendations for stakeholder consultation are:

- **that 14 items should be deleted from the MBS;**
- **22 items should be changed; and**
- **51 items should remain unchanged.**

The Committee has proposed 4 new items expected to be referred to the Medicare Services Advisory Committee (MSAC). Forty-three tests were reviewed in the first chemical report.

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.

- **Frequent and common clinical chemistry tests –** introduce three new items that would group some of the tests covered under 66500 into three commonly requested panels.
- **Antenatal testing for chromosomal abnormalities in pregnancy –** Change the item descriptors of items 66750 and 66751 to stipulate first trimester screening and second trimester screening tests.
- **Quantitation of HDL-cholesterol –** Create a new item for lipids that includes moving cholesterol and triglycerides from item 66500 into this new item.
- **Tumour markers –** Change the item descriptors to specify which cancer and stage of disease a tumour marker is indicated for and remove cancer-associated serum antigen (CASA) and thyroglobulin from the list of TMs in item 66650.

Recommendations for referral to other committees

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

- **ApoB and Lipoprotein (a) testing**
- **Brain natriuretic peptide**
- **Chromogranin A –** for inclusion in the list of tumour markers in item 66650; very clear descriptors will be required to ensure appropriate use in the most suitable patient populations
- **Human epididymis protein 4 –** for inclusion in the list of tumour markers in item 66650; very clear descriptors will be required to ensure appropriate use in the most suitable patient populations.

1.4 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 A, 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); and subsidised health professional services listed on the Medicare Benefits Schedule (MBS).

What is the MBS?

The MBS is a listing of the health professional services subsidised by the Australian Government. There are more than 5700 MBS items, which provide benefits to patients for a comprehensive range of services including consultations, diagnostic tests and operations.

2.2 The MBS Review Taskforce

What is the MBS Review Taskforce?

The Government established an MBS Review Taskforce (the Taskforce) to review all 5700 MBS items to ensure that they align with contemporary clinical evidence and practice, and to improve health outcomes for patients. The Review is clinician-led, and there are no targets for savings attached to the Review. Following stakeholder feedback, the Taskforce will present its recommendations to the Minister for Health for consideration by the Government.

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-serviced.
- **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 Medical Services Advisory Committee (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 (Elshaug).[1] The framework consists of seven steps:

1. Develop an initial fact base for all items under consideration, drawing on the relevant data and literature.
2. Identify items that are obsolete, are of questionable clinical value, are misused 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 items. This step also involves consultation with relevant stakeholders within the Committee, Working Groups, and relevant colleagues or colleges. For complex cases, full appropriate use criteria were developed for the item's explanatory notes.
5. Review the provisional recommendations and the accompanying rationales, and gather further evidence as required.
6. Finalise the recommendations in preparation for broader stakeholder consultation.

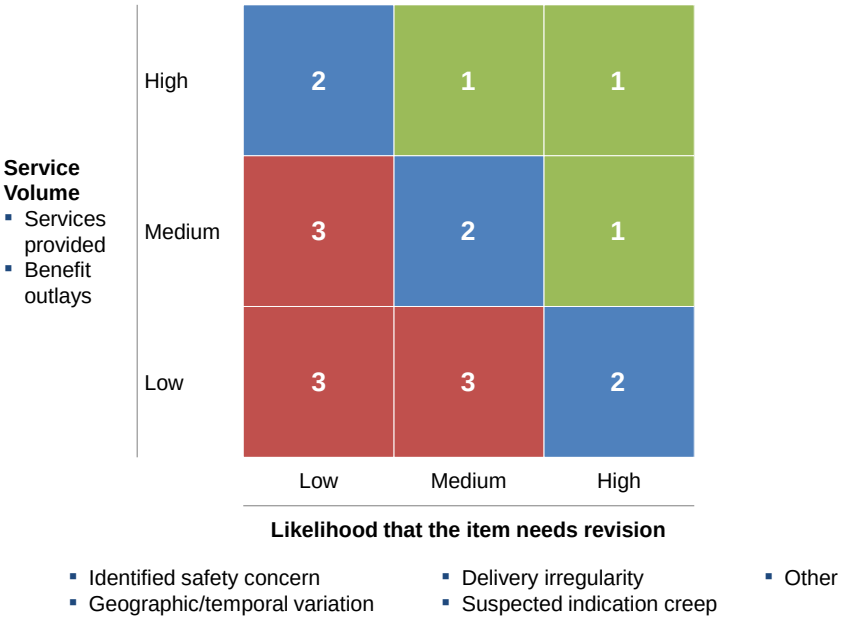
7. Incorporate feedback gathered during stakeholder consultation and finalise the Review report, which provides recommendations for the Taskforce.

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

- 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 Committee consists of 17 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.

3.1 Pathology Clinical Committee members

Table 1: Pathology Clinical Committee Members

Name	Position/Organisation	Declared conflict of interest
Associate Professor Peter Stewart (Chair)	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
Professor Hans Schneider	Director of Pathology, Alfred Hospital Melbourne (Public)	None
Dr Melody Caramins	Specialist Diagnostic Services (Primary)	None
Dr John Rowell	Royal Brisbane & Women's Hospital (Public)	None
Professor Dominic Mallon	PathWest	None
Dr Peter Roberts	Ryde Hospital (AESM)	None
Associate Professor Anthony Landgren	Australian Clinical Labs	None

Name	Position/Organisation	Declared conflict of interest
Associate Professor Mary-Jo Waters	St Vincent's Pathology (CHA)	None
Professor Richard Maclsaac	St Vincent's Hospital	None
Dr Emil Djakic	General practitioner	None
Dr Bev Rowbotham	MBS Taskforce	None
Dr Jill Thistlethwaite	General practitioner	None
Ms Valerie Hanrahan	Consumers Health Forum	None
Dr Robyn Lindner	NPS MedicineWise	None
Associate Professor Adrienne Morey	ACT Pathology (Public): formerly SydPath, St Vincent's (Catholic)	None

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

3.2 Chemical Working Group

The Chemical Working Group is one of six clinical working groups that have been established to support the work of the Pathology Clinical Committee. It was established to review chemical pathology items, and make recommendations to the Pathology Clinical Committee based on rapid evidence review and clinical expertise. This report has been endorsed by the Pathology Clinical Committee to go out for consultation before MBS Taskforce consideration.

The Chemical Working Group consists of eight members, whose names, positions/organisations and declared conflicts of interest are listed in Table 2 below. The following members were involved in the Chemical Working Group and have since resigned from the working group. Dr Nimalie Perera was involved from June to August 2016, Dr Glenn Edwards was involved from June to November 2016 and Dr Simon Morgan from October to November 2016. These members resigned before finalisation of the report.

Table 2: Chemical Working Group Members

Name	Position/organisation	Declared conflict of interest
Professor Hans Schneider (Chair)	Director of Pathology, Alfred Pathology Service (Melbourne); Adjunct Clinical Professor, Central Clinical School, Monash University; President, Public Pathology Australia	None
Dr Lawrie Bott	Pathologist, Sonic Healthcare	None
Dr David Deam	Chemical Pathologist, Australian Clinical Labs	None
Dr Alan McNeil	Chemical Pathologist, Dorevitch Pathology, Melbourne	None
Associate Professor Ken Sikaris	Chemical Pathologist, Sonic	None
Dr Trina Gregory	Clinical Director, Watson General Practice, ACT Member, Expert Committee for Systems Innovations and eHealth, RACGP	None
Dr Rashmi Sharma	Adjunct Associate Professor, GP supervisor ANU; Regional of Head of Education, North Coast NSW, GP Synergy. Member of PBAC	None
Ms Helen Maxwell-Wright	Director, Maxwell-Wright Associates Consumer representative	None

3.3 Tumour Marker Working Group

The Tumour Marker Working group (a subset of the Chemical Working Group) consists of seven members, whose names, positions/organisations and declared conflicts of interest are listed in Table 3 below.

Table 3: Tumour Marker Working Group Members

Name	Position/organisation	Declared conflict of interest
Professor Hans Schneider (Chair)	Director of Pathology, Alfred Pathology Service (Melbourne); Adjunct Clinical Professor, Central Clinical School, Monash University; President, Public Pathology Australia	None
Associate Professor Mustafa Khasraw	Medical oncologist, Royal North Shore Hospital, Sydney; Senior Research Fellow, NHMRC Clinical Trials Centre, University of Sydney	None
Dr David Deam	Chemical Pathologist, Australian Clinical Labs	None
Associate Professor Paul Craft	Clinical Director, Canberra Region Cancer Centre; Senior Staff Specialist in Medical Oncology, Associate Professor, ANU Medical School	None
Dr Trina Gregory	Clinical Director, Watson General Practice, ACT; Member, Expert Committee for Systems Innovations and eHealth, RACGP	None
Dr Rashmi Sharma	Adjunct Associate Professor, GP supervisor ANU; Regional of Head of Education, North Coast NSW, GP Synergy. Member of PBAC	None
Ms Helen Maxwell-Wright	Director, Maxwell-Wright Associates Consumer representative	None

3.4 Areas of responsibility of the Committee

The Committee was assigned 134 MBS chemical pathology items (MBS 2014-15).

3.5 Summary of the Committee's review approach

The Committee completed a review of 87 chemical pathology items and four 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.

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 requestor, geography of service provision)
- patients (demographics and services per patient)
- co-claiming or episodes of services (same-day claiming and claiming with specific items over time)
- additional requestor 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.

Stakeholders are now engaged in consultation on the recommendations resulting from this process, which are outlined in this report. 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

4.1 Frequent and common clinical chemistry tests, blood gas and calcium

4.1.1 Items 66500, 66503, 66506, 66509, 66512

Table 4. Item introduction table for items 66500, 66503, 66506, 66509, 66512

Item	Long item descriptor	Schedule fee	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66500	Quantitation in serum, plasma, urine or other body fluid (except amniotic fluid), by any method except reagent tablet or reagent strip (with or without reflectance meter) of: acid phosphatase, alanine aminotransferase, albumin, alkaline phosphatase, ammonia, amylase, aspartate aminotransferase, bicarbonate, bilirubin (total), bilirubin (any fractions), c-reactive protein, calcium (total or corrected for albumin), chloride, creatine kinase, creatinine, gamma glutamyl transferase, globulin, glucose, lactate dehydrogenase, lipase, magnesium, phosphate, potassium, sodium, total protein, total cholesterol, triglycerides, urate or urea - 1 test	9.70	$6,308,575	773,058	615,911	1.9%
66503	2 tests described in item 66500	11.65	$4,145,309	420,472	364,532	-1.5%
66506	3 tests described in item 66500	13.65	$3,024,195	261,076	245,291	-6.5%
66509	4 tests described in item 66500	15.65	$977,610	74,626	66,029	-0.9%
66512	5 or more tests described in item 66500	17.70	$213,288,912	14,459,663	6,654,498	4.0%

Recommendation

The Committee proposes the following:

- Introduce three new items that would group some of the tests covered under 66500 into three commonly requested panels. The three panels would cover: electrolytes, urea and creatinine (EUC), liver function tests (LFTs) and calcium, phosphate with albumin. Lipids tests will be taken out of the group and integrated into the HDL item. The tests that are currently covered under 66500 that would be grouped under the three panels are set out in Table 5 underneath
- For each clinical group, a minimum panel has been developed with laboratories free to add additional tests to the panel if they wish to. Most of the individual tests will also be retained within 66500 to enable requesting of that specific test if needed.
- Remove acid phosphatase from item 66500 as it is a superseded test.
- Remove globulin from item 66500 as it is a calculated test.
- Move cholesterol and triglycerides tests from item 66500 and group these with the HDL item 66536 on the Schedule.
- Retain glucose in list of single tests and do not include it in the new EUC panel.
- Retain lactate dehydrogenase in list of single tests and not include it in the LFT panel.
- Add neonatal bilirubin as a single test for infants.
- Develop an education program for GPs about the appropriate collection and transport of samples (and in particular glucose tests) to ensure reliable testing.
- Provide education to requestors about these changes to item 66500. The proposed clinical test groupings will need data modelling for funding, and the Schedule fee structure should be considered by the Pathology Business Group. Laboratories will have to modify their billing systems to account for this change to item 66500.

Table 5. Recommended clinical groupings of tests in item 66500

Clinical groupings	Tests	Item
Urea, electrolytes, creatinine	bicarbonate sodium potassium urea creatinine chloride	New item
Liver function tests	alanine aminotransferase albumin alkaline phosphatase bilirubin (total) gamma glutamyl transferase total protein	New item
Single tests	ammonia amylase C-reactive protein creatine kinase glucose lipase magnesium urate neonatal bilirubin lactate dehydrogenase chloride aspartate aminotransferase	Item 66500
Calcium and phosphate	calcium phosphate albumin	New item

Rationale

Recommended changes to these items are based on the following observations.

- These tests are the most frequently requested tests in the chemical pathology schedule. The large majority of these tests are provided in the item stating 5 or more tests. During the 2014–2015 financial year, there were 773,058 services provided at a cost of $6.3 million for item 66500, while the large majority of services (14,459,663 services) were provided for the item 66512 at an outlay of $213,288,912. For item 66500, the most times a patient received this service was 102 and for item 66512, the most times a patient received this service was 206. The main requestors for items 66500–66512 were GPs. Utilisation of item 66500 across States and Territories appear to be equal with the highest per capita use of services seen in Tasmania with 4,321 per 100,000 people and the lowest number in Queensland with 2,283 services per 100,000.
- Item 66500 and the associated ladder items accounted for more than 15 million services and more than $225 million expenditure during the 2014–15 financial year, and include the most commonly requested chemical pathology tests. These tests had been grouped together under item 66500 because modern chemical pathology analysers generally perform any or all of these tests off a single platform from a single sample. However, this grouping does not reflect

common requesting practice. Instead, clinicians commonly request tests as a panel with each panel comprising a number of standard tests that are relevant to a particular clinical question. For instance, liver function tests as a group comprise at least alanine aminotransferase, albumin, alkaline phosphatase, bilirubin, gamma glutamyl transferase and total protein. Aspartate aminotransferase, although less liver specific, is frequently measured in patients with existing hepatitis, as it is useful in the prediction of prognosis of liver cirrhosis.

- A number of tests listed in item 66500 have a specific purpose (eg, C-reactive protein for the detection of inflammation/infection) as an individual test. The Committee considered the clinical value of each test stated in the item descriptor in item 66500. Most of the current tests have well-accepted clinical utility. The Committee suggests that there would be merit in moving to a system where the items better align with clinical rather than laboratory practice. Not only would this standardise the tests performed under the three suggested panels but would also enable better use of MBS data to inform public health. For example, the use of the current item 66500 and associated ladders for lipid testing mean that it is not possible to use MBS data to assess the use of lipid testing in Australia despite important public health implications. Further lipids may be ordered without HDL, which is a crucial part of the lipid panel and required in all clinical risk predictors for patients. Although coning means that the MBS data set is incomplete, with very large volume testing there is still considerable public health value in using MBS data to reveal patterns of usage including overall volumes of testing, patient demographics and rates of repeat testing. None of this is currently available for any of the tests covered under 66500 and the ladder items.
- The Committee has recommended that the new items should cover a minimum number of agreed tests and laboratories could add to the panel (under the same item) if they so choose. For each of the proposed panels the Committee has developed the recommended test panel listed in Table 1 which represents the consensus view of the Committee. For instance, the minimum tests required for a urea, electrolytes, or creatinine group of tests would be: sodium, bicarbonate, potassium, urea, creatinine and chloride. For liver function tests, the minimum tests suggested are: alanine aminotransferase, albumin, alkaline phosphatase, bilirubin (total), gamma glutamyl transferase, total protein; aspartate aminotransferase should be performed as a reflex test if alanine aminotransferase is abnormal.
- The Committee considered whether glucose should be included in the EUC panel as a means of improving the incidental detection of diabetes, noting that currently serum glucose is commonly reported by laboratories even when not specifically requested. However, glucose is metabolised by red cells and levels fall when there is delay between sampling and processing. This can lead to artificially lower readings of glucose and hence missed cases of diabetes. This problem is minimised when glucose is collected in fluoride oxalate collection tubes with the correct media and stored and transported in ice (to prevent glucose metabolism) when delays are anticipated. For this reason the Committee recommended that glucose be retained as a single test and not included in the EUC panel and proposed that GPs be educated about the appropriate collection, storage and transport of samples to ensure more reliable results.

- The clinical utility of lactate dehydrogenase as a test was reviewed by the Committee, as it has been noted that it is associated with high rate of false-positives. Lactate dehydrogenase is primarily used for detecting haemolysis. It was formerly used to diagnose myocardial infarction, although there are more sensitive and specific tests available. The Committee suggests that lactate dehydrogenase has little clinical value and should not be included in the liver function tests panel, as the test itself does not change the clinical management of liver disease. However, lactate dehydrogenase can be a useful test to detect other conditions, such as conditions with increased cell turnover. For this reason, the Committee recommended that lactate dehydrogenase be retained in the list of available single tests but not be included as one of the liver function tests.
- It was recommended that two tests be removed from item 66500 as they no longer have clinical utility. These are acid phosphatase and globulin.
- Acid phosphatase is rarely requested and may have clinical relevance in extremely rare patients with de-differentiated prostate cancer where prostate-specific antigen is unreliable. This patient population is very small and the Committee recommended the deletion of this test from item 66500.
- The globulin test is a calculation rather than a test and the Committee recommended the deletion of this test from item 66500.

While the Committee proposed these changes, it recognised that there may be a potential impact on coning as a result of increasing the number of items in the schedule.

4.2 Tests done in diagnosing pregnancy and disease in pregnancy

4.2.1 Amniotic fluid: item 66749

Table 6. Item introduction table for item 66749

Item	Long item descriptor	Schedule fee	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66749	Amniotic fluid, spectrophotometric examination of, and quantitation of: (a) lecithin/sphingomyelin ratio; or (b) palmitic acid, phosphatidylglycerol or lamellar body phospholipid; or (c) bilirubin, including correction for haemoglobin 1 or more tests	32.95	$1,283	46	33	14.9%

Recommendation

The Committee proposes the following:

- Delete item 66749 from the MBS Schedule.

Rationale

- During the 2014–2015 financial year, there were 46 services provided at a cost of $1,238 for item 66749. The test is only performed in major cities, with the majority performed at one site in Victoria. Item 66749 is a test to measure foetal lung maturity and is used when deciding whether to deliver the foetus or wait longer to allow the lungs to develop. The item is split into three tests and the specific use of each test can't be determined. The lecithin: sphingomyelin ratio test is no longer used in clinical practice.
- Although this item is currently requested by obstetricians, there are no guidelines from Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) on the use of this item and the subsequent follow-up tests. The Committee sought expert advice from the Obstetrics and Gynaecology Clinical Committee on the clinical appropriateness of this test. They advised that the test is used infrequently, but that it can be helpful in a small group of patients. However this advice did not explain why this item is only used in one site in Victoria.
- The Committee undertook a review of international clinical guidelines regarding the use of this test in clinical practice. A clinical paper published in *Reviews in Obstetrics and Gynecology* in 2013 concluded that amniocentesis for foetal lung maturity may be obsolete, with the exception of patients where foetal dating does not meet the American College of Obstetricians and Gynecologists' standards. A further review article published in 2014 reported similar conclusions about foetal lung maturity testing having passed its clinical utility. This review article further stated that a mature foetal lung index in antenatal testing does not lead to improved neonatal outcomes. The Society for Maternal–Fetal Medicine Clinical Guidelines state that amniotic fluid delta should not be used to diagnose foetal anaemia.
- The Committee recommended deleting item 66749 from the Schedule, due to low utilisation and evidence confirming that the test has diminishing clinical utility. The Committee further noted that quality assurance is difficult to maintain for very low volume tests.

4.2.2 Antenatal testing for chromosomal abnormalities in pregnancy: items 66750 and 66751

Table 7. Item introduction table for items 66750 and 66751

Item	Long item descriptor	Schedule fee	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66750	Quantitation, in pregnancy, of any two of the following - total human chorionic gonadotrophin (total HCG), free alpha human chorionic gonadotrophin (free alpha HCG), free beta human chorionic gonadotrophin (free beta HCG), pregnancy-associated plasma protein a (PAPP-A), unconjugated oestriol (uE3), alpha-fetoprotein (AFP) - to detect foetal abnormality, including a service described in 1 or more of items 73527 and 73529 (if performed) - (Item is subject to rule 25)	39.75	$3,671,596	101,240	101,054	0.2%
66751	Quantitation, in pregnancy, of any three or more tests described in 66750 (Item is subject to rule 25)	55.25	$2,136,248	43,850	43,790	-1.7%

Recommendation

The Committee proposed the following:

- Change the wording in item descriptor of item 66750 to stipulate that the test is performed as a first trimester screening test.
- Change the wording in the item descriptor of item 66751 to stipulate that the test is performed as a second trimester screening test.

Table 8. Current and proposed item descriptor for items 66750 and 66751

Item	Current item descriptor	Proposed item descriptor
66750	Quantitation, in pregnancy, of any two of the following - total human chorionic gonadotrophin (total HCG), free alpha human chorionic gonadotrophin (free alpha HCG), free beta human chorionic gonadotrophin (free beta HCG), pregnancy associated plasma protein a (PAPP-A), unconjugated oestriol (uE3), alpha-fetoprotein (AFP) - to detect foetal abnormality, including a service described in 1 or more of items 73527 and 73529 (if performed) - (Item is subject to rule 25)	Quantitation, in pregnancy, of free beta human chorionic gonadotrophin (free beta HCG) and pregnancy associated plasma protein A (PAPP-A) to detect foetal abnormality, in the first trimester of pregnancy. including a service described in 1 or more of items 73527 and 73529 (if performed) – (Item is subject to rule 25)
66751	Quantitation, in pregnancy, of any three or more tests described in 66750	Quantitation, in pregnancy, of three or more of the following - total human chorionic gonadotrophin (total HCG), free alpha human chorionic gonadotrophin (free alpha HCG), unconjugated oestriol (uE3), alpha-fetoprotein (AFP) - to detect foetal abnormality *in the second trimester of pregnancy when a test described under 66750 has not been performed in the first trimester of pregnancy*, including a service described in 1 or more of items 73527 and 73529 (if performed) *this test is not be used with item 55707* - (Item is subject to rule 25)

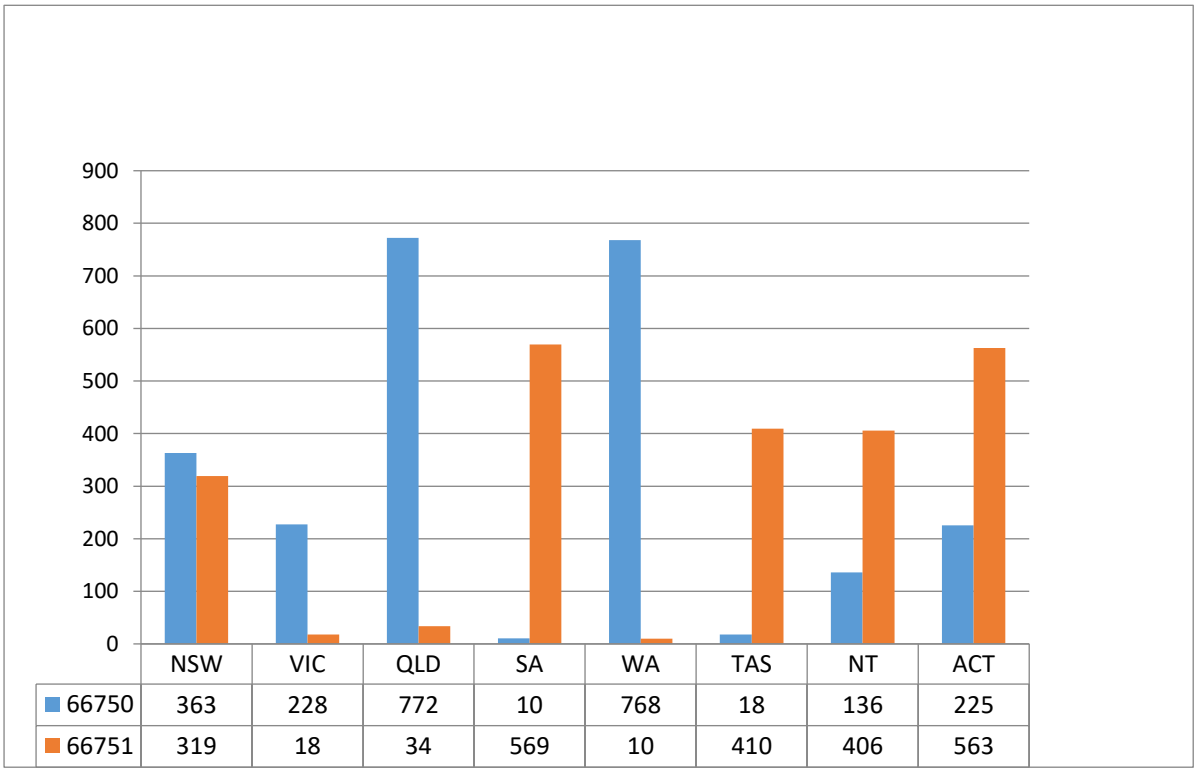
Rationale

- Items 66750 and 66751 are tests mainly used in pregnancy to assist in detection of congenital malformations in the foetus before birth. During the 2014–2015 financial year, there were 101,240 services provided at a cost of approximately $3.6 million for item 66750 and 43,850 services provided at a cost of approximately $2.1 million for item 66751.
- The Committee sought advice from the Obstetrics and Gynaecology Clinical Committee on first trimester screening in pregnant women.
- Combined first trimester screening includes a nuchal translucency ultrasound, PAPP-A and beta-HCG at 11–13 weeks. If first trimester screening is not performed then second trimester screening can be performed which includes testing of AFP, free beta-HCG, unconjugated oestriol and inhibin A. Nuchal translucency (NT) ultrasound is not a component of second trimester screening. Based on accepted guidelines and usual practice, most pregnant women in Australia who are undergoing antenatal screening should undergo first trimester screening.
- Review of MBS data showed marked clinical variation in the use of items 66750 and 66751 (see Figure 2). The Committee noted that first trimester screening is covered under the tests listed under 66750. To determine whether women in states with high rates of 66751 relative to 66750 were not accessing first trimester screening and instead undergoing second trimester screening,

MBS data for items 66750 and 66751 were matched with MBS items for nuchal translucency scans (NTS). It would be anticipated that women who have second trimester screening (and hence tests done under 66751) would not have had an accompanying NT scan.

- The Committee reviewed nuchal translucency ultrasound data, which did not demonstrate the anticipated pattern of use (ie, the two test item 66750 being performed with NTS and the three or more test item 66751 not being associated with NTS). Instead NTS was commonly associated with each item (see Table x). There were more episodes (58,659) where item 66750 was provided with an NTS (item 55707), which is clinically appropriate. However, there were 33,359 episodes where item 66751 was associated with an NTS. This suggests that most women are having first trimester screening, rather than second trimester screening but that some laboratories are performing three or more tests (item 66751) when only two tests (item 66750) are necessary for first trimester screening.
- The Committee recommended that the item descriptors be amended to specify that 66750 is for first trimester screening and item 66751 is available for second trimester screening which is available when a patient had not undergone first trimester screening. These amendments will fit with how these tests are commonly requested ("first trimester screening" or "second trimester screening") and direct laboratories as to what test should be performed for these two patient groups. It should address the concern that first trimester patients are undergoing unnecessary testing.

Figure 2. State variation in utilisation of items 66750 and 66751 represented as tests/100,000 people



	NSW	VIC	QLD	SA	WA	TAS	NT	ACT
66750	363	228	772	10	768	18	136	225
66751	319	18	34	569	10	410	406	563

Table 9. Co-claiming data for items 66750 and 66751 and nuchal translucency scan (item 55707)

Financial year of service	Trigger combination	Co-claimed combination	Timeframe when co-claimed	Episodes
2015-16	66750	55707.	Same day	8,337
2015-16	66750	55707.	8 weeks before or after	58,659
2015-16	66750	TOTAL	Same day	95,793
2015-16	66751	55707	Same day	15,565
2015-16	66751	55707	8 weeks before or after	33,359
2015-16	66751	TOTAL	Same day	42,092

4.3 Markers of cardiac risk or heart failure

4.3.1 Cardiac or skeletal muscle damage: items 66518 and 66519

Table 10. Item introduction table for items 66518 and 66519

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66518	Investigation of cardiac or skeletal muscle damage by quantitative measurement of creatine kinase isoenzymes, troponin or myoglobin in blood - testing on 1 specimen in a 24-hour period	20.05	$6,833,426	424,285	304,377	2.0%
66519	Investigation of cardiac or skeletal muscle damage by quantitative measurement of creatine kinase isoenzymes, troponin or myoglobin in blood - testing on 2 or more specimens in a 24-hour period	40.15	$1,662,420	53,543	46,650	4.2%

Recommendation

The Committee proposes the following:

- Change the wording of the item descriptor for item 66518 to remove creatine kinase isoenzymes and myoglobin.
- Change the wording of the item descriptor for item 66519 to remove creatine kinase isoenzymes and myoglobin.

Table 11: Current and proposed new item descriptor for items 66518 and 66519

Item	Current item descriptor	Proposed item descriptor
66518	Investigation of cardiac or skeletal muscle damage by quantitative measurement of creatine kinase isoenzymes, troponin or myoglobin in blood - testing on 1 specimen in a 24-hour period	Investigation of cardiac muscle damage by quantitative measurement of troponin I or T - testing on 1 specimen in a 24-hour period
66519	Investigation of cardiac or skeletal muscle damage by quantitative measurement of creatine kinase isoenzymes, troponin or myoglobin in blood - testing on 2 or more specimens in a 24-hour period	Investigation of cardiac muscle damage by quantitative measurement of troponin I or T - testing on 2 or more specimens in a 24-hour period.

Rationale

- Items 66518 and 66519 are used to detect cardiac damage. During the 2014–15 financial year, there were 424,285 services provided at a cost of $6.8 million for item 66518 and there were 53,543 services provided at a cost of $1.7 million for item 66519.
- Compared to city and regional Australia, these items are underutilised in remote and very remote regions of Australia (see table 12). Currently, there are no data on the split of the items between inpatient tests in hospitals versus community testing. Nonetheless, the Committee noted that item 66519 would be used more in hospital inpatients and item 66518 used in community patients.
- Troponin is a superior test to creatine kinase isoenzymes to detect cardiac ischaemia and as a result creatine kinase isoenzymes test are no longer routinely performed. Myoglobin does not have clinical utility in cardiac ischaemia disease testing. The Committee considered that while myoglobin testing might be appropriate occasionally in patients with acute kidney injury and rhabdomyolysis, it is not routinely used for this purpose in Australian health care, and thus proposed its deletion from the item descriptors for cardiac damage.
- The preferred test for assessing cardiac damage is cardiac troponin I or T and there is no longer a role for measuring creatine kinase isoenzymes or myoglobin in modern clinical practice.[2]

Table 12: Number of services per 100,000 persons

Item	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Very remote Australia
66518	1 803	1 940	1 773	1 096	717
66519	237	235	179	111	58

4.3.2 Quantitation of HDL-cholesterol: item 66536

Table 13. Item introduction table for item 66536

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66536	Quantitation of HDL cholesterol	11.05	$15,279,415	1,627,953	1,359,313	-3.3%

Recommendation

The Committee proposes the following:

- Δ Create a new item for lipids that includes moving cholesterol and triglycerides from item 66500 into this new item.
- Δ Seek MSAC evaluation of new item(s) for ApoB and Lipoprotein(a) testing

Rationale

- Δ As discussed at 4.1.1, the Committee reviewed items 66500, 66503, 66506, 66509 and 66512 and recommends that the tests covered under these items be grouped in a manner that matches clinical practice, to allow better tracking of clinical utilisation. As part of this revision, the Committee recommends that cholesterol and triglycerides tests covered under item 66500 be grouped with the HDL item 66536.There was a strong view among the Committee that a stand-alone lipids item is required. National and international recommendations support the HDL test as a crucial mandatory test in any lipid profile, as it provides important clinical information. As an example, the absolute cardiovascular disease risk calculator requires an HDL result.
- Δ Evidence suggests that elevated plasma concentrations of ApoB-100 containing LDL and VLDL cholesterol can induce atherosclerosis even in the absence of other risk factors. The European Guidelines include the option to use APO A1 and APO B, pointing out that they can be measured non-fasting. Apo B testing further enhances the benefits of non-HDL cholesterol measurement. These tests are particularly useful in the setting of hypertriglyceridaemia, where homogeneous HDL cholesterol assays may be compromised.
- Δ ApoB was introduced in the 2009 Canadian dyslipidaemia guidelines as an alternate primary target of therapy.[3] Growing evidence indicates that the risk of CV events during therapy correlates more strongly with ApoB or non-HDL-cholesterol than LDL-cholesterol.
- Δ Lipoprotein (a) (a specialised form of LDL, where one molecule of apoprotein (a) is bound to an LDL particle) is an independent risk factor for cardiovascular disease events, especially myocardial infarction. Evidence points to a causative role in acute myocardial infarction. While in the past this conditions was not easily treated, there is new evidence that PCSK9 inhibitors influence its levels and its measurement might improve management of patients who qualify

for these medications. Lipoprotein (a) measurement is indicated in high risk groups for AMI (eg, in patients with a personal or family history of premature CVD, or those with family history of elevated lipoprotein (a)).

Table 14: Current and proposed new item descriptor for items 66536 and ladder

Item	Current item descriptor	Proposed item descriptor
66536	Quantitation of HDL cholesterol	Quantitation of HDL–cholesterol, *triglycerides, total cholesterol, LDL–cholesterol, non-HDL–cholesterol(fee to be determined)*
Ladder item (subject to MSAC assessment)		*Quantitation of HDL–cholesterol, triglycerides, total cholesterol, LDL–cholesterol, non-HDL–cholesterol and Apo B in patients with hypertriglyceridaemia*
Ladder item (subject to MSAC assessment)		*Quantitation of HDL–cholesterol, triglycerides, total cholesterol, LDL–cholesterol, non-HDL–cholesterol and LP (a) in patients on PCSK9 inhibitors and on nicotinic acid*

The recommendations of the Committee will need review by the Business group in relations to fee-setting, and by MSAC in relation to new items.

4.4 Brain natriuretic peptide (BNP)

Table 15. Item introduction table for item 66830

Item	Long item descriptor	Schedule fee	Services FY 2014-15	Benefits FY2014-15	Patient count 2014-15	5-year service change % (CAGR)
66830	Quantitation of BNP or NT-proBNP for the diagnosis of heart failure in patients presenting with dyspnoea to a hospital emergency department(item is subject to rule 25)	$58.50	9,820	$455,734	8,483	23.4%

Recommendation

Δ Refer to MSAC a proposal to create a new item to allow GPs to order BNP or NT-proBNP in a primary care setting

Rationale

Δ The diagnosis of heart failure (HF) remains a difficult clinical challenge in all settings. Unlike patients presenting to emergency rooms with symptoms of acute heart failure, patients

presenting to primary care settings often have mild or no obvious symptoms, or they present with only risk factors for the condition. In primary care, diagnosis is based predominantly on clinical symptoms, as more specific diagnostics such as echocardiography may not be readily available. While many national and international guidelines recommend the use of natriuretic peptides as an aid to diagnosis of heart failure in acute settings, few specific recommendations exist for using these peptides in primary care populations.

- Δ The Committee requested a literature review on the use of BNP/NT-proBNP in the diagnosis of heart failure in primary care.[4] The literature concluded that information provided in the included clinical practice guidelines and systematic reviews suggests that there is evidence to support the use of BNP/NT-proBNP testing to exclude a diagnosis of heart failure in the primary care setting in patients who present with dyspnoea. The literature supports different exclusion thresholds for patients presenting with acute onset or worsening of symptoms (eg, to a hospital emergency department) and those presenting with a more gradual onset of symptoms (eg, such as in the primary care setting).
- Δ Based on the conclusions of the review, the Committee recommended a new MBS item descriptor to support testing of BNP or NT-proBNP for the diagnosis of heart failure in primary care. Such an item would enable general practitioners working in primary care to order BNP or NT-proBNP test for a subpopulation.

Table 16: Proposed new item descriptor

Item	Proposed new item descriptor
New item	Quantitation of BNP or NT-proBNP for the diagnosis of heart failure in patients, without previous myocardial infarction, presenting with dyspnoea in primary care (Item is subject to rule 25)

4.5 Urine and faeces-related tests

4.5.1 Quantitation of disaccharides: item 66680

Table 17. Item introduction table for item 66680

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66680	Quantitation of disaccharidases and other enzymes in intestinal tissue - 1 or more tests	74.45	$2,723,789	47,952	47,734	11.2%

Recommendation

- Change the wording of the item descriptor of item 66680 to include the following wording: 'This test is useful in patients who can't perform the breath test or in patients who have false positive breath test results because of small bowel bacterial overgrowth'.
- Develop an education program aimed at gastroenterologists to outline the proposed changes to the item 66680

Table 18. Current and proposed new item descriptor for item 66680

Item	Current item descriptor	Proposed new item descriptor
66680	Quantitation of disaccharidases and other enzymes in intestinal tissue - 1 or more tests	Quantitation of disaccharidases and other enzymes in intestinal tissue - 1 or more tests. *This test is useful in patients who can't perform the breath test or in patients who have false positive breath test results because of small bowel bacterial overgrowth*

Rationale

- Item 66680 is a technically complex test used to test for lactase deficiency in malabsorption; gastroenterologists are the main requestors of this test. There has been a steady 11.2% annual increase in utilisation over the last 5 years. The utilisation of item 66680 is uneven across the States and Territories with utilisation concentrated in QLD, NSW and ACT (see Figure 3). The Committee sought advice from gastroenterologists (as the main requestors of this test) before proposing changes to this item. The advice from the gastroenterologists was as follows:
    - the test is not considered a clinically useful test in adults because there is poor correlation between symptoms and enzyme levels
    - paediatricians in Victoria tend to use the test for lactase deficiency and malabsorption deficiencies
    - not many gastroenterologists use this test in the adult population for lactose deficiency
    - the test is automatically performed to detect lactose intolerance, even in asymptomatic patients, which is inappropriate use.
- The Committee reviewed co-claiming data of items 66680 and 66674. Item 66674 is a test for faecal fat used to detect fat malabsorption. The Committee requested this data to determine whether these two items were being claimed together to investigate the possibility of inappropriate requesting. Item 66680 is rarely co-claimed with 66674, only accounting for 3% of episodes within a 24-week period during 2015–16 (see Table 17).
- In view of the marked differences between states and the rapid growth rate of the test the Committee requested a rapid literature review on the clinical utility of 66680.[5]
- The literature review aimed to answer the following research questions: What is the clinical utility of the quantitation of disaccharides and other enzymes in intestinal tissue testing? What is the diagnostic performance of the test? Is it accurately predictive of disease? Is there a clearly

identifiable patient cohort? Are there any differences in test performance between adults and children?

- Δ The literature review concluded that although a correlation between carbohydrate malabsorption and abdominal pain may exist, testing for quantitation of enzymes may not clarify the underlying aetiology of symptoms, which is likely to be multifactorial. A further limitation is that no assessment of symptoms can be made based on the assay alone. This has an impact on the clinical relevance of these investigations because only a small proportion of patients with lactase deficiency develop abdominal symptoms after ingesting lactose. The literature review also concluded that while lactase activity assay is considered the gold standard for lactose malabsorption, this is rarely performed because of the need to perform an upper endoscopy and the availability of non-invasive diagnostic tests. The literature review identified that breath testing is the mainstay of diagnosis for lactose intolerance or lactose deficiency. There was no direct evidence as to the diagnostic performance of the test or level of accuracy. None of the identified studies provided data on adult subjects. The literature review also concluded that the assay may be more suitable for patients with autism-spectrum disorders and others who cannot cooperate with breath testing. Based on the findings of the literature review, the Committee recommended that information about when the test should be used in clinical practice be included in the item descriptor.

Figure 3. State utilisation of item 66680 per 100,000 services

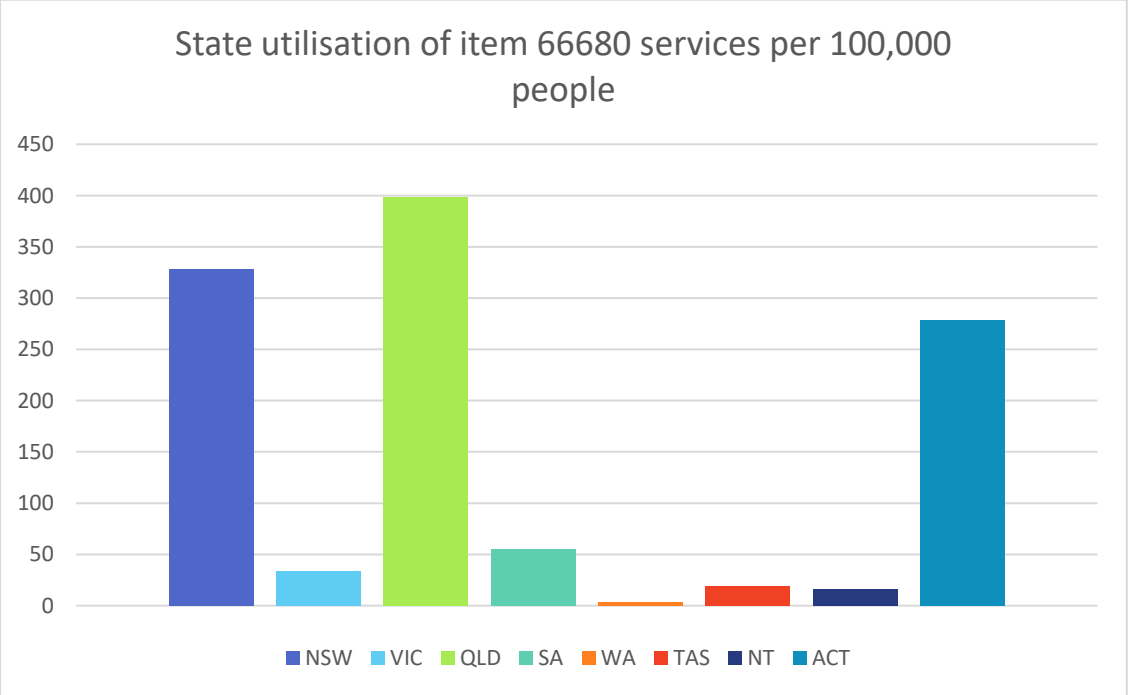


Table 19: Co-claiming data for items 66680 and 66674

Trigger combination	Co-claimed combination	Episodes %	Number of items in combination	Patients	Episodes	Trigger services	Co-claimed services	Services
66674	TOTAL	100.00%	-	3,746	4,187	4,187	127	4,314
66674	None.	97.01%	1	3,634	4,062	4,062	-	4,062
66674	66680.	2.99%	2	118	125	125	127	252

4.5.2 Quantitation of faecal fat: item 66674

Table 20. Item introduction table for item 66674

Item	Long item descriptor	Schedule fee ($)	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66674	Quantitation of: (a) faecal fat; or (b) breath hydrogen in response to loading with disaccharides; 1 or more tests within a 28-day period	39.95	$133,326	3,639	3,364	2.4%

Recommendation

The Committee proposes the following:

- Δ add extra wording to the item descriptor to include monosaccharides
- Δ add faecal elastase in the investigation of pancreatic insufficiency
- Δ add methane to the item descriptor wording.

Table 21: Current and proposed new item descriptor for items 66674

Item	Current item descriptor	Proposed new item descriptor
66674	Quantitation of: (a) faecal fat; or (b) breath hydrogen in response to loading with disaccharides; 1 or more tests within a 28-day period	Quantitation of: (a) faecal fat or *faecal elastase in the investigation of pancreatic insufficiency*; (b) breath hydrogen *and/or methane* in response to loading with disaccharides *or monosaccharides*; 1 or more tests

Rationale

- Δ Item 66674 covers faecal fats or breath hydrogen tests used to detect malabsorption in patients.

- The Committee recommended the inclusion of methane in the item descriptor as some people don't produce a measurable breath hydrogen, and methane is more useful in these cases.
- Monosaccharides are included in the item descriptor because lactulose can be used as a positive control in breath hydrogen testing to determine whether an individual is a hydrogen producer or a methane producer, or to determine how vigorous the breath hydrogen response is in an individual (or a basal response to lactose).
- In a number of pathology laboratories, faecal elastase has replaced faecal fat testing as it allows a shorter collection instead of the 72 hour stool collection for faecal fats and offers good diagnostic performance for fat malabsorption.

4.6 Vitamins

4.6.1 Vitamins B1, B3, B6 or C

Table 22. Item introduction for items 66605, 66606

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66605	vitamins - quantitation of vitamins B1, B2, B3, B6 or C in blood, urine or other body fluid - 1 or more tests	30.60	$667,269	25,613	23,885	23.2%
66606	A test described in item 66605 if rendered by a receiving APP - 1 or more tests(Item is subject to rule 18 and 25)	30.60	$102,466	3,945	3,719	-13.3%

Recommendation

- The Committee did not recommend any changes to these items.

Rationale

- Items 66605 and 66606 are tests for vitamins B1, B2, B3, B6 and C in blood or urine. There has been a marked increase in the utilisation of item 66605 over 5 years. The tests for vitamin B and C are grouped together and the Committee were unable to distinguish the requests for the different tests. As there was a steady increase in utilisation, the Committee queried the clinical utility of vitamin C testing among the Australian population as true deficiency is diminishing. The Committee requested a literature review on vitamin C testing.[6]

- Δ The literature review aimed to answer the following questions:
    - What is the prevalence of vitamin C deficiency in the community?
    - What are the health consequences of vitamin C deficiency?
    - What pre-analytical problems impact on the accuracy of vitamin C testing? What is the likelihood of vitamin C testing being reported incorrectly as deficient?
- Δ The literature review identified that there was a lack of epidemiological studies specific to Australia and therefore the prevalence of vitamin C deficiency is unknown. The prevalence was inferred from international survey data based on nutrient intake. Vitamin C deficiency for men could range 8%–25% and 6%–16% for women and is less prevalent in children and adolescents.
- Δ The literature review identified research data that suggests that vitamin C deficiency is associated with greater risk of mortality from CVD. Patients with poor glomerular filtration rate (GFR) or patients undergoing dialysis are at higher risk of deficiency; lower vitamin C levels in these patients predict fatal and non-fatal major cardiac outcomes. Plasma concentrations of vitamin C are positively correlated with cognitive performance and are significantly reduced in elderly patients with dementia.
- Δ The literature review also concluded that the oxidation and degradation of ascorbic acid may occur due to delays or technical shortcomings in blood sampling, handling, preservation or the analysis procedure. Degradation of dehydroascorbic acid following oxidation of ascorbic acid can potentially result in underestimation of vitamin C concentrations. A diagnosis of vitamin C deficiency should not be made on the basis of the pathology test result alone but in conjunction with a detailed history of dietary inadequacy and clinical signs and symptoms. Based on the conclusions, the Committee recommended that no changes be made to items 66605 and 66606.

4.6.2 Vitamin A and E

Table 23: Item introduction table for items 66607, 66610

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66607	Vitamins - quantitation of vitamins A or E in blood, urine or other body fluid - 1 or more tests within a 6-month period	75.75	$1,041,806	16,003	15,455	11.5%
66610	A test described in item 66607 if rendered by a receiving APP - 1 or more tests	75.75	$92,578	1,440	1,401	-

Recommendation

- Δ The Committee did not recommend any changes to these items.

Rationale

Δ Items 66607 and 66610 are tests used to measure vitamin A or E in blood, urine or other body fluid. They are mainly determined in patients with fat malabsorption. The utilisation of these items is fairly evenly distributed across the different states in Australia and 65% of these tests are requested by specialists. The utilisation seems clinically appropriate.

4.7 Drugs

4.7.1 Drugs of abuse: items 66623, 66626

Table 24. Item introduction table for items 66623 and 66626

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66623	All qualitative and quantitative tests on blood, urine or other body fluid for: (a) a drug or drugs of abuse (including illegal drugs and legally available drugs taken other than in appropriate dosage); or (b) ingested or absorbed toxic chemicals; including a service described in item 66800, 66803, 66806, 66812 or 66815 (if performed), but excluding: (c) the surveillance of sports people and athletes for performance improving substances; and (d) the monitoring of patients participating in a drug abuse treatment program	41.50	$3,714,612	105,956	53,533	13.4%
66626	Detection or quantitation or both (not including the detection of nicotine and metabolites in smoking withdrawal programs) of a drug, or drugs, of abuse or a therapeutic drug, on a sample collected from a patient participating in a drug abuse treatment program; but excluding the surveillance of sports people and athletes for performance improving substances; including all tests on blood, urine or other body fluid (Item is subject to rule 25)	24.10	$2,478,036	121,830	29,232	-1.4%

Recommendation

Δ The Committee did not recommend any changes to these items.

Rationale

Δ These tests remain clinically appropriate and cover a range of testing when drugs are taken illicitly or where there is concern about drug toxicity usually following accidental or intentional drug overdose. The annual increase in 5 years of utilisation of item 66623 is over 13%. However, it is noted that drug testing has been introduced in number of work (non-MBS) and other settings. There is some state variation in the utilisation of item 66623 with VIC, NSW, SA and NT having relatively higher utilisation rates (see Figure 4). The utilisation of item 66626 has decreased slightly over the last 5 years, and there is a wide variation between states in the utilisation of this item. NSW, WA and the NT have the highest utilisation rates (Figure 5)

Figure 4. State utilisation for item 66623 services per 100,000 people

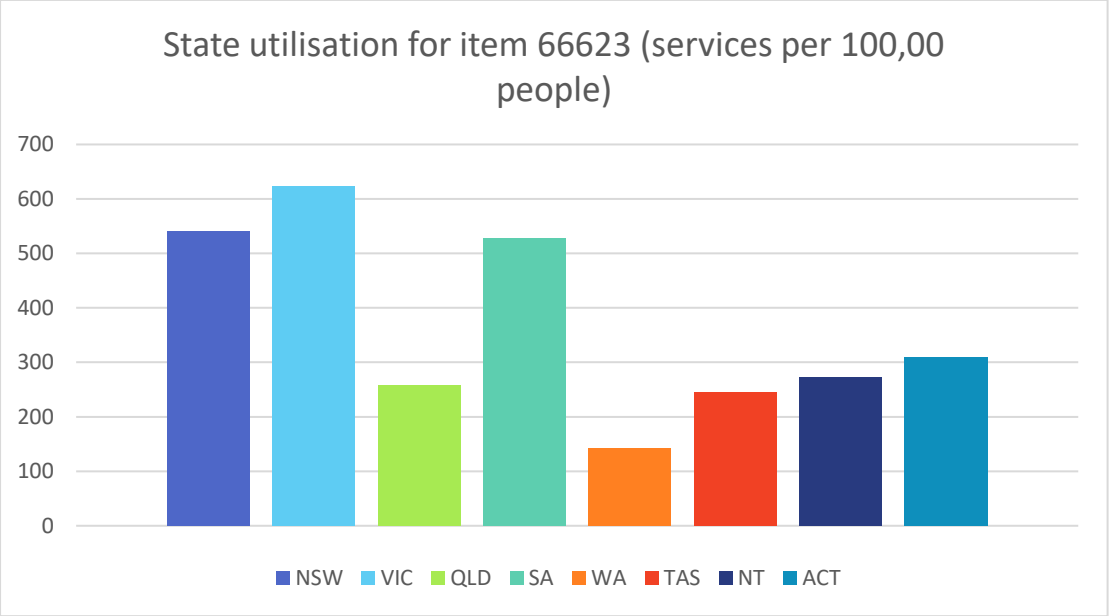
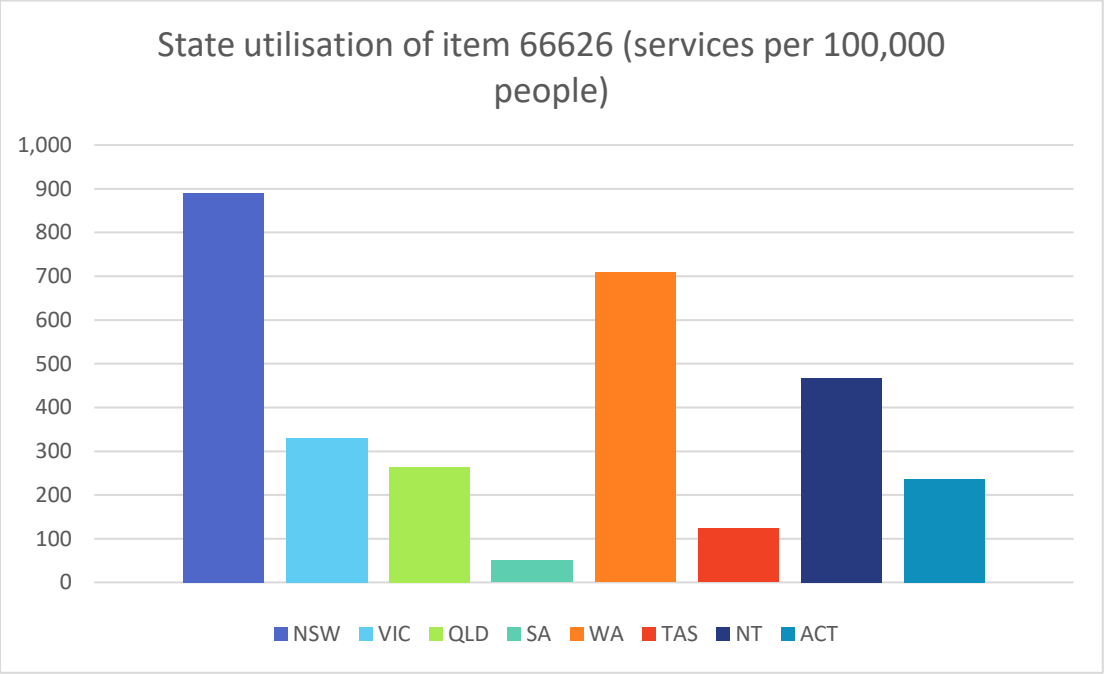


Figure 5. State utilisation for item 66626 services per 100,000 people



4.7.2 Therapeutic drug monitoring: items 66800, 66803, 66804, 66805, 66806

Table 25. Item introduction table for items 66800, 66803, 66804, 66805, 66806

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66800	Quantitation in blood, urine or other body fluid by any method (except reagent tablet or reagent strip) of any of the following being used therapeutically by the patient from whom the specimen was taken: amikacin, carbamazepine, digoxin, disopyramide, ethanol, ethosuximide, gentamicin, lithium, lignocaine, netilmicin, paracetamol, phenobarbitone, primidone, phenytoin, procainamide, quinidine, salicylate, theophylline, tobramycin, valproate or vancomycin - 1 test (Item to be subject to rule 6)	18.15	$4,953,203	332,469	164,128	-2.0%
66803	2 tests described in item 66800 (Item is subject to rule 6)	30.50	$512,679	20,358	12,514	-7.4%

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66804	A test described in item 66800 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)	18.15	$25,916	1,705	1,007	-3.6%
66805	A test described in item 66800 other than that described in 66804, if rendered by a receiving APP - each test to a maximum of 2 tests(Item is subject to rule 6 and 18)	12.35	$4,940	478	351	6.3%
66806	3 tests described in item 66800 (Item is subject to rule 6)	41.85	$36,186	1,085	811	-14.0%

Recommendation

Δ The Committee recommended that the following drugs be removed from the item descriptor of item 66800:

- disopyramide, ethosuximide, lignocaine, netilmicin, procainamide, quinidine, salicylate

Δ The Committee recommended that the following drugs remain in the item descriptor:

- antibiotics: amikacin, gentamicin, tobramycin, vancomycin
- antiepileptic drugs: carbamazepine, phenytoin, phenobarbitone, primidone, valproate
- digoxin, ethanol, lithium, paracetamol, theophylline

Table 26: Current and proposed new item descriptor for item 66800

Item	Current item descriptor	Proposed new item descriptor
66800	Quantitation in blood, urine or other body fluid by any method (except reagent tablet or reagent strip) of any of the following being used therapeutically by the patient from whom the specimen was taken: amikacin, carbamazepine, digoxin, disopyramide, ethanol, ethosuximide, gentamicin, lithium, lignocaine, netilmicin, paracetamol, phenabarbitone, primidone, phenytoin, procainamide, quinidine, salicylate, theophylline, tobramycin, valproate or vancomycin - 1 test (Item to be subject to rule 6)	Quantitation in blood, urine or other body fluid by any method (except reagent tablet or reagent strip) of any of the following being used therapeutically by the patient from whom the specimen was taken: amikacin, carbamazepine, digoxin, ethanol, gentamicin, lithium, paracetamol, phenabarbitone, primidone, phenytoin, theophylline, tobramycin, valproate or vancomycin - 1 test (Item to be subject to rule 6)

Rationale

- The utilisation of items 66800, 66803 and 66806 is relatively evenly-distributed across the states, centred in the major cities, and is declining. This may be due to increased use of drugs that do not require monitoring, and because some of the drugs listed in item 66800 may not be currently used in clinical practice. Several of the drugs described in item 66800 are no longer or very rarely measured in patients – the drugs are not used and/or outdated, or drug monitoring is not helpful.
- These drugs are tested under item 66800 for a therapeutic purpose, and not for toxicity. Tests for toxicity, including salicylate toxicity, are covered under item 66623.
- Tests for therapeutic monitoring of drugs removed from the list covered under 66800 are rarely requested and /or do require therapeutic monitoring. Testing may be helpful rarely and in these instances can be provided in specialised laboratories with quality assurance.

4.7.3 Special therapeutic drug monitoring: items 66812, 66815, 66816, 66817

Table 27. Item introduction table for items 66812, 66815, 66816, 66817

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66812	Quantitation, not elsewhere described in this Table by any method or methods, in blood, urine or other body fluid, of a drug being used therapeutically by the patient from whom the specimen was taken - 1 test (This fee applies where 1 laboratory performs the only test specified on the request form or performs 1 test and refers the rest to the laboratory of a separate APA (Item is subject to rule 6)	34.80	$4,276,391	145,824	36,763	7.4%
66815	2 tests described in item 66812 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs the only 2 tests specified on the request form or performs 2 tests and refers the rest to the laboratory of a separate APA) (Item is subject to rule 6)	59.55	$478,067	9,527	3,902	3.2%

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66816	A test described in item 66812 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)	34.80	$736,244	24,999	11,841	10.0%
66817	A test described in item 66812, other than that described in 66816, if rendered by a receiving APP - to a maximum of 1 test (Item is subject to rule 6 and 18)	24.75	$171,770	8,199	5,102	8.6%

Recommendation

Δ The Committee recommended that these items be left unchanged.

Rationale

Δ Utilisation of item 66812 increased by 10% over the last 12 months. Some of these tests are performed on an auto-analyser, others by high performance liquid chromatography (HPLC) or by liquid chromatography tandem mass spectrometry (LC-MS/MS). These are relatively low volume items and there is no concern about clinically inappropriate use. The items 66812 and 66815 are tests that are used frequently to monitor immunosuppressant drugs in transplantation, and are mainly requested by nephrologists. Items 66816 and 66817 are requested by both gastroenterologists and nephrologists.

Δ The tests in items 66812 can be performed by either immunoassay or mass spectrometry, and were currently billed at the same rate, regardless of methodology. While mass spectrometry is a more accurate method of testing than immunoassay, it is often more important to have test results rapidly, which immunoassay can provide. For patients who are undergoing organ transplantation highly accurate results are required, and mass spectrometry might be preferable.

4.8 Proteins and electrophoresis

4.8.1 Caeruloplasmin, haptoglobins, or prealbumin: Item 66632

Table 28. Item introduction table for item 66632

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66632	Caeruloplasmin, haptoglobins, or prealbumin - quantitation in serum, urine or other body fluids - 1 or more tests	20.10	$996,907	59,454	46,439	6.0%

Recommendation

- The Committee recommended that this item be left unchanged.

Rationale

- Covered under item 66632 are multiple tests used for different purposes: caeruloplasmin to detect Wilson's disease, haptoglobin to detect intravascular haemolysis and prealbumin to determine nutritional status. There has been a steady increase in the utilisation of this item, with the highest utilisation in NSW. The main requestors of item 66632 are haematologists and gastroenterologists.
- There were no issues identified in the use of this item although steady growth was noted.

4.8.2 Alpha-1-antitrypsin: items 66635, 66638, and 66639

Table 29. Item introduction table for item 66635, 66638 and 66639

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66635	Alpha-1-antitrypsin - quantitation in serum, urine or other body fluid - 1 or more tests	20.10	$368,956	21,745	20,513	2.2%
66638	Isoelectric focussing or similar methods for determination of alpha-1-antitrypsin phenotype in serum - 1 or more tests	49.05	$49,068	1,186	1,173	-2.3%
66639	A test described in item 66638 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	29.20	$34,003	1,371	1,360	3.9%

Recommendation

The Committee proposes the following:

- Δ Leave item 66635 unchanged.
- Δ Change the item descriptor of item 66638 (and subsequently 66639) to require abnormal alpha-1-antitrypsin levels or a family history of alpha-1-antitrypsin deficiency for the phenotype testing.

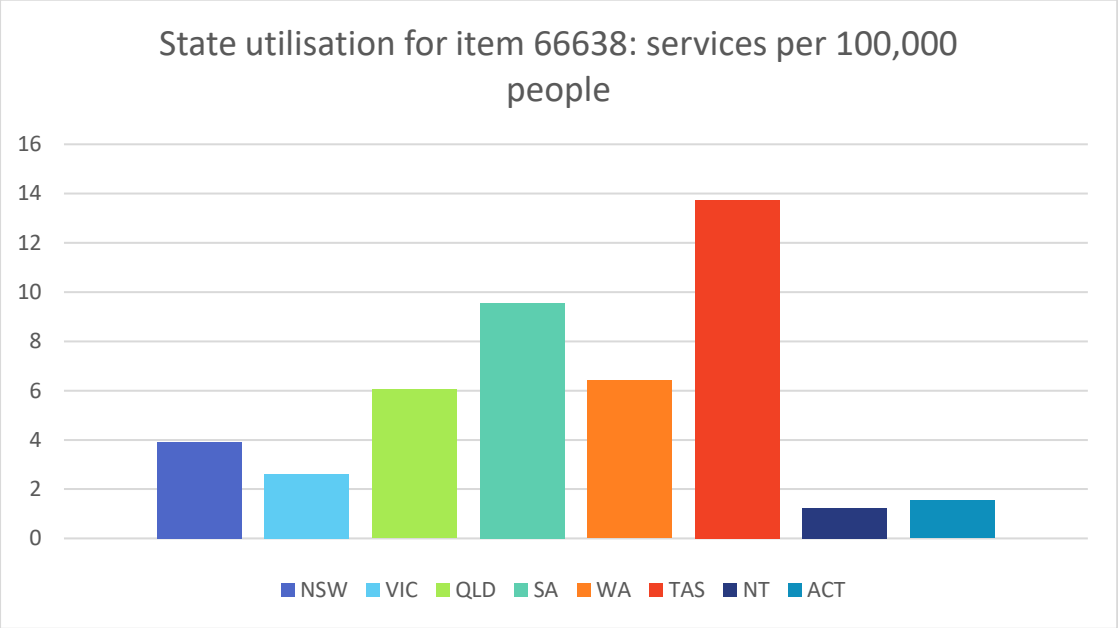
Table 30. Current and proposed new item descriptor for items 66638 and 66639

Item	Current item descriptor	Proposed item descriptor
66638	Isoelectric focussing or similar methods for determination of alpha-1-antitrypsin phenotype in serum - 1 or more tests	Isoelectric focussing or similar methods for determination of alpha-1-antitrypsin phenotype in serum *where alpha-1-antitrypsin levels are abnormally low or there is a family history of alpha-1-antitrypsin deficiency* -1 or more tests
66639	A test described in item 66638 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	

Rationale

- Items 66635, 66638 and 66639 are tests used to detect alpha-1-antitrypsin. Alpha-1-antitrypsin testing is used in patients with airway disease, and it is under-tested within the population. This may contribute to a number of COPD/emphysema patients undiagnosed with this deficiency. Genetic studies indicate that ~ 10% of the Australian population are at risk of adverse effects of alpha-1-antitrypsin deficiency.[7]
- The utilisation of item 66638 is evenly distributed between major cities and remote and rural Australia with the exception of TAS, where there is a much higher utilisation (Figure 6).
- The rare alpha-1-antitrypsin deficiency with abnormal genotype X and M (malton) has been associated with chronic liver disease and cirrhosis. This is usually associated with low alpha-1-antitrypsin levels.
- The Committee noted that antitrypsin levels can be artificially elevated in patients with an inflammatory response, which may mask a true deficiency, and would require clinicians to wait for the acute inflammatory phase to pass prior to retesting.

Figure 6. State utilisation for item 66638 services per 100,000 people



4.8.3 Electrophoresis of serum isoenzymes: items 66641 and 66642

Table 31. Item introduction table for item 66641 and 66642

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66641	Electrophoresis of serum or other body fluid to demonstrate: (a) the isoenzymes of lactate dehydrogenase; or (b) the isoenzymes of alkaline phosphatase; including the preliminary quantitation of total relevant enzyme activity - 1 or more tests	29.20	$130,068	5,202	4,431	3.9%
66642	A test described in item 66641 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	29.20	$12,511	504	485	-1.6%

Recommendation

The Committee proposes the following:

- Add creatine kinase isoenzymes to the item descriptor 66641.

Table 32. Current and proposed new item descriptor for item 66641

	Current item descriptor	Proposed item descriptor
66641	Electrophoresis of serum or other body fluid to demonstrate: (a) the isoenzymes of lactate dehydrogenase; or (b) the isoenzymes of alkaline phosphatase; including the preliminary quantitation of total relevant enzyme activity - 1 or more tests	Electrophoresis of serum or other body fluid to demonstrate: (a) the isoenzymes of lactate dehydrogenase; (b) creatinine kinase isoenzymes; including the preliminary quantitation of total relevant enzyme activity - 1 or more tests

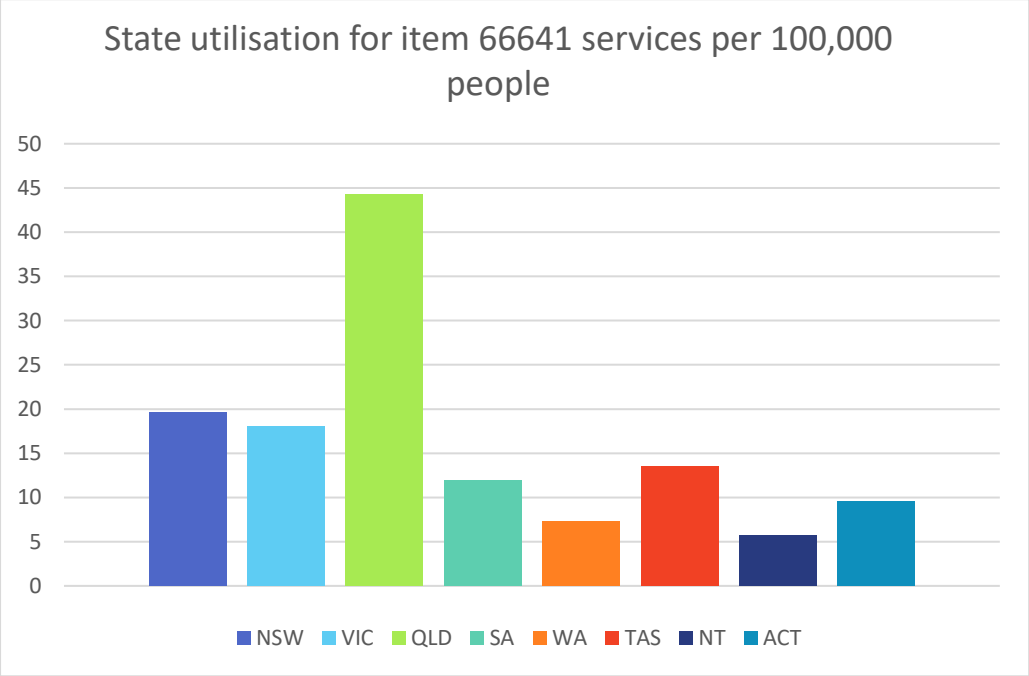
Rationale

- Item 66641 is a test used to detect isoenzymes of lactate dehydrogenase and alkaline phosphatase and is mainly requested by vocationally registered GPs. The annual growth rate over 5 years is 3.9%. The rate of use of item 66641 in Queensland is double that of other states (for example, 40 per 100,000 in QLD, compared with 20 per 100,000 in NSW [Figure 7]).
- Alkaline phosphatase isoenzymes differentiate between bone and liver sources of elevated alkaline phosphatase. Occasionally there are patients in whom the relative contributions of liver or bone or other forms of alkaline phosphatase (intestinal AP and Regan enzyme) to the

elevated alkaline phosphatase level is unclear and the isoenzyme determination will help to clarify the origin and likely pathology of the underlying disease.

Δ Previously the isoenzymes for creatine kinase were measured in myocardial infarction and covered under item 66518 and 66519. Due to the improvement in troponin assays there is no longer an indication for CK isoenzymes in that condition. However, there are patients with elevated creatine kinase, where electrophoresis will identify a macro-CK (CK bound to immunoglobulin) with a favourable prognosis or an alternative source. The most appropriate item is 66641, as it uses the same methodology as for alkaline phosphatase isoenzyme identification.

Figure 7. State utilisation for item 66641 services per 100,000 people



4.8.4 C1 inhibitor levels: items 66644, 66647

Table 33. Item introduction table for items 66644 and 66647

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66644	C-1 esterase inhibitor - quantitation	20.15	$43,934	2,569	2,403	7.0%
66647	C-1 esterase inhibitor - functional assay	45.10	$115,057	2,973	2,802	10.0%

Recommendation

- The Committee recommended that this item be left unchanged.

Rationale

- Items 66644 and 66647 are used to detect inherited and acquired angioedema with deficient C1 inhibitor levels (and function); item 66647 is a test for C1 esterase inhibitor using the functional assay. The use of these items is clinically appropriate, and they are normally requested by immunologists.
- There are high 5-year growth rates for both these items, but overall utilisation is low (see Table 36).

4.8.5 Angiotensin Converting Enzyme: item 66758

Table 34. Item introduction table for item 66758

Item	Long item descriptor	Schedule free	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66758	Quantitation of angiotensin converting enzyme, or cholinesterase - 1 or more tests	24.70	$849,866	40,609	35,838	5.8%

Recommendation

- The Committee recommended that this item be left unchanged.

Rationale

- Angiotensin converting enzyme is used for the diagnosis and monitoring of sarcoid, and it is mainly requested by neurologists and respiratory and sleep specialists.
- The test has limited sensitivity and specificity,[8] but is the only blood test available in the diagnosis of sarcoidosis.

4.9 Immunology items: 71057, 71058, 71059, 71060, 71062, 71064, 71066, 71068, 71069, 71071, 71072, 71073, 71074, 71075, 71076, 71077, 71200

Table 35. Item introduction table for items 71057, 71058, 71059, 71060, 71062, 71064, 71066, 71068, 71069, 71071, 71072, 71073, 71074, 71075, 71076, 71077, 71200

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
71057	Electrophoresis, quantitative and qualitative, of serum, urine or other body fluid all collected within a 28-day period, to demonstrate: (a) protein classes; or (b) presence and amount of paraprotein; including the preliminary quantitation of total protein, albumin and globulin - 1 specimen type	32.90	$7,445,181	266,770	198,828	5.6
71058	Examination as described in item 71057 of 2 or more specimen types	50.50	$1,688,215	39,204	33,921	6.6
71059	Immunofixation or immunoelectrophoresis or isoelectric focusing of:(a) urine for detection of Bence Jones proteins; or(b) serum, plasma or other body fluid; and characterisation of a paraprotein or cryoglobulin - examination of 1 specimen type (eg. serum, urine or CSF)	35.65	$4,348,373	143,431	109,409	14.4
71060	Examination as described in item 71059 of 2 or more specimen types	44.05	$899,314	24,043	19,970	16.1
71062	Electrophoresis and immunofixation or immunoelectrophoresis or isoelectric focussing of CSF for the detection of oligoclonal bands and including if required electrophoresis of the patient's serum for comparison purposes - 1 or more tests	44.05	$66,069	1,873	1,825	8.9
71064	Detection and quantitation of cryoglobulins or cryofibrinogen - 1 or more tests	20.75	$126,810	7,302	6,579	7.5%

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
71066	Quantitation of total immunoglobulin A by any method in serum, urine or other body fluid – 1 test	14.55	$63,549	5,150	4,867	–5.5%
71068	Quantitation of total immunoglobulin G by any method in serum, urine or other body fluid - 1 test	14.55	$227,826	18,765	13,543	14.2%
71069	2 tests described in items 71066, 71068, 71072 or 71074	22.75	$176,206	9,172	7,904	1.2%
71071	3 or more tests described in items 71066, 71068, 71072 or 71074	30.95	$4,680,461	178,803	127,637	7.0
71072	Quantitation of total immunoglobulin M by any method in serum, urine or other body fluid - 1 test	14.55	$12,340	1,004	708	–17.7%
71073	Quantitation of all 4 immunoglobulin G subclasses	106.15	$1,806,647	20,209	17,719	10.4
71074	Quantitation of total immunoglobulin D by any method in serum, urine or other body fluid - 1 test	14.55	$3,054	250	226	–0.8%
71075	Quantitation of immunoglobulin E (total), (IgE) - 1 test. (Item is subject to rule 25)	23.00	$2,619,828	133,831	127,901	5.5%
71076	A test described in item 71073 if rendered by a receiving APP - 1 test (Item is subject to rule 18)	106.15	$179,881	2,009	1,902	7.8
71077	Quantitation of immunoglobulin E (total) (IgE) in the follow up of a patient with proven immunoglobulin-E-secreting myeloma, proven congenital immunodeficiency or proven allergic	27.05	$43	2	2	14.9%

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
	bronchopulmonary aspergillosis - 1 test. (Item is subject to rule 25)					
71200	Detection and quantitation, if present, of free kappa and lambda light chains in serum for the diagnosis or monitoring of amyloidosis, myeloma or plasma cell dyscrasias.	59.60	$5,197,217	103,074	52,277	27.6%

Recommendations

The Committee proposes the following:

- Δ The following items should remain unchanged: 71057, 71058, 71059, 71060, 71062, 71068, 71069, 71071, 71073, and 71076.
- Δ Remove the wording 'urine or other body fluid' from items 71066, 71072 and 71074.
- Δ Consolidate item 71077 into item 71075 and change the fee of item 71075 to the same fee as item 71077.
- Δ Increase the Schedule fee for item 71064 to reflect the cost associated with transport and 'hot box' collection, particularly in rural and remote areas.
- Δ Restrict utilisation of item 71106 by adding rule 25 to limit testing to 4 tests within a 12-month period.
- Δ Develop an education program aimed at rheumatologists on how frequently to request item 71106 in patients with known rheumatoid disease.
- Δ Create a new item for cyclic citrullinated peptide antigens with the following wording*: Investigation for rheumatoid arthritis: citrullinated peptide antibodies*. This new item should be restricted to 4 tests within a 12-month period.
- Δ Amend the item descriptor for item 71200 by including the wording: 'this test is not to be used for the diagnosis or monitoring of lymphoma'.

Rationale

The rationale presented below has been developed by the Immunology Working Group as part of the MBS Review, when reviewing the immunology pathology items. The Committee agrees and supports the proposals of the Immunology Working Group.

Quantitation of total immunoglobulin A, M, D: items 71066, 71072, 71074

- Δ For items 71066 (Quantitation of total Immunoglobulin A [Ig A]), 71072 (Quantitation of total Immunoglobulin M [Ig M] and 71074 (Quantitation of total Immunoglobulin D [Ig D]), these

tests should not be performed in urine or other body fluid as there is no clinical reason to perform an Ig A, Ig M or Ig D test on body fluids.

- Δ Testing for the presence of extractable Ig A, Ig M or Ig D in samples other than peripheral blood is not recommended because: (i) there are no clinically validated indications for such testing; and (ii) reference intervals cannot be established for such samples, which precludes useful interpretation of such results. The proposed change does not have a direct effect on patients.

Quantitation of immunoglobulin E: items 71075, 71077

- Δ For items 71075 and 71077 (Quantitation of Immunoglobulin E [Ig E]), the low usage of item 71077 is due to the difficulty in the coding, with item 71077 being billed as item 71075. Items 71075 and 71077 are the essentially same tests but are used for different indications.
- Δ Deleting item 71077 and consolidating it into item 71075 will simplify the MBS and avoid confusion in terms of claiming. Monitoring total Ig E levels is appropriate for allergic bronchopulmonary aspergillosis and Ig E-secreting myeloma (the latter is extremely rare), and such testing should be able to be accommodated with four tests per year.
- Δ During the financial year 2014–2015, a total of 123,188 patients received service for item 71075 once, 4,522 patients received the service twice, 386 patients received the service 3 times and 97 patients received the service 4 times. The maximum number of times a patient received a service for item 71075 was 12 during 2014–2015; 77 patients received a service for item 71075 more than 4 times. There is no clinical utility in testing more than 4 times within a 12-month period.

Rheumatoid factor: item 71106

- Δ Item 71106 is a test used to determine the autoantibody rheumatoid factor. Rheumatoid factor is elevated in chronic and acute inflammation and it can be used to monitor inflammation in rheumatoid arthritis (RA).
- Δ During the financial year 2014–2015, for item 71106, a total of 126,263 patients received the service once, 9,214 patients received the service twice, 1,359 patients received the service 3 times and 314 patients received the service 4 times. The maximum number of services received by a single patient was 14 and approximately 212 patients received the service more than 4 times in the year.
- Δ The Committee used guidelines for RA to extrapolate from. The European League Against Rheumatism management guidelines state that 'monitoring should be frequent in active disease (every 1–3 months); if there is no improvement by at most 3 months after the start of treatment or the target has not been reached by 6 months, therapy should be adjusted.'[9]
- Δ The Committee notes that the guidelines refer to monitoring of biomarkers of disease activity, which includes patient pain, patient function, number of swollen / tender joints, ultrasound assessment of blood flow around joints, and blood tests for inflammation. The tests the Committee has reviewed are not markers of activity but are rather markers of diagnostic utility

and prognostic impact, therefore the antibodies referred to should be tested less than the markers of activity.

- Δ The Committee proposes a targeted education program for rheumatologists on utility of the test and alternative biomarkers of disease activity.
- Δ The Committee proposes to remove other body fluids from the item descriptor because testing in samples other than peripheral blood is not recommended because: (i) there are no clinically validated indications for such testing; and (ii) reference intervals cannot be established for such samples, which precludes useful interpretation of such results.
- Δ Restricting testing of rheumatoid factor will have no direct impact on patients but may indirectly reduce rates of unnecessary venepuncture, reduce rates of false-positive results and subsequently reduce patient anxiety.

Antibodies to citrullinated peptide antigens: new item

- Δ For cyclic citrullinated peptide antigens, the Committee recognises that this test has been in clinical practice for approximately 15 years; this test has not been on the Schedule. Currently, there is no item specifically for this test and it is being billed under item 71119. The Committee proposes creating a new item to test for cyclic citrullinated peptide antibodies for consideration by MSAC.
- Δ This is a high utility test that impacts greatly on treatment and disease classification. It is a robust test that produces quality results with an increase in amount of antibodies. It is standard of care in rheumatoid arthritis to have this test done and has high clinical utility in the monitoring of drugs but not in monitoring of disease.
- Δ The Committee has proposed that this item also be limited to 2 tests in a 12-month period as there is no clinical need to test more often than this and allows for a doubtful result or if clinical activity changes. Other biomarkers are available which are superior for disease monitoring such as CRP or swollen and/or tender joint count.

Free kappa and lambda light chains: item 71200

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

Table 36. MBS items that do not require amendment

Item	Item descriptor	Schedule fee ($)	Services (2014–15)
71057	Electrophoresis, quantitative and qualitative, of serum, urine or other body fluid all collected within a 28-day period, to demonstrate: (a) protein classes; or (b) presence and amount of paraprotein; including the preliminary quantitation of total protein, albumin and globulin - 1 specimen type	32.90	266,770
71058	Examination as described in item 71057 of 2 or more specimen types	50.50	39,204
71059	Immunofixation or immunoelectrophoresis or isoelectric focusing of:(a) urine for detection of Bence Jones proteins; or(b) serum, plasma or other body fluid; and characterisation of a paraprotein or cryoglobulin - examination of 1 specimen type (eg. serum, urine or CSF)	35.65	143,431
71060	Examination as described in item 71059 of 2 or more specimen types	44.05	24,043
71062	Electrophoresis and immunofixation or immunoelectrophoresis or isoelectric focusing of CSF for the detection of oligoclonal bands and including electrophoresis of the patient's serum for comparison purposes - 1 or more tests	44.05	1,873
71068	Quantitation of total immunoglobulin G by any method in serum, urine or other body fluid - 1 test	14.55	18,765
71069	2 tests described in items 71066, 71068, 71072 or 71074	22.75	9,172
71071	3 or more tests described in items 71066, 71068, 71072 or 71074	30.95	178,803
71073	Quantitation of all 4 immunoglobulin G subclasses	106.15	20,209
71076	A test described in item 71073 if rendered by a receiving APP - 1 test(Item is subject to rule 18)	106.15	2,009

Table 37. Current and proposed item descriptor 71066, 71072, 71074

Item	Current item descriptor	Proposed item descriptor
71066	Quantitation of total immunoglobulin A by any method in serum, urine or other body fluid – 1 test	Quantitation of total immunoglobulin A by any method in serum – 1 test
71072	Quantitation of total immunoglobulin M by any method in serum, urine or other body fluid - 1 test	Quantitation of total immunoglobulin M by any method in serum - 1 test
71074	Quantitation of total immunoglobulin D by any method in serum, urine or other body fluid - 1 test	Quantitation of total immunoglobulin D by any method in serum - 1 test

Table 38. Current and proposed item descriptors 71075 and 71077

Item	Current item descriptor	Proposed item descriptor
71075	Quantitation of immunoglobulin E (total), (IgE) - 1 test. (Item is subject to rule 25)	Quantitation of immunoglobulin E (total), (IgE) - 1 test. (Item is subject to rule 25)
71077	Quantitation of immunoglobulin E (total) (IgE) in the follow up of a patient with proven immunoglobulin-E-secreting myeloma, proven congenital immunodeficiency or proven allergic bronchopulmonary aspergillosis, 1 test. (Item is subject to rule 25)	Delete

Table 39. Current and proposed new item descriptor for item 71062, 71066, 71072 and 71074

Item	Current item descriptor	Proposed item descriptor
71062	Electrophoresis and immunofixation or immunoelectrophoresis or isoelectric focussing of CSF for the detection of oligoclonal bands and including if required electrophoresis of the patient's serum for comparison purposes - 1 or more tests	Electrophoresis and immunofixation or immunoelectrophoresis or isoelectric focussing of CSF for the detection of oligoclonal bands and including electrophoresis of the patient's serum for comparison purposes - 1 or more tests
71066	Quantitation of total immunoglobulin A by any method in serum, urine or other body fluid – 1 test	Quantitation of total immunoglobulin A by any method in serum – 1 test
71072	Quantitation of total immunoglobulin M by any method in serum, urine or other body fluid - 1 test	Quantitation of total immunoglobulin M by any method in serum - 1 test
71074	Quantitation of total immunoglobulin D by any method in serum, urine or other body fluid - 1 test	Quantitation of total immunoglobulin D by any method in serum - 1 test

Table 40. Current and proposed item descriptor for item 71200

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

4.9.1 Thyroid antibodies

Based on initial advice from the Endocrine Clinical Committee and subsequent input from the Immunology and Chemical Working Groups, the following recommendations are made.

Recommendations

- Δ Remove the thyroid antibodies (anti-thyroglobulin Ab, thyroid microsome Ab and thyroid stimulating hormone receptor Ab) from the suite of tests currently covered under items 71165–71168 and create new distinct thyroid antibodies items.
- Δ Remove the word thyroglobulin from items 71165-71168:
- Δ Create new item descriptors for thyroid antibodies:
    - 71171: Thyroid peroxidase antibody. To a maximum of 2 within in a 12-month period (Item is subject to rule 25).
    - 71172: In patients with newly diagnosed hyperthyroidism. Two antibodies: thyroid peroxidase antibody and thyroid receptor antibody (TRAB) and/or thyroid stimulating antibodies (TSI) for the differential diagnosis of hyperthyroidism. To a maximum of 1 in a 12-month period (Item is subject to rule 25).
    - 71173: Thyroid receptor antibody (TRAB) or thyroid stimulating antibodies (TSI) for diagnosis and monitoring of patients with previously diagnosed Graves disease. To a maximum of 4 tests in a 12-month period (Item is subject to rule 25).
    - 71174: Testing for thyroglobulin as well as thyroglobulin antibody for monitoring of patients with thyroid cancer. To a maximum of 2 of this item in a 12-month period (Item is subject to rule 25).

Rationale

- Δ The recommendation focuses on encouraging best practice and optimal patient care. Simplifying the item numbers was identified as the primary lever for achieving this, based on the following observations.
- Δ A large number of tests are performed under these item numbers. In financial year 2014/15, the items accounted for approximately 500,000 services (this figure has increased by 11.1% per year over the last five years) and $18.5 million in total benefits.[10]
- Δ The current list within the item descriptor for item 71165 contains 20 antibodies, which makes it impossible to discern how much thyroid antibody testing is undertaken. The Committee felt

that there is no clinical reason for including these antibodies in a single item number as there is no relationship between the tests. This makes it confusing for both requesting doctors and providing pathologists, often leading to sub-optimal testing and the incorrect billing of patients. To address this, the Committee felt that the thyroid antibody testing should have distinctive items, and that the clinical purpose of the tests should be included in the item descriptors. This will enable data collection and support the appropriate use of these tests.

- Δ There is no clinical value in doing several antibody tests in the investigation of hypothyroidism but some patients require two tests in the investigation of hyperthyroidism.
- Δ The Committee proposes to remove 'thyroglobulin antibodies' from item descriptor as thyroglobulin Abs have inferior diagnostic performance compared to anti-thyroid peroxidase antibody Ab in patients with incipient Hashimotos hypothyroidism. The levels of such antibodies vary typically from year to year, and rarely change within a three-month period.
- Δ The Committee proposes to limit this test to 4 tests within a 12-month period for the investigation of Graves disease as there is no clinical need to perform more than this within this patient population. The Committee proposes to limit testing for thyroglobulin and thyroid peroxidase to 2 tests with a 12-month period as there is no clinical need to perform this test more than this within this patient population. The Committee proposes to limit testing for hyperthyroidism to 1 occasion within a 12-month period to identify the cause of the hyperthyroidism.
- Δ In the follow up of patients with papillary or follicular thyroid cancer, thyroglobulin is a valuable test after the thyroid has been ablated and only tumour tissue remains as the thyroglobulin-producing tissue. The presence of anti-thyroglobulin antibodies interferes with the test performance and therefore it is clinically appropriate to don these tests together.

Table 41. Current and proposed item descriptors for Items 71165–71168

Item	Current item descriptor	Proposed item descriptor
71165	Detection of 1 antibody to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, salivary gland, skeletal muscle, skin basement membrane and intercellular substance, thyroglobulin, thyroid microsome or thyroid stimulating hormone receptor)	Detection of 1 antibody to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, salivary gland, skeletal muscle, skin basement membrane and intercellular substance).
71166	Detection of 2 antibodies to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, salivary gland, skeletal muscle, skin basement membrane and intercellular substance,	Detection of 2 antibodies to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, salivary gland, skeletal muscle, skin basement membrane and intercellular substance)

Item	Current item descriptor	Proposed item descriptor
	thyroglobulin, thyroid microsome or thyroid stimulating hormone receptor)	
71167	Detection of 3 antibodies to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, salivary gland, skeletal muscle, skin basement membrane and intercellular substance, thyroglobulin, thyroid microsome or thyroid stimulating hormone receptor)	Detection of 3 antibodies to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, salivary gland, skeletal muscle, skin basement membrane and intercellular substance)
71168	Detection of 4 or more antibodies to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, salivary gland, skeletal muscle, skin basement membrane and intercellular substance, thyroglobulin, thyroid microsome or thyroid stimulating hormone receptor)	Detection of 4 or more antibodies to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, salivary gland, skeletal muscle, skin basement membrane and intercellular substance)

Table 42. New item descriptors for Items 71171, 71172, 71173 and 71174

Item	Proposed new item descriptor
71171	Thyroid peroxidase antibody. To a maximum of 2 within in a 12-month period (Item is subject to rule 25)
71172	In patients with newly diagnosed hyperthyroidism. Two antibodies: thyroid peroxidase antibody and thyroid receptor antibody (TRAB) and/or thyroid stimulating antibodies (TSI) for the aetiology of hyperthyroidism. To a maximum of 1 in a 12-month period (Item is subject to rule 25)
71173	TSH receptor antibody (TRAB or TSI): for monitoring of patients with previously diagnosed Graves disease. To a maximum of 4 tests in a 12-month period (item is subject to rule 25)
71174	Thyroglobulin and thyroglobulin antibody for monitoring of patients with thyroid cancer. To a maximum of 2 of this item in a 12-month period (Item is subject to rule 25)

4.10 Metals for toxicity or deficiency

4.10.1 Lead: items 66665, 66666

Table 43. Item introduction table for items 66665, 66666

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66665	Lead quantitation in blood or urine (other than for occupational health screening purposes) to a maximum of 3 tests in a 6-month period - each test	30.60	$336,746	12,867	12,335	5.8%
66666	A test described in item 66665 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	30.60	$26,577	1,021	988	-0.8%

Recommendation

Δ The Committee recommended that these items remain unchanged.

Rationale

Δ Items 66665 and 66666 are tests to detect lead in blood or urine. Item 66665 is mainly requested in remote Australia (Figure 8). There is state variation for item 66666 which may be accounted for by soil contamination, house renovation or mining sites.

Δ The utilisation of these items appears to be clinically appropriate.

Figure 8. Utilisation of item 66665 by services by location per 100,000 people

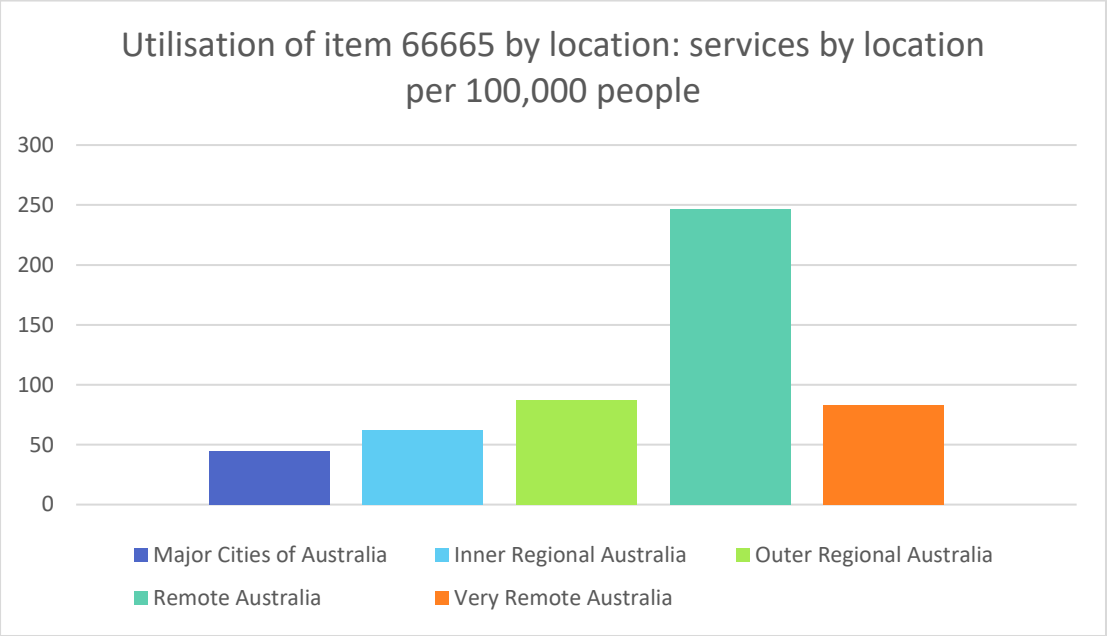
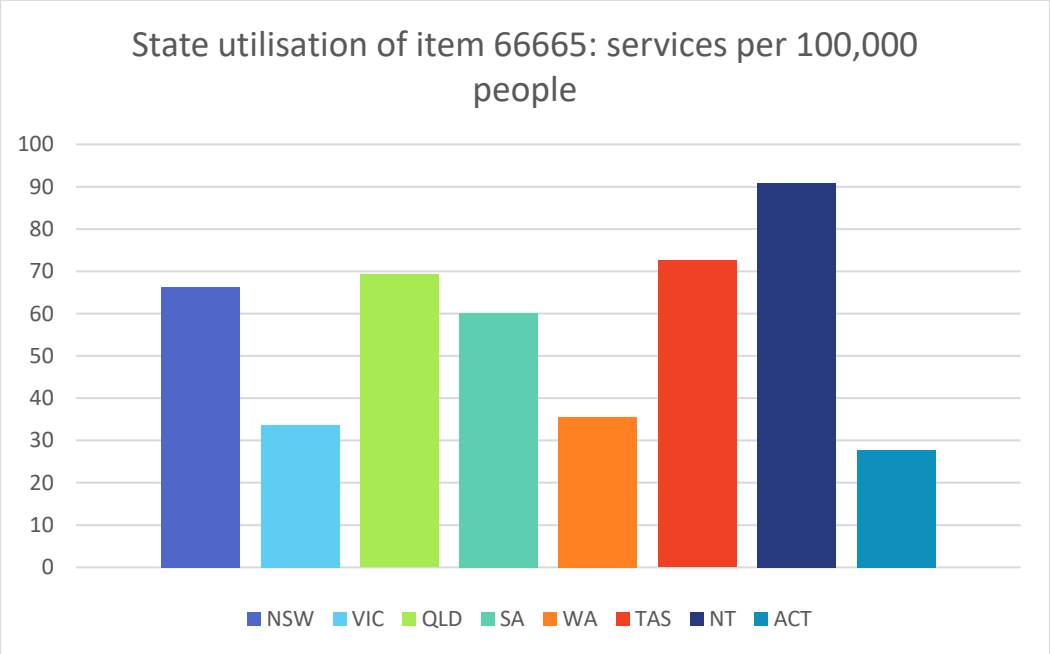


Figure 9. State utilisation of item 66665 services per 100,000 people



4.10.2 Zinc, aluminium, arsenic, beryllium, cadmium, chromium, gold, mercury, nickel, strontium, copper and iron: items 66667, 66671, 66825, 66826, 66827, 66828, 66831, 66832

Table 44. Item introduction table for item 66667, 66671, 66825, 66826, 66827, 66828, 66831, 66832

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66667	Quantitation of serum zinc in a patient receiving intravenous alimentation - each test	30.60	$54,130	2,066	1,950	3.3%
66671	Quantitation of serum aluminium in a patient in a renal dialysis program - each test	36.90	$38,294	1,279	965	0.9%
66825	Quantitation of aluminium (except if item 66671 applies), arsenic, beryllium, cadmium, chromium, gold, mercury, nickel, or strontium, in blood, urine or other body fluid or tissue - 1 test. To a maximum of 3 of this item in a 6-month period (Item is subject to rules 6, 22 and 25)	30.60	$260,100	10,018	8,887	14.9%
66826	A test described in item 66825 if rendered by a receiving APP where no tests have been rendered by the referring APP - 1 test(Item is subject to rules 6, 18, 22 and 25)	30.60	$32,923	1,268	1,206	-17.2%
66827	A test described in item 66825, other than that described in 66826, if rendered by a receiving APP to a maximum of 1 test(Item is subject to rules 6, 18, 22 and 25)	21.80	$15,840	854	810	13.2%
66828	Quantitation of aluminium (except if item 66671 applies), arsenic, beryllium, cadmium, chromium, gold, mercury, nickel, or strontium, in blood, urine or other body fluid or tissue - 2 or more tests. to a maximum of 3 of this item in a 6-month period (Item is subject to rules 6, 22 and 25)	52.45	$110,166	2,438	2,344	9.5%

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66831	Quantitation of copper or iron in liver tissue biopsy	30.95	$1,249	49	49	-14.1%
66832	A test described in item 66831 if rendered by a receiving app (item is subject to rules 18a and 22)	30.95	$1,254	49	49	-3.6%

Recommendation

- The Committee recommended that these items remain unchanged

Rationale

- Item 66667 is a test used to detect zinc in blood in patients receiving intravenous alimentation (parenteral nutrition). The utilisation of item 66667 has increased, possibly due to a change in the item descriptor. There could be a coding error and subsequent incorrect billing of this item, as there is another zinc item 66819 within the Schedule. The item is mainly requested in NSW, by GPs (Figure 10).
- Item 66671 is a test used to detect aluminium in blood in patients in a renal dialysis program. There has been minimal change in use over the last 5 years. Testing of patients in renal dialysis programs is often driven by dialysis departmental protocols and inconsistency in the protocols or guidelines may account for the overall state variation seen for this item (Figure 11).
- The utilisation of items 66667 and 66671 appears to be clinically appropriate.
- Item 66825 is a test used to detect: aluminium, arsenic, beryllium, cadmium, chromium, gold, mercury, nickel, or strontium, in blood, urine or other body fluid or tissue. The main requestors for items 66825, 66826, 66827, and 66828 are GPs, surgeons and neurologists. Although overall volumes are low, there has been a large increase in use of the items, much of which could be attributed to the concern about chromium toxicity in patients who have undergone metal-on-metal hip replacements. The Committee queried the clinical justification for some of the tests listed in this item, such as gold or strontium, but generally did not have concerns about the use of these tests.
- Items 66831 and 66832 are low volume items that have shown a decline in utilisation. Utilisation of both of these items is consistent across the states, and they are mainly requested by diagnostic radiologists.

Figure 10. State utilisation for item services per 100,000 people

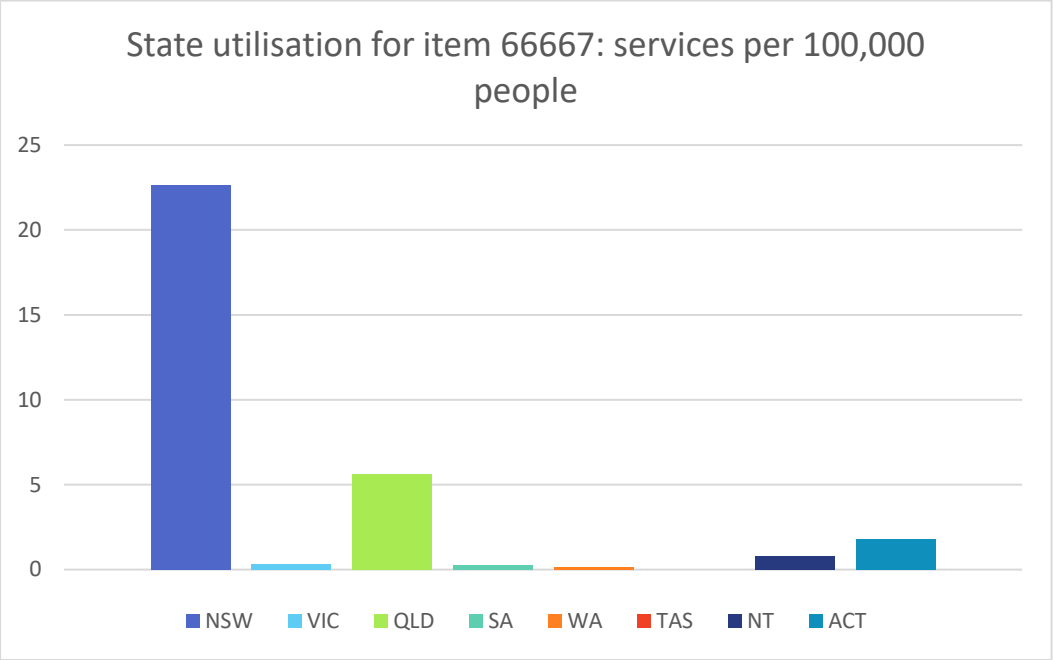
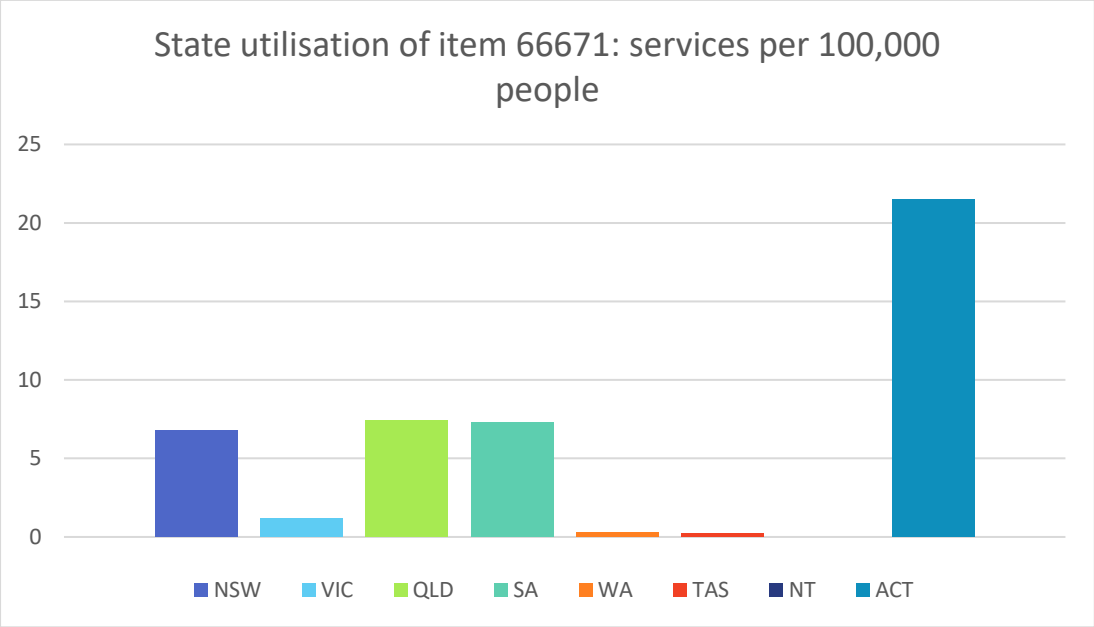


Figure 11. State utilisation of item 66671 services per 100,000 people



4.10.3 Copper, manganese, selenium or zinc: items 66819, 66820, 66821, 66822

Table 45. Item introduction table for items 66819, 66820, 66821, 66822

Item	Long item descriptor	Schedule fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5-year service change % (CAGR)
66819	Quantitation of copper, manganese, selenium, or zinc (except if item 66667 applies), in blood, urine or other body fluid - 1 test (Item is subject to rules 6, 22 and 25)	30.60	$2,448,742	93,843	85,852	8.8%
66820	A test described in item 66819 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, 18, 22 and 25)	30.60	$160,835	6,194	5,873	-5.4%
66821	A test described in item 66819 other than that described in 66820 if rendered by a receiving APP to a maximum of 1 test (Item is subject to rules 6, 18, 22 and 25)	21.80	$81,119	4,379	4,122	27.9%
66822	Quantitation of copper, manganese, selenium, or zinc (except if item 66667 applies), in blood, urine or other body fluid - 2 or more tests. (Item is subject to rules 6, 22 and 25)	52.45	$1,518,514	33,630	30,031	23.0%

Recommendation

Δ Add explanatory notes to items 66819 and 66822 to provide clinical guidance on when copper and zinc testing is useful.

Rationale

Δ Items 66819, 66820, 66821 and 66822 are tests to detect: copper, manganese, selenium or zinc in blood, urine or body fluids. The Committee noted the steady increase in testing for trace elements (Table 48 above). The Committee discussed the clinical utility of these tests as there were concerns that much of this testing may have little clinical benefit to patients. The Committee noted that the increase in trace element testing could be due to a trend towards complementary medicine and patient-initiated requests for these types of tests. The clear

exception is testing of copper levels in patients with Wilsons disease. Private laboratory data suggests that approximately 75% of tests performed under these items is for zinc and 20% for copper.

- The Committee reviewed clinical guidelines to determine clinical indications for the tests listed in items 66819, 66820, 66821 and 66822. The Committee recognises that there are no clinical guidelines published by large traditional associations on the clinical utility of trace element testing. A review article published by Stehle et al in *European Journal of Clinical Nutrition* in 2016 stated that blood tests for trace elements should be performed periodically but did not provide advice on frequency of testing and clinical conditions for each element.[11] The Australasian Society for Parenteral and Enteral Nutrition Guidelines state that there is insufficient evidence to specify frequency of monitoring for zinc and selenium; for manganese, 3- to 6-monthly monitoring in patients on home parenteral nutrition is recommended.[12] The British Obesity and Metabolic Surgery Society GP guidance on nutrition management following bariatric surgery recommends that patients require lifelong nutritional supplementation and monitoring of nutritional status because all bariatric procedures affect macro- and micro-nutrient absorption.[13] Based on these resources and the advice of the Committee, the Committee recommends that the following explanatory note to guide appropriate use should be added to the MBS: Copper testing is useful in the management of Wilson's disease. Zinc testing may be useful in patients with malnutrition or on total parenteral nutrition. There is little evidence to suggest that testing of other trace elements has clinical benefit.
- The Committee considered including urinary iodine to items 66819 and 66822 but questioned whether urinary iodine had utility. The Royal College of Pathologists of Australasia guidelines recognise that there is limited evidence for the utility of iodine. The Committee also considered the challenges of determining reference ranges for urinary iodine and that creatinine would need to be measured with iodine. It was also unclear what the rate of true iodine deficiency in Australia is, as iodine is found in both bread and salt. In contrast there are situations, where patient exposure to iodine might result in toxicity.[14,15]

Table 46. Current and proposed item descriptor 66819 - 66822

Item	Current item descriptor	Proposed item descriptor
66819	Quantitation of copper, manganese, selenium, or zinc (except if item 66667 applies), in blood, urine or other body fluid - 1 test (Item is subject to rules 6, 22 and 25)	Quantitation of copper, manganese, selenium, or zinc (except if item 66667 applies), in blood, urine or other body fluid - 1 test (Item is subject to rules 6, 22 and 25) ***Explanatory note:*** *Copper testing is useful in Wilson's disease. Zinc testing is useful in patients with malnutrition or on TPN. There is little evidence to suggest that testing of other trace elements has clinical benefit.*
66820	A test described in item 66819 if rendered by a receiving APP, where no tests in the item have been	

Item	Current item descriptor	Proposed item descriptor
	rendered by the referring APP - 1 test (Item is subject to rules 6, 18, 22 and 25)	
66821	A test described in item 66819 other than that described in 66820 if rendered by a receiving APP to a maximum of 1 test (Item is subject to rules 6, 18, 22 and 25)	
66822	Quantitation of copper, manganese, selenium, or zinc (except if item 66667 applies), in blood, urine or other body fluid - 2 or more tests. (Item is subject to rules 6, 22 and 25)	Quantitation of copper, manganese, selenium, or zinc (except if item 66667 applies), in blood, urine or other body fluid - 2 or more tests. (Item is subject to rules 6, 22 and 25) ***Explanatory note:*** *Copper testing is useful in Wilson's disease. Zinc testing is useful in patients with malnutrition or on TPN.*

4.11 Amino acids and porphyrins

4.11.1 Porphyrin testing: items 66782–66792

Table 47. Item introduction table for items 66782-66792

Item	Long item descriptor	Schedule fee	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66782	Porphyrins or porphyrins precursors - detection in plasma, red cells, urine or faeces - 1 or more tests	13.15	$9,283	859	643	29.8%
66783	A test described in item 66782 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	13.15	$7,409	668	631	–5.7%
66785	Porphyrins or porphyrins precursors - quantitation in plasma, red cells, urine or faeces - 1 test (Item is subject to rule 6)	39.95	$44,012	1,300	1,145	-4.5%
66788	Porphyrins or porphyrins precursors - quantitation in plasma, red cells, urine or faeces - 2 or more tests (Item is subject to rule 6)	65.85	$40,518	725	672	-1.5%
66789	A test described in item 66785 if rendered by a receiving APP, where no tests in the item have been	39.95	$18,475	545	521	-7.7%

Item	Long item descriptor	Schedule fee	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
	rendered by the referring APP - 1 test (Item is subject to rule 6 and 18)					
66790	A test described in item 66785 other than that described in 66789, if rendered by a receiving APP - to a maximum of 1 test (Item is subject to rule 6 and 18)	25.90	$32,309	1,473	1,370	3.3%
66791	Porphyrin biosynthetic enzymes - measurement of activity in blood cells or other tissues - 1 or more tests	74.45	$253	4	3	-
66792	A test described in item 66791 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	74.45	$428	7	7	-6.9%

Recommendation

The Committee proposes the following:

- Delete item 66783
- Items 66782, 66785, 66788 and 66789 should remain unchanged.
- The Schedule fee for item 66790 should be increased to the fee for item 66789.
- Delete items 66791, 66792.

Rationale

- Porphyrins cause diseases that affect skin or the nervous system or both. Porphyrin testing requires both considerable laboratory expertise and clinical interpretative skill.
- The simpler part of the test, ie, the urine testing, is performed in one laboratory and the other part of the test, such as the faecal testing, is referred to an expert laboratory centre within Australia. TAS, ACT, NT do not have expert porphyrin testing centres.
- The volumes and costs of porphyrin testing are low and there has been little increase in the volume of service use.
- The Committee noted that Item 66782 is a qualitative test. Qualitative testing is specified in a suspected acute attack, and should be followed by a quantitative test, if the result is positive.

- Item 66783 is a referral to subsequent qualitative test. This item should be deleted, as all specimens referred on to other laboratories should be accompanied by quantitation (items 66785 or 66789).
- Item 66785 should be used for monitoring, and there appears to be high utilisation of items 66785 and 66788 in QLD.
- The Committee recommended that items 66785, 66788 and 66789 be left unchanged, as these tests are clinically appropriate.
- Item 66790 allows for workup to be done in two laboratories: simpler testing in one laboratory and complex testing in another laboratory. The Committee recommended that the Schedule fee for item 66790 should be increased to the same fee as for item 66789.
- Items 66791 and 66792 should be deleted as these tests are no longer performed. These items have become obsolete, and have been replaced by genetic testing in the last 15 years.

4.11.2 Amino acid quantitation: items 66756, 66757

Table 48. Item introduction table for items 66756 and 66757

Item	Long item descriptor	Schedule fee	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66756	Quantitation of 10 or more amino acids for the diagnosis of inborn errors of metabolism - up to 4 tests in a 12-month period on specimens of plasma, CSF and urine.	98.30	$376,016	4,298	3,956	5.8%
66757	Quantitation of 10 or more amino acids for monitoring of previously diagnosed inborn errors of metabolism in 1 tissue type.	98.30	$37,071	446	182	4.0%

Recommendations

The Committee proposes the following:

- Consolidate items 66756 and 66757 into a single item.
- Reword the item descriptor to reflect this change.

Table 49. Current and proposed new item descriptor for item 66756/66757

Item	Current item descriptor	Proposed new item descriptor
66756/66757	Quantitation of 10 or more amino acids for the diagnosis of inborn errors of metabolism - up to 4 tests in a 12-month period on specimens of plasma, CSF and urine.	Quantitation of 10 or more amino acids for the diagnosis and management of inborn errors of metabolism - up to 4 tests in a 12-month period on specimens of plasma, CSF and urine.

Rationale

- Δ These items are mainly requested by paediatricians, and have very low utilisation. Low utilisation may be due to them being provided more frequently as inpatient services within the public hospital system.
- Δ Item 66756 is designed so that testing for diagnosis is comprehensive and can be carried out on all required specimens. However, the Committee has received expert advice from biochemical genetics, recommending the consolidation of the two items into one, to simplify the Schedule.

4.11.3 Quantitation of analytes: items 66752, 66755

Table 50. Item introduction table for items 66752 and 66755

Item	Long item descriptor	Schedule fee	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66752	Quantitation of acetoacetate, beta-hydroxybutyrate, citrate, oxalate, total free fatty acids, cysteine, homocysteine, cystine, lactate, pyruvate or other amino acids and hydroxyproline (except if performed as part of item 66773 or 66776) - 1 test	24.70	$2,176,771	104,565	88,489	0.6%
66755	2 or more tests described in item 66752	38.85	$165,830	5,119	4,355	0.7%

Recommendations

The Committee proposes the following:

- Δ Separate item 66752 into metabolites and amino acids
- Δ Adjust item Schedule fees
- Δ Remove hydroxyproline from the amino acids list.

Rationale

- These items include a diverse mix of both simple and complex tests for metabolites, organic acids and amino acids. During the financial year 2014–2015, the total expenditure was ~$2 million, with 85% of this done out of hospital. The main requestors of these items are GPs and surgeons, and the main driver of utilisation is likely to be homocysteine testing. Citrate, oxalate and cysteine are commonly ordered for investigation and management of renal stones.
- The Committee noted that there is a separate item for lactate in blood gases (item 66566).
- Item 66752 should be divided into separate categories of metabolites and amino acids. This would enable better data collection on test ordering and Schedule billing practices.
- The Committee recommended a fee adjustment to these items to reflect the complexity of these tests.
- The use of hydroxyproline has been superseded by other more specific bone markers such as C-terminal telopeptide of collagen and Procollagen-1 N-terminal propeptide.

Table 51. Current and proposed item descriptor for item 66752

Item	Current item descriptor	Proposed item descriptor
66752	Quantitation of acetoacetate, beta-hydroxybutyrate, citrate, oxalate, total free fatty acids, cysteine, homocysteine, cystine, lactate, pyruvate or other amino acids and hydroxyproline (except if performed as part of item 66773 or 66776) - 1 test	*Quantitation of acetoacetate, beta-hydroxybutyrate, citrate, oxalate, total free fatty acids, (except if performed as part of item 66773 or 66776) - 1 test*
New item		*Quantitation of cysteine, homocysteine, cysteine, lactate, pyruvate or other amino acids (except if performed as part of item 66773 or 66776) - 1 test*

4.12 Bone markers, HPLC, hormones and other

4.12.1 Collagen breakdown products: items 66773, 66776

Table 52. Item introduction table for items 66773, 66776

Item	Long item descriptor	Schedule fee	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66773	Quantitation of products of collagen breakdown or formation for the monitoring of patients with proven low bone mineral density, and if performed, a service described in item 66752 - 1 or more tests (Low bone densitometry is defined in the explanatory notes to Category 2 - Diagnostic Procedures and Investigations of the Medicare Benefits Schedule)	24.65	$906,370	43,017	34,260	15.5%
66776	Quantitation of products of collagen breakdown or formation for the monitoring of patients with metabolic bone disease or Paget's disease of bone, and if performed, a service described in item 66752 - 1 or more tests	24.65	$562,509	26,409	22,820	10.3%

Recommendations

The Committee proposes the following:

- Limit testing to 2 tests within a 12-month period.

Rationale

- Item 66773 is used to test collagen breakdown or formation products in patients with proven low bone mineral density. The definition for low bone mineral density for item 66773 is bone mineral density decrease of 1.5 SD below the age-matched mean or more than 2.5 SD below the young normal mean at the same site and in the same gender.
- Item 66776 is used for monitoring patients with metabolic bone disease, and is used in conjunction with item 66752.
- The International Osteoporosis Foundation and the International Federation of Clinical Chemistry and Laboratory Medicine recommend that C-terminal telopeptide of type 1 collagen (CTX) and procollagen type 1 N propeptide (P1NP) are used as markers for bone resorption and

bone formation, respectively.[16] Other markers such as alkaline phosphatase are still useful in detecting conditions with gross elevations in bon turnover such as Paget's disease. Two recent papers published addressing this issues are: the Belgian Bone Club[17] and Vasikaran & Chubb.[18] The paper by Vasikaran & Chubb states that there is no evidence for the use of biochemical markers of bone turnover for decision to treat or treatment selection.

- Δ The Alfred Hospital in VIC is a significant provider of these services with ~75% of requests for these items for both P1NP and CTX.
- Δ The Committee noted that the Endocrine Clinical Committee has previously reviewed items 66773 and 66776, and recommended that the items remain unchanged on the Schedule.
- Δ The Committee recommend limiting testing to two tests within a 12-month period as there is no clinical necessity to repeat the test more often than that.

4.13 Adrenaline, 5HIAA, metanephrins: items 66779, 66780

Table 53. Item introduction table for items 66779, 66780

Item	Long item descriptor	Schedule fee	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66779	Adrenaline, noradrenaline, dopamine, histamine, hydroxyindoleacetic acid (5HIAA), hydroxymethoxymandelic acid (HMMA), homovanillic acid (HVA), metanephrines, methoxyhydroxyphenylethylene glycol (MHPG), phenylacetic acid (PAA)or serotonin quantitation - 1 or more tests	39.95	$1,448,373	42,115	36,899	4.5%
66780	A test described in item 66779 if rendered by a receiving APP - 1 or more tests(Item is subject to rule 18)	39.95	$745,570	22,010	19,017	8.2%

Recommendations

The Committee proposes the following:

- Δ Split item 66779 into two items, based on their clinical differences:
  - first item: catecholamines and metanephrines in 24-hour urine samples or as plasma free metanephrines
  - second item: 5HIAA and serotonin tests (which are important in the diagnosis of carcinoid tumours).
- Δ Remove histamine from item 66779.

Rationale

- Items 66779 and 66780 are tests are used in the diagnosis of phaecochromocytoma and paraganglioma. These two items are requested by GPs and specialists (10% endocrinologists, 10% internal medicine physicians, 6–7% cardiologists, 4% nephrologists). The repeat testing rate is 10% for 2 tests and 2% for 3 tests. The Committee noted that hydroxymethoxymandeliac acid (HMMA), homovanillic acid (HVA) and methoxyhydroxyphenylethylene glycol (MHPG) are outdated tests. LC-MS/MS is a newer technology used for these tests to diagnose phaeochromocytoma and paraganglioma. The Committee recommended removing HMMA, MHPG and phenylacetic acid from the item descriptors for items 66779 and 66780 as these tests are obsolete.
- The Committee also noted the published literature supporting both urine catecholamines and metanephrines[19-21] or plasma free metanephrines[22,23] testing. The endocrine practice guidelines[24] support the use of both approaches (ie, plasma free or urinary fractionated metanephrines). The published literature also supports the use of 3-methoxythyramine as an additional marker for paragangliomas and malignant tumours;[25,26] phenylacetic acid was found to have no function. There might be a role for homovanillic acid in neuroblastoma in children. The Committee also queried whether the item descriptor should stipulate that liquid chromatography tandem-mass spectrometry (LC-MS/MS) is the preferred measurement technique as it has been reported that high-performance liquid chromatography (HPLC) does not detect certain cases of phaeochromocytoma.
- UpToDate states that 24-hour urinary 5HIAA is a useful initial diagnostic test for carcinoid syndrome; the test has over 90% sensitivity and 90% specificity for carcinoid syndrome, and sensitivity is low in patients with carcinoid tumours without the carcinoid syndrome.[27] Measurement of blood serotonin levels as a standard diagnostic test for the carcinoid syndrome is not recommended; measurement of urinary serotonin may have clinical utility in rare patients with foregut carcinoid.
- The Committee recommended changing the item descriptor for item 66779 to require catecholamines and metanephrins either as 24-hour urine samples or as plasma free metanephrins. The Committee also recommended to split the item descriptor to have a separate item for hydroxyinodoleacetic acid (5HIAA) and/or serotonin for the diagnosis and follow-up of carcinoid tumours. This item should include information on the recommended method of testing, and usual indication, in the explanatory notes. The members requested information around how often these tests were performed, as they are potentially items that could be misused.
- The Committee noted that histamine and histamine metabolites could be included in this group. Tryptase is an additional valuable test in mastocytosis and anaphylactic reactions that is already in the pathology table (item 71198). Histamine is present in mast cell granules and released into the bloodstream in increased amounts either acutely, for example, immediate allergic reactions, or chronically, in conditions of mast cell proliferation. Tryptase, an enzyme in mast cell granules, is released after Ig E-mediated anaphylactic and non-Ig E-mediated

anaphylactoid reactions. Serum levels typically peak after one hour and decline to baseline over the next 8-24 hours. Levels are persistently raised in some chronic disorders.

Δ Blood histamine levels are insensitive and unreliable as a marker of mast cell proliferation (for example, mastocytosis), urine being preferred. However, while elevated urine histamine or N-methyl histamine levels can be useful, normal levels also do not exclude mast cell activation.[28] Tryptase is reported to be a more sensitive marker of mast cell proliferation and to show better correlation with disease activity. The optimal time for measuring tryptase in anaphylaxis is 1–2 h after the reaction (not greater than 6 h), whereas for plasma histamine it was 10 min to 1 h. Measurement of plasma tryptase along with measurement of plasma histamine may aid in diagnosis of anaphylaxis. Measurement of histamine in blood (plasma) is difficult, due to very short half-life of about 2 minutes, and possible artefact, due to release from basophils during collection and separation.[29] Blood samples can be taken after an acute allergic, flushing or hypotensive episode, but elevation in blood is very short and timing collection is usually impractical. A review of requesting indicates that histamine and tryptase are rarely co-requested. Tryptase tends to be requested for anaphylaxis and mastocytosis, whereas histamine has a wider range of clinical notes being provided with requests and appears to be a popular alternative health test. After considering the available evidence and analysing requesting behaviour, the Committee recommended that histamine be removed from item 66779.

Δ The Committee also noted that that dopamine would require additional information in the explanatory notes, particularly in relation to application and usual indication. For example, dopamine should be measured but not reported if elevated in isolation, as it would have questionable clinical significance.

Table 54. Current and proposed item descriptor for item 66779

Item	Current item descriptor	Proposed item descriptor
66779	Adrenaline, noradrenaline, dopamine, histamine, hydroxyindoleacetic acid (5HIAA), hydroxymethoxymandelic acid (HMMA), homovanillic acid (HVA), metanephrines, methoxyhydroxyphenylethylene glycol (MHPG), phenylacetic acid (PAA)or serotonin quantitation - 1 or more tests	Catecholamines and metanephrines in 24-hour urine samples or as plasma free metanephrines - 1 or more tests ***Explanatory note*** *Dopamine should be measured but not reported if dopamine levels are elevated without an elevation in catecholamines or metanephrins.*
New item		*5HIAA or serotonin quantitation in 24 hour urine*

4.13.1 Enzymes in solid tissue: item 66683

Table 55. Item introduction table for item 66683

Item	Long item descriptor	Schedule fee	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66683	Enzymes - quantitation in solid tissue or tissues other than blood elements or intestinal tissue - 1 or more tests	74.45	$1,110	19	19	-43.3%

Recommendations

The Committee proposes the following:

Δ Delete item 66683.

Rationale

Δ This item was requested only 19 times during the 2014–15 financial year, and was mainly requested by specialists (surgeons and neurologists). The Committee recommend deleting this item due to low volume/utilisation.

5. Tumour marker items – 66650–66653 and 66629

Before the start of the MBS Review process, the requesting of tumour markers (TM) had already been identified as an area of concern, where reform might be required. Due to the specialised nature of these items, a subgroup was formed to review the TM items, comprising pathologists, GP representatives, practising oncologists and a government medical adviser with a professional background in oncology. The recommendations that follow were made over two meetings, after careful consideration of the current data and a literature review.[30]

Table 56. Item introduction table for items 66650, 66651, 66652, 66653 and 66629

Item	Long item descriptor	Schedule fee	Services FY 2014-15	Benefits FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66650	Alpha-fetoprotein, CA-15.3 antigen (CA15.3), CA-125 antigen (CA125), CA-19.9 antigen (CA19.9), cancer-associated serum antigen (CASA), carcinoembryonic antigen (CEA), human chorionic gonadotrophin (HCG), neuron specific enolase (NSE), thyroglobulin in serum or other body fluid, in the monitoring of malignancy or in the detection or monitoring of hepatic tumours, gestational trophoblastic disease or germ cell tumour - quantitation - 1 test	$24.35	513,703	$10,616,167	318,833	2.5%
66651	A test described in item 66650 if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test	$24.35	9,166	$189,339	7,604	1.8%
66652	A test described in item 66650 if rendered by a receiving APP - other than that described in 66651, if rendered by a receiving AP - 1 test	$20.30	4,117	$71,106	3,380	5.2%
66653	2 or more tests described in item 66650	$44.60	264,540	$10,020,483	198,722	5.6%
66629	Beta-2-microglobulin - quantitation in serum, urine or other body fluids - 1 or more tests	$20.10	66,823	$1,129,587	38,029	4.7%

Recommendation

The Committee proposes the following:

- Δ Rewording the item descriptors to specify which cancer and stage of disease a TM is indicated for (outlined in Table 57 below), to encourage appropriate, evidence-based requesting.
- Δ To remove cancer-associated serum antigen (CASA) from the list of TMs in item 66650.
- Δ To remove thyroglobulin from the list of TMs in item 66650.
- Δ To refer chromogranin A for MSAC assessment, with a view to its inclusion in the list of TMs in item 66650, noting that a very clear descriptor will be required to ensure appropriate use in the most suitable patient populations.
- Δ To refer human epididymis protein 4 (HE-4) for MSAC assessment, with a view to its inclusion in the list of TMs in item 66650, noting that a very clear descriptor will be required to ensure appropriate use in the most suitable patient populations.
- Δ That item 66629 be retained as an MBS item rather than including beta-2-microglobulin in the list of TMs in item 66650.
- Δ A comprehensive campaign to educate requestors about the changes to these items and to encourage more appropriate requesting of TMs.

Rationale

- Δ The recommendations from this Committee is supported by a brief literature review undertaken by Health Consult on behalf of Secretariat for the Pathology Services Advisory Committee (PSAC) in early 2015;[31] that is, prior to the MBS Review. The purpose of the review was to determine whether current MBS TM tests remained clinically relevant, but also whether there were other TMs that were clinically relevant and not currently on the MBS. While not undertaken systematically, the overview of recent systemic reviews identified a number of publications indicating the potential utility of HE-4 as a diagnostic TM in ovarian and endometrial cancer, with the authors suggesting it could be considered for a more detailed assessment.
- Δ MBS tumour marker (TM) expenditure in 2014-15 was $20.9 million. While only moderate in terms of cost to the government, inappropriate TM testing, particularly in the case of screening, can lead to unnecessary downstream imaging and other interventions, driven by high rates of false positive testing. Data show moderate growth, with services for item 66650 growing at 2.5% annually, 66653 at 5.6% annually and 66629 at 4.7% per year.
- Δ In 2014-15, GPs requested approximately 30% of item 66650 services, and almost 50% of services for item 66653 (when including data for both VR and non-VR GPs), compared with approximately 20% ordered by medical oncologists. Item 66629 (beta-2-microglobulin) was predominantly ordered by haematologists (almost 50% of requests) with approximately 8% ordered by nephrologists (Figures 13 and 14).
- Δ Both published[32] and anecdotal[31] evidence and the growth in MBS services for these items point to inappropriate use of TMs for screening. The Committee concluded that these tests are being

used for screening even though the current items preclude their use for screening and make clear that the tests are only available for diagnosis and monitoring and in quite specific circumstances. Indeed the TM items are a good example of how item descriptors alone do not lead to appropriate care and that other strategies are needed. The Royal College of Pathologists of Australia identified TMs as one of the tests that should be questioned in its Choosing Wisely recommendations, noting that: 'testing for a broad range of biomarkers in patients with non-specific symptoms in the hope of finding an undetected cancer is not supported by the evidence from numerous systematic reviews.'[33] The Committee believes that including more prescriptive descriptors for these items may help as part of the effort to discourage inappropriate use of TMs. This needs to be supported by appropriate education of requestors. MBS data showed that in 30% of GP requests for TM items, there was no specialist involvement. Anecdotal evidence suggests that some GPs are using these items as screening tests for cancer, which was not their intended purpose and is not supported by evidence. Whereas, in other instances GPs are requesting the item as intended to monitor a patient's progress after a tumour is excised in partnership with their specialist.

- Δ Cancer-associated serum antigen (CASA) is obsolete.
- Δ The Endocrine Clinical Committee (ECC) has recommended the removal of thyroglobulin from item 66650 and that thyroglobulin and thyroglobulin antibody be instead grouped together in a new MBS item for thyroid cancer follow-up. The Committee supports the ECC recommendations.
- Δ There is evidence for the utility of chromogranin A for assessment and follow-up of neuroendocrine tumours.[34-39] The Royal College of Pathologists of Australasia also supports inclusion of chromogranin A in the MBS tumour marker items. The Committee has referred this recommendation to the MSAC for further evaluation.
- Δ There is evidence for the utility of human epididymis protein 4 (HE-4) in ovarian cancer.[30] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) supports inclusion of HE-4 on the MBS, noting:
    - The test is used in conjunction with CA125 to calculate the Risk of Malignancy Algorithm (ROMA). HE-4 is useful in women with an elevated CA125 and a pelvic mass, in order to determine whether a mass is likely to be malignant. Common benign causes of raised CA125 and pelvic mass (endometriosis, fibroids) will have a normal HE-4 and therefore a different ROMA score.
    - HE-4 and other TMs should not be used for screening, but have value in the assessment and triage of patients with a pelvic mass.
- Δ The Committee has referred this recommendation to the MSAC for further evaluation.
- Δ Beta-2-microglobulin is a TM, primarily requested by haematologists for the assessment and follow up of multiple myeloma and lymphoma. However, around 8% of requests for item 66629 in 2014-15 were from nephrologists, with beta-2-microglobulin testing also used for assessing the efficiency of dialysis. While use of item 66629 in nephrology is decreasing with the

increasing uptake of hi-flux dialysis, it still has clinical utility and needs to be retained on the Schedule.

- Δ Committee members were unanimous in their belief that to achieve meaningful change in behaviour, any changes in the TM descriptors will need to be accompanied by an education campaign targeted at requestors, including both GPs and specialist requestors. Organisations that could be enlisted to support this campaign include NPS MedicineWise, pathology providers and the relevant medical colleges.
- Δ To better identify usage of specific items and better direct education efforts, the Committee recommended individual items for specific tumour markers.

*Table 57. Current and proposed item descriptor for items 66650 – 66653 and 66629**

Item	Current descriptor	New descriptor
66650	Alpha-fetoprotein, CA-15.3 antigen (CA15.3), CA-125 antigen (CA125), CA-19.9 antigen (CA19.9), cancer-associated serum antigen (CASA), carcinoembryonic antigen (CEA), human chorionic gonadotrophin (HCG), neuron specific enolase (NSE), thyroglobulin in serum or other body fluid, in the monitoring of malignancy or in the detection or monitoring of hepatic tumours, gestational trophoblastic disease or germ cell tumour - quantitation - 1 test	Alpha-fetoprotein in the detection or monitoring of a hepatic tumour in a patient with existing liver cirrhosis or for the initial diagnostic work-up or follow up of a germ cell tumour (Item is subject to rule 6)
New item		Human chorionic gonadotrophin (HCG) quantitation for the initial diagnostic work-up or follow up of gestational trophoblastic disease, choriocarcinoma or germ cell tumour (Item is subject to rule 6)
New item		CA-15.3 antigen (CA15.3) in the initial diagnostic work-up and follow up of metastatic breast cancer (Item is subject to rule 6)
New item		CA-125 antigen (CA125) for early detection in a woman with a hereditary cancer syndrome, or in the initial diagnostic work-up or follow up of ovarian cancer (Item is subject to rule 6)
New item		Human epididymis protein 4 (HE-4) in conjunction with CA125 in the initial diagnostic work-up of a woman with a pelvic mass to calculate a Risk of Ovarian Malignancy Algorithm (ROMA) (Item is subject to rule 6)
New item		CA-19.9 antigen (CA19.9) in the initial diagnostic work-up or follow up of pancreatic or gastric cancer (Item is subject to rule 6)

Item	Current descriptor	New descriptor
New item		Carcinoembryonic antigen (CEA) in the initial diagnostic work-up or follow up of a patient with an adenocarcinoma (Item is subject to rule 6)
New item		Chromogranin A (CgA) or neuron specific enolase (NSE) in the initial diagnostic work-up or follow up of a neuroendocrine tumour (Item is subject to rule 6)
66651	A test described in item 66650 if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test	A test described in item 66650 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)
66652	A test described in item 66650 if rendered by a receiving APP - other than that described in 66651, if rendered by a receiving APP, 1 test	
66653	2 or more tests described in item 66650	2 or more tests described in item 66650 or for tumour marker estimation in the management of metastatic adenocarcinoma of unknown primary.
66629	Beta-2-microglobulin - quantitation in serum, urine or other body fluids - 1 or more tests	Beta-2-microglobulin - quantitation in serum, urine or other body fluids - 1 or more tests

* The Committee recognises that agreement to the proposed items is not unanimous. An alternate view and concerns have been raised and are described below:

Alternative view considered

General

- The new item does not acknowledge the fact that many tumours do not express the classical markers that are being proposed.
- Not all tumours are documented in these new proposed items.
- It is good practice in oncology management to form a care team of the oncologists with the patient's GP, thus many GP-ordered tumour markers tests are requested under the guidance of a specialist.

Item 66650 specific points

- Requests by general practitioners may be made in consultation with and at the behest of specialists, as the care of patients with neoplastic conditions is frequently shared between specialists and general practitioners.
- With regard to the varied expression of tumour markers with different tumours; as an example, there are well-known occurrence of colorectal cancers that commonly express CA19.9 and are

often best monitored by this marker. Yet colorectal cancer is not mentioned in the descriptor related to CA19.9.

Δ The current item allows testing of a single tumour marker that permits some flexibility in terms of a primary source, eg, hepatic tumours may be of primary or metastatic origin. This is relevant because tumour markers are neither tissue- nor organ-specific. The new item does not. Under the new item proposed, a tumour marker is only eligible for a rebate if requested for the initial assessment or follow-up of specific neoplastic conditions. Such a limited approach fails to properly take into account:

- The information that is widely available in published sources, such as the references - in this document together with the RCPA Position Statement cited below but not referenced.
- The range of malignant conditions as well as different histological types for which tumour marker testing is useful for initial assessment and follow-up of neoplastic disease.
- Current clinical practice, in particular that of specialists who are responsible for the management of patients with malignant disease.

Δ With respect to the particular conditions that are specified in the proposed new item, some of the shortcomings identified include, but are not limited to, the following:

- *"CA-15.3 antigen (CA15.3) in the initial diagnostic work-up and follow up of metastatic breast cancer*." It is unclear whether CA15.3 testing would be eligible for a rebate in a patient who has suspected or diagnosed primary breast cancer without any evidence of metastatic involvement. Follow-up CA15.3 testing should be available as part of the ongoing surveillance of a patient who not only has diagnosed secondary breast cancer but who is also at risk of metastatic disease.
- "*CA-19.9 antigen (CA19.9) in the initial diagnostic work-up and follow up of pancreatic or gastric cancer."* The eligibility of CA19.9 should not be restricted to pancreatic or gastric cancer. CA19.9 can be the principal clinically useful marker in other forms of malignancy including, but not limited to, cholangiocarcinoma, carcinoma of the gallbladder, oesophageal cancer and colorectal cancer.
- *"Carcinoembryonic antigen (CEA) in the initial diagnostic work-up and follow up of a patient with an adenocarcinoma."* The eligibility of CEA should not necessarily be limited to the assessment of patients with adenocarcinoma. For example, CEA can be a useful marker for non-small cell lung cancer which not only includes adenocarcinoma but other histological types.
- There is no allowance made under item 66650 for choosing to perform a single test from the various markers described for the assessment of patients with metastatic disease where the primary source is unknown (see below).

Item 66653 comments

- The new item descriptor specifies that two or more tests may be performed *"in the management of metastatic adenocarcinoma of unknown primary"*.
  This presupposes that a specific diagnosis of adenocarcinoma has already been made. Such a restrictor, however, overlooks the important role played by tumour marker testing in the assessment of patients with evidence of malignancy when it has yet to be histologically categorised.

Conclusion

Suggested amendments to proposed new items.

- As outlined above, the proposed new items fail to meet the need to ensure optimal care for patients with different forms of malignancy and do not reflect current clinical practice, in particular that of specialists, such as oncologists, who are primarily responsible for managing such patients.
- Rather than include specific conditions that render appropriate tumour testing for some patients ineligible for a rebate, an alternative approach could be adopted whereby an explanatory note could be included as part of a more general descriptor for item 66650. This approach has been proposed for adoption with other items such as those involving the appropriate requesting of thyroid function tests. Reference could be made to the association between neoplastic conditions and the use of particular tumour markers in an explanatory note as exemplified by the following:

Example explanatory note for Item 66650

- A single tumour marker is often sufficient for the initial assessment and follow up of a patient with cancer. Examples of recommendations are listed below;
  - Alpha-fetoprotein in the detection or monitoring of an hepatic tumour in a patient with existing liver cirrhosis or for the initial diagnostic work-up or follow up of a germ cell tumour.
  - Human chorionic gonadotrophin (HCG) quantitation for the initial diagnostic work-up or follow up of gestational trophoblastic disease, choriocarcinoma or germ cell tumour.
  - CA-15.3 antigen (CA15.3) in the initial diagnostic work-up and follow up of metastatic breast cancer.
  - CA-125 antigen (CA125) for early detection in a woman with an hereditary cancer syndrome, or in the initial diagnostic work-up or follow up of ovarian cancer.
  - Human epididymis protein 4 (HE-4) in conjunction with CA125 in the initial diagnostic work-up of a woman with a pelvic mass to calculate a Risk of Ovarian Malignancy Algorithm (ROMA).

- CA-19.9 antigen (CA19.9) in the initial diagnostic work-up or follow up of pancreatic or gastric cancer.
- Carcinoembryonic antigen (CEA) in the initial diagnostic work-up or follow up of a patient with an adenocarcinoma.
- Chromogranin A (CgA) or neuron specific enolase (NSE) in the initial diagnostic work-up or follow up of a neuroendocrine tumour.

Descriptor for Item 66650

Δ CEA, CA 15-3, CA 19-9, CA 125, alpha-fetoprotein, HE-4, chromogranin A in the initial diagnostic work-up of a patient at high risk of cancer or in the follow up of a patient with cancer.

Descriptor for Item 66653

Δ If the above amendments were adopted for item 66650, then it would not be necessary to make any change to the current version of item 66653 – the descriptor could remain as: "2 or more tests described in item 66650."

Final note

Δ The RCPA Position Statement "Serum Tumour Marker Requesting, Testing and Reporting Results" is not included among the references and is a significant opinion that draws on the literature search that was done by Health. It supports many of the points made above.

Figure 12. State utilisation for items 66629, 66650 and 66653

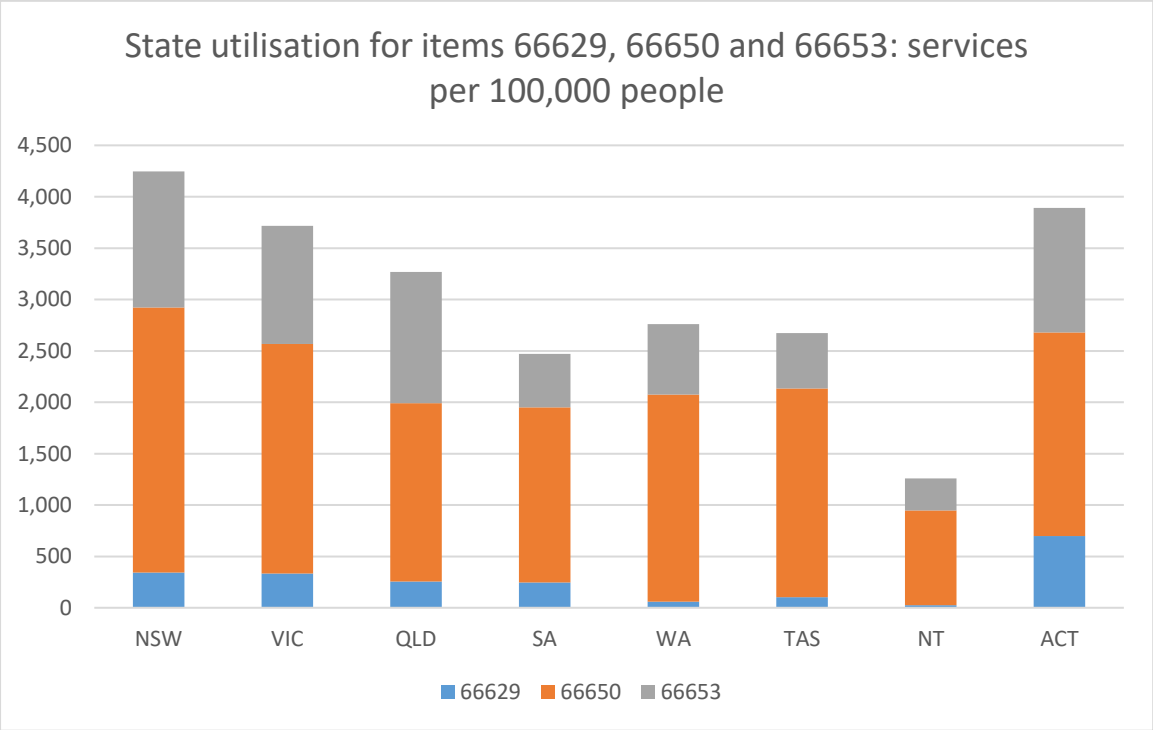


Table 58. Repeat testing for items 66650, 66651, 66652 and 66653

Item	1	2	3	4	5	6	7	8	9	10	11	12	Max
66650	236,997	46,994	15,016	6,959	3,235	2,002	1,470	1,159	850	701	543	532	46
66651	5,841	783	172	51	21	10	6	0	0	0	0	0	11
66652	2,988	292	85	31	10	0	7	0	0	0	0	0	12
66653	168,851	18,992	4,713	2,301	1,089	658	451	335	272	234	148	147	37

Table 59. Laboratory data from a large metropolitan laboratory

Marker	Total/fixed period	Percentage
AFP	1296	20%
CA125	1530	24%
CA15.3	488	8%
Ca19.9	857	13%
CEA	2171	34%
HCG	35	1%

Figure 13. Item 66650 requested by speciality

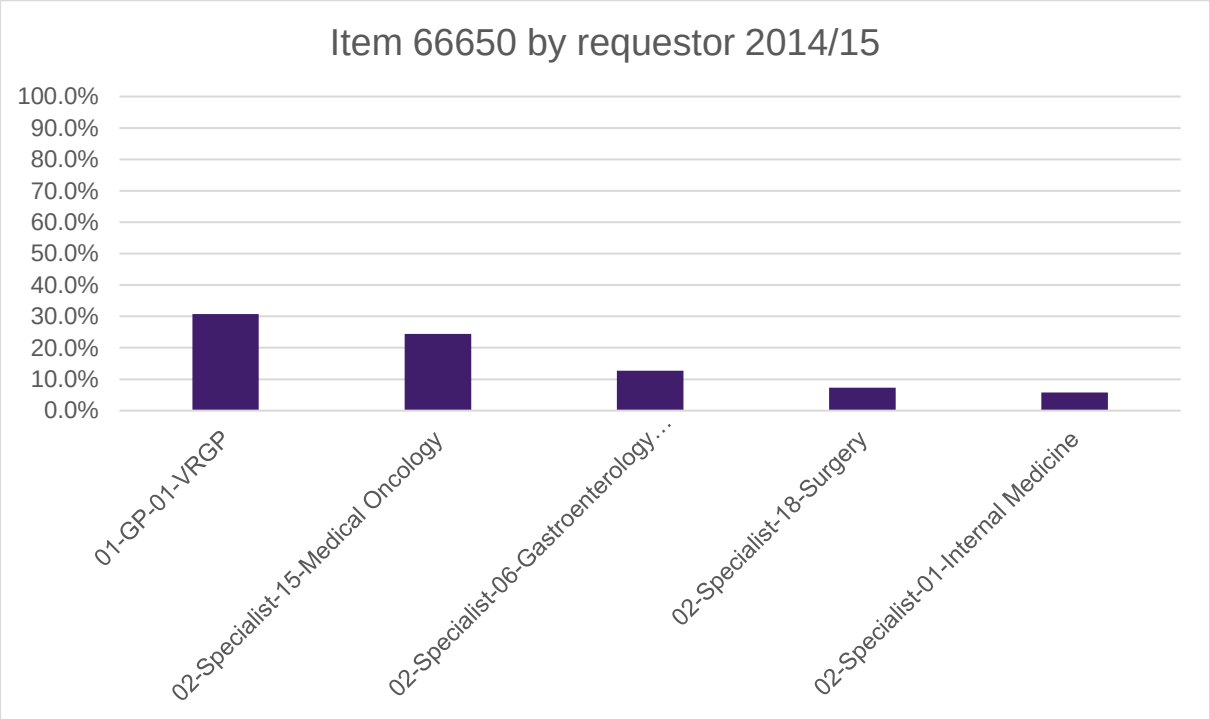
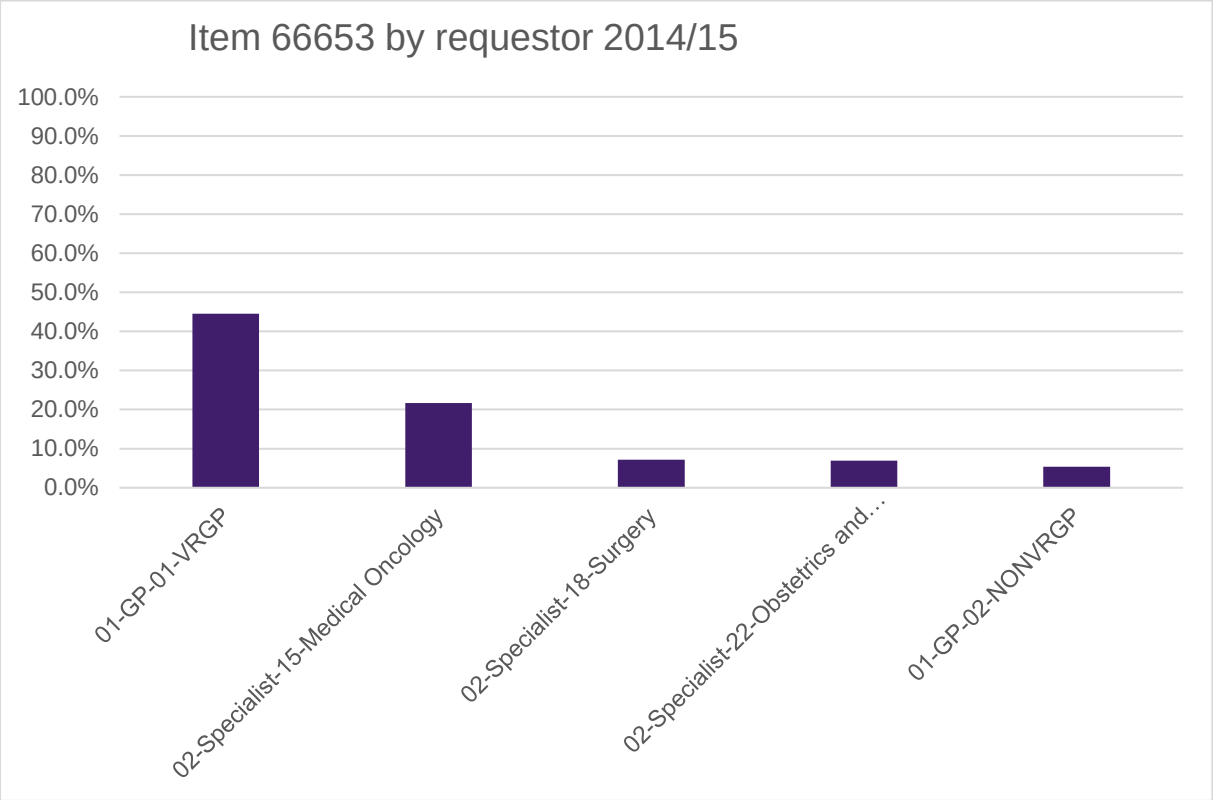


Figure 14. Item 66653 requested by speciality



6. Items reviewed by the Diagnostic Medicine Clinical Committee

The Diagnostic Medicine Clinical Committee (DMCC) is part of the third tranche of Clinical Committees. It was established in March 2017 to make recommendations to the Taskforce on MBS items within its remit, based on clinical expertise and rapid evidence review. The Taskforce asked the DMCC to review MBS items related to diagnostic medicine. Eleven of the 14 Committee members are clinicians, including six GPs, two pathologists, two radiologists and one gastroenterologist. Their work covers most Australian states and a mixture of metropolitan, regional, public and private practice, reflecting the use of MBS items across sectors. The clinicians on the Committee also represent a broad range of clinical and other expertise, including healthcare quality, clinical governance, policy and academic experience. Members were appointed in an individual capacity, not as representatives of nominating or other bodies. Members were selected to provide a broad perspective on requesting diagnostic medicine tests, and to share insights into the interests of the community, who fund the majority of billable diagnostic medicine services (through taxes, MBS rebates, health insurance and other payments). Two consumer representatives and a health economist are also part of the DMCC.

Between March and August 2017, the Committee considered eight referred pathology item groups, which accounted for 11.9 million services and $274.3 million in benefits paid in FY2014–15. Recommendations are based on evidence and the clinical expertise of the Committee. Presented below are the recommendations for vitamin B12 and folate testing.

6.1 Vitamin B12

Table 60. Item introduction table for 66838, 66839

Item	Long item descriptor	Schedule fee	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66838	Serum vitamin B12 test (Item is subject to Rule 25)	23.60	$18,083,490	899,124	899,124	
66839	Quantification of vitamin B12 markers such as holotranscobalamin or methylmalonic acid, where initial serum vitamin B12 result is low or equivocal	42.95	$24,124,151	656,016	612,817	

Advice from the Diagnostic Medicine Clinical Committee (DMCC)

1. The DMCC found sufficient evidence to conclude that the comparative use of serum vitamin B12 testing and vitamin B12 marker testing is not as expected. Unpublished GP practice data1 (unaffected by the 'coning' rule) showed that less than 20% of vitamin B12 tests returned a low result. This suggests that the vitamin B12 marker test should only be performed in a minority of cases, as per the qualifying criteria for item 66839 ('…where initial serum vitamin B12 result is low or equivocal'). However, the relative frequencies of items 66839 and 66840 are approximately 1.5 rather than 0.2. Approximately 30% of vitamin B12 tests were repeated in less than 12 months.[2]

Δ The DMCC agreed that the following factors were possibly contributing to the high usage rates for vitamin B12 marker testing.

- Low GP awareness of the MBS annual restriction on vitamin B12 testing is likely to be contributing to frequent vitamin B12 testing (that is, more than once every 12 months).
- A small group of clinicians may be directly requesting the vitamin B12 marker tests for consumers (even though the MBS indicates it is currently not the first-line test).
- When clinicians incorrectly request a repeat vitamin B12 test less than a year after the most recent vitamin B12 test (with the intention of requesting another serum vitamin B12 test; item 66838), laboratories may perform the vitamin B12 marker test (item 66839), which has no annual limit. In some cases, this may be undertaken due to a previous 'low or equivocal' vitamin B12 result. In other cases, it may be because item 66839 is unrestricted.
- Reference ranges for serum vitamin B12 tests and vitamin B12 marker tests vary. Furthermore the cut-off limits below which pathology laboratories reflex test for vitamin B12 markers are currently independently determined by each pathology laboratory. If the cutoffs are set at too high a value, this would increase the number of 'low or equivocal' results, and consequently the number of repeat vitamin B12 marker tests.

Δ The DMCC agreed that a 12-month frequency restriction was appropriate to reduce inappropriate vitamin B12 marker testing, given that:

- The MSAC's intention was for vitamin B12 marker testing to be used as a second-line test in a minority of cases. (At present, vitamin B12 marker testing outstrips serum vitamin B12 testing, partly because the vitamin B12 marker test is not subject to a frequency restriction.)
- MBS data indicated that the 12-month interval was reasonable in more than 90% of cases when the frequency restriction was introduced for the serum vitamin B12 item.

[1] NPS MedicineInsight 2017

[2] MBS data FY2015–16, date of servicing

- No guidelines exist to support repeat vitamin B12 testing more frequently than annually.

Δ After considering the verbal advice from the DMCC, the Committee endorsed the recommendations, which are below.

Recommendations

Δ Add a rule to item 66839 to limit testing to once within a 12-month period* to match the restriction that is already in place for item 66838.

Δ Change the descriptors for items 66838 and 66839 to stipulate that lethargy/tiredness alone is not an adequate or appropriate indication for any form of vitamin B12 testing.

Δ Add an explanatory note to item 66839 detailing that pathology laboratories that bill for quantification of vitamin B12 markers must be performing this test on the same pathology episode that returned the initial low or equivocal serum vitamin B12 result. Amend the item descriptor for item 66839 to reflect same.

Δ Establish nationally harmonised vitamin B12 limits at which the pathology provider will reflex test for item 66839 in addition to 66838. The Committee recommends that the taskforce request the Royal College of Pathologists of Australasia to help establish these limits.

Δ If laboratories adopt nationally harmonised limits for reflex testing for vitamin B12 markers (instead of independently setting these ranges), item 66839 will continue to be a pathologist-determinable test. This recommendation should be reviewed 12 months after submission of this report if a nationally harmonised limit for reflex testing for vitamin B12 markers has not been achieved.

Δ Provide requestor education on appropriate testing frequency.

Δ Provide consumer education on the above changes.

Rationale

Δ A review of vitamin B12 testing was initiated in 2014 following an increase in the utilisation of the (then) items: 66599 and 66602. During the financial year 2012/2013, there were 618,744 services provided that equated to $12.4 million for item 66599 and more than 2 million services provided at a cost of $78.5 million for item 66602.

Δ A review of folate testing occurred concurrently with vitamin B12 testing because the MBS item descriptors included serum folate/red cell folate and vitamin B12 and it was difficult to identify which test or tests were being ordered at a patient level.

Δ Following a review, including an evidence review and a review of analytical methods used for vitamin B12 testing, MSAC decided to split serum folate/red cell folate and vitamin B12. It was recommended that a GP education program on vitamin B12 testing be implemented to introduce the change and encourage best practice.

Δ In 2014, two separate MBS items were created for:

- serum vitamin B12 (benefits payable once in a 12-month period)

- quantification of vitamin B12 markers such as holotranscobalamin or methylmalonic acid when initial serum vitamin B12 is low or equivocal.

Δ The vitamin B12 marker test was made a pathologist-determinable test, so that the laboratory can conduct the quantification test without referring to the requesting provider, after finding a low or equivocal result with the serum B12 test. MSAC proposed a fee of $23.60 for serum vitamin B12 test and a fee of $42.95 for the vitamin B12 marker test.

Δ During financial year 2014/2015, there were 1,338,161 services provided at a cost of $26,909,434 for item 66838 and 1,100,598 services provided at a cost of $40,423,209 for item 66839.

Δ During financial year 2015/2016, there were 1,149,208 services provided at a cost of $23,090,315 for item 66838 and 1,556,982 services provided at a cost of $57,067,536 for item 66839.

Δ There are a number of patients who have several determinations of 66389 made in one year, while the limit for vitamin B12 testing was one test per year.

Δ The recommendation of the Committee is that the pathology industry agrees on a common cut-off level for vitamin B12 levels, below which testing with 66389 is indicated.

Δ The frequency of the testing is limited to one test per year.

* The Committee recognises that agreement to the proposed items is not unanimous. An alternate view and concern has been described below:

Alternative point for consideration

Allowance should be made to confirm a B12 deficient result before lifelong therapy and this should be included in the item descriptor.

Folate testing

Table 61. Item introduction table for item 66840

Item	Long item descriptor	Schedule fee	Benefits FY 2014-15	Services FY 2014-15	Patient count 2014-15	5-year service change % (CAGR)
66840	Serum folate test and, if required, red cell folate test for a patient at risk of folate deficiency, including patients with malabsorption conditions, macrocytic anaemia or coeliac disease	23.60	$8,945,265	448,378	412,907	-

Advice from the Diagnostic Medicine Clinical Committee (DMCC)

- The Diagnostic Medicine Clinical Committee (DMCC) analysed the utilisation of folate testing following the introduction of item 66840, and found sufficient evidence to conclude that folate testing is being used inappropriately. The DMCC also found that:
    - Less than 3.5% of the 0.75 million tests conducted each year return a result of deficiency.
    - 28% of tests are conducted within 12 months of an initial test.
    - 88% of tests are co-claimed with either iron or vitamin B12 testing, and 67% are co-claimed with vitamin B12 testing and may be requested out of habit rather than clinical necessity.
- The DMCC agreed that breaking the connection between vitamin B12 and folate testing is essential to reduce overuse of folate testing.
- The DMCC noted there is no clinical requirement for folate testing to be repeated within 12 months of initial testing.
- The DMCC noted the current item restrictions appear to have had little impact on the practices of requesting clinicians.
- The DMCC recommended removing 'at risk of folate deficiency' from the current item descriptor because it is leading to over-testing. Only consumers with macrocytic anaemia or malabsorption issues should be tested.
- In pregnancy, supplementation is recommended for all consumers in the first trimester, which means that testing is unnecessary. After reviewing the advice from the DMCC, the Committee endorsed the recommendations from the DMCC, which appear below.

Recommendation

Change the item descriptor for item 66840 (serum folate test) to provide greater clarity. The proposed item descriptor is as follows:

- Serum folate test and, if required, red cell folate test for a patient with malabsorption conditions or macrocytic anaemia.
- Add a rule to item 66840 to limit testing to once within a 12-month period.
- Add an explanatory note to item 66840 to clarify who may require folate testing. The proposed explanatory note is as follows:
    - Folate testing is only required for patients with macrocytic anaemia or malabsorption issues such as coeliac disease and other small bowel pathology.
    - Two groups of patients should be supplemented with folate and do not require testing: women who are pregnant or planning pregnancy, and those on methotrexate.
- Carry out requesting clinician education that communicates details of the changed item descriptor. Pathology laboratories should begin to include a standard message about inappropriate folate testing on pathology reports going back to requesting clinicians. The Committee recommended that the RCPA develop this message.

- Δ Review the impact of the above recommendations 12 months after implementation. In the event of no/minimal impact, the Committee recommended:
    - Mandating that requesting clinicians specify the reason for their request (that is, malabsorption or macrocytic anaemia) on pathology request forms.
    - Further requesting restrictions should be considered.

Rationale

- Δ A review of folate testing was initiated following an increase in the utilisation of items: 66599 and 66602. During the FY 2012/2013, there were 618,744 services provided that equated to $12.4 million for item 66599 and more than 2 million services provided at a cost of $78.5 million for item 66602.
- Δ Folate levels in the general population have increased since the fortification of wheat flour in 2009 and consequently, there are currently very low rates of folate deficiency in Australia. The RACGP guidelines recommend that pregnant and lactating women use folate prior to and during pregnancy.
- Δ Following a review of folate testing, including an evidence review and review of costing of folate testing, MSAC recommended that item 66602 be deleted due to the test being obsolete and introduced a new item for serum folate, as serum folate is the preferred testing method and folate testing should only be conducted in patients at risk of folate deficiency. These changes took place in 2014.

7. Items with no changes

The Committee recommends that the MBS items listed in Table 62 do not require amendment, as they are clinically appropriate.

Table 62: MBS items that do not require amendment

Item	Item descriptor	Schedule fee ($)	Benefits (2014–15)
66563	Osmolality, estimation by osmometer, in serum or in urine - 1 or more tests	24.70	$748,144
66566	Quantitation of: (a) blood gases (including pO2, oxygen saturation and pCO2); and (b) bicarbonate and pH; including any other measurement (eg, haemoglobin, lactate, potassium or ionised calcium) or calculation performed on the same specimen - 1 or more tests on 1 specimen	33.70	$4,357,317
66569	Quantitation of blood gases, bicarbonate and pH as described in item 66566 on 2 specimens performed within any 1 day	42.60	$1,813,114
66572	Quantitation of blood gases, bicarbonate and pH as described in item 66566 on 3 specimens performed within any 1 day	51.55	$1,045,369
66575	Quantitation of blood gases, bicarbonate and pH as described in item 66566 on 4 specimens performed within any 1 day	60.45	$882,305
66578	Quantitation of blood gases, bicarbonate and pH as described in item 66566 on 5 specimens performed within any 1 day	69.35	$817,929
66581	Quantitation of blood gases, bicarbonate and pH as described in item 66566 on 6 or more specimens performed within any 1 day	78.25	$2,138,054
66584	Quantitation of ionised calcium (except if performed as part of item 66566) - 1 test	9.70	$274,220
66563	Osmolality, estimation by osmometer, in serum or in urine - 1 or more tests	24.70	$748,144

Item	Item descriptor	Schedule fee ($)	Benefits (2014–15)
66566	Quantitation of: (a) blood gases (including pO2, oxygen saturation and pCO2); and (b) bicarbonate and pH; including any other measurement (eg. haemoglobin, lactate, potassium or ionised calcium) or calculation performed on the same specimen - 1 or more tests on 1 specimen	33.70	$4,357,317
66569	Quantitation of blood gases, bicarbonate and pH as described in item 66566 on 2 specimens performed within any 1 day	42.60	$1,813,114
66517	Quantitation of bile acids in blood in pregnancy. To a maximum of 3 tests in a pregnancy	19.65	$156,240
66743	Quantitation of alpha-fetoprotein in serum or other body fluids during pregnancy except if requested as part of items 66750 or 66751	20.10	$37,828
66785	Porphyrins or porphyrins precursors - quantitation in plasma, red cells, urine or faeces - 1 test (Item is subject to rule 6)	39.95	$44,012
66788	Porphyrins or porphyrins precursors - quantitation in plasma, red cells, urine or faeces - 2 or more tests (Item is subject to rule 6)	65.85	$40,518
66789	A test described in item 66785 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)	39.95	$18,475
66566	Quantitation of: (a) blood gases (including pO2, oxygen saturation and pCO2); and (b) bicarbonate and pH; including any other measurement (eg, haemoglobin, lactate, potassium or ionised calcium) or calculation performed on the same specimen - 1 or more tests on 1 specimen	33.70	$4,357,317
66569	Quantitation of blood gases, bicarbonate and pH as described in item 66566 on 2 specimens performed within any 1 day	42.60	$1,813,114

Item	Item descriptor	Schedule fee ($)	Benefits (2014–15)
66572	Quantitation of blood gases, bicarbonate and pH as described in item 66566 on 3 specimens performed within any 1 day	51.55	$1,045,369
66575	Quantitation of blood gases, bicarbonate and pH as described in item 66566 on 4 specimens performed within any 1 day	60.45	$882,305
66578	Quantitation of blood gases, bicarbonate and pH as described in item 66566 on 5 specimens performed within any 1 day	69.35	$817,929
66581	Quantitation of blood gases, bicarbonate and pH as described in item 66566 on 6 or more specimens performed within any 1 day	78.25	$2,138,054
66584	Quantitation of ionised calcium (except if performed as part of item 66566) - 1 test	9.70	$274,220
66812	Quantitation, not elsewhere described in this Table by any method or methods, in blood, urine or other body fluid, of a drug being used therapeutically by the patient from whom the specimen was taken - 1 test (This fee applies where 1 laboratory performs the only test specified on the request form or performs 1 test and refers the rest to the laboratory of a separate APA) (Item is subject to rule 6)	34.80	$4,276,391
66815	2 tests described in item 66812 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs the only 2 tests specified on the request form or performs 2 tests and refers the rest to the laboratory of a separate APA) (Item is subject to rule 6)	59.55	$478,067
66816	A test described in item 66812 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)	34.80	$736,244

Item	Item descriptor	Schedule fee ($)	Benefits (2014–15)
66817	A test described in item 66812, other than that described in 66816, if rendered by a receiving APP - to a maximum of 1 test (Item is subject to rules 6 and 18)	24.75	$171,770
66632	Caeruloplasmin, haptoglobins, or prealbumin - quantitation in serum, urine or other body fluids - 1 or more tests	20.10	$996,907
66644	C-1 esterase inhibitor - quantitation	20.15	$43,934
66647	C-1 esterase inhibitor - functional assay	45.10	$115,057
66758	Quantitation of angiotensin converting enzyme, or cholinesterase - 1 or more tests	24.70	$849,866
66665	Lead quantitation in blood or urine (other than for occupational health screening purposes) to a maximum of 3 tests in a 6-month period - each test	30.60	$336,746
66666	A test described in item 66665 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	30.60	$26,577
66667	Quantitation of serum zinc in a patient receiving intravenous alimentation - each test	30.60	$26,577
66671	Quantitation of serum zinc in a patient receiving intravenous alimentation - each test	30.60	$54,130
66825	Quantitation of aluminium (except if item 66671 applies), arsenic, beryllium, cadmium, chromium, gold, mercury, nickel, or strontium, in blood, urine or other body fluid or tissue - 1 test. To a maximum of 3 of this item in a 6-month period (Item is subject to rules 6, 22 and 25)	30.60	$260,100
66826	A test described in item 66825 if rendered by a receiving APP where no tests have been rendered by the referring APP - 1 test (Item is subject to rules 6, 18, 22 and 25)	30.60	$32,923
66827	A test described in item 66825, other than that described in 66826, if rendered by a receiving APP to a maximum of 1 test (Item is subject to rules 6, 18, 22 and 25)	21.80	$15,840

Item	Item descriptor	Schedule fee ($)	Benefits (2014–15)
66828	Quantitation of aluminium (except if item 66671 applies), arsenic, beryllium, cadmium, chromium, gold, mercury, nickel, or strontium, in blood, urine or other body fluid or tissue - 2 or more tests. to a maximum of 3 of this item in a 6-month period (Item is subject to rules 6, 22 and 25)	52.45	$110,166
66831	Quantitation of copper or iron in liver tissue biopsy	30.95	$1,249
66832	A test described in item 66831 if rendered by a receiving APP (Item is subject to rules 18a and 22)	30.95	$1,254
66711	Quantitation in saliva of cortisol in: (a) the investigation of Cushing's syndrome; or (b) the management of children with congenital adrenal hyperplasia (Item is subject to rule 6)	30.15	$59,115
66712	Two tests described in item 66711 (Item is subject to rule 6)	43.05	$7,330
66714	A test described in item 66711, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP (Item is subject to rules 6 and 18)	30.15	$4,967
66785	Porphyrins or porphyrins precursors - quantitation in plasma, red cells, urine or faeces - 1 test (Item is subject to rule 6)	39.95	$44,012
66788	Porphyrins or porphyrins precursors - quantitation in plasma, red cells, urine or faeces - 2 or more tests (Item is subject to rule 6)	65.85	$40,518
66789	A test described in item 66785 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)	39.95	$18,475
73527	Human chorionic gonadotrophin (HCG) - detection in serum or urine by 1 or more methods for diagnosis of pregnancy - 1 or more tests	10.00	$818,190
73529	Human chorionic gonadotrophin (HCG), quantitation in serum by 1 or more methods (except by latex, membrane, strip or other pregnancy test kit) for diagnosis of	28.65	$12,728,417

Item	Item descriptor	Schedule fee ($)	Benefits (2014–15)
	threatened abortion, or follow up of abortion or diagnosis of ectopic pregnancy, including any services performed in item 73527 - 1 test		

8. Items to be deleted

The following items are to be deleted from the MBS Schedule as the items are obsolete or have been superseded, and are no longer used in clinical practice.

Table 63. MBS items recommended for deletion.

Item	Item descriptor	Schedule fee ($)	Services (2014–15)
66749	Amniotic fluid, spectrophotometric examination of, and quantitation of: (a) lecithin/sphingomyelin ratio; or (b) palmitic acid, phosphatidylglycerol or lamellar body phospholipid; or (c) bilirubin, including correction for haemoglobin - 1 or more tests	32.95	46
71095	Quantitation of serum or plasma eosinophil cationic protein, or both, to a maximum of 3 assays in 1 year, for monitoring the response to therapy in corticosteroid-treated asthma, in a child aged less than 12 years	40.55	
66783	A test described in item 66782 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	13.15	668
66791	Porphyrin biosynthetic enzymes - measurement of activity in blood cells or other tissues - 1 or more tests	74.45	4
66792	A test described in item 66791 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	74.45	7
66715	Tests described in item 66711, other than that described in 66714, if rendered by a receiving APP, each test to a maximum of 1 test (Item is subject to rules 6 and 18)	12.85	151
66683	Enzymes - quantitation in solid tissue or tissues other than blood elements or intestinal tissue - 1 or more tests	74.45	19

Source: Department of Human Services

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10. Glossary

Term	Description
ACSQHC	The Australian Commission on Safety and Quality in Health Care
AHMAC	Australian Health Ministers' Advisory Council
Department, The	Australian Government Department of Health
DHS	Australian Government Department of Human Services
GP	General practitioner
High-value care	Services of proven efficacy reflecting current best medical practice, or for which the potential benefit to consumers exceeds the risk and costs.
Inappropriate use / misuse	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.
Low-value care	The use of an intervention which evidence suggests confers no or very little benefit on patients, or that the risk of harm exceeds the likely benefit, or, more broadly, that the added costs of the intervention do not provide proportional added benefits.
MBS item	An administrative object listed in the MBS and used for the purposes of claiming and paying Medicare benefits, comprising an item number, service descriptor and supporting information, Schedule fee and Medicare benefits.
MBS service	The actual medical consultation, procedure, test to which the relevant MBS item refers.

Term	Description
MMM	Monash Modifier Model - is a classification system that categorises metropolitan, regional, rural and remote areas according to both geographical remoteness and population size. The system was developed to recognise the challenges in attracting health workers to more remote and smaller communities.
MSAC	Medical Services Advisory Committee
NICE	National Institute for Health and Care Excellence
OCC	Obstetrics Clinical Committee
Obsolete services	Services that should no longer be performed as they do not represent current clinical best practice and have been superseded by superior tests or procedures.
PBS	Pharmaceutical Benefits Scheme
PHCAG	Primary Health Care Advisory Group

Appendix A Summary for consumers

Table A1: Pathology Clinical Committee recommendations

Recommendation 1: Regrouping common tests

Item	What it does	Committee recommendation	What would be different	Why
66500	Wide range of frequently requested blood, urine and other body fluid tests, when requested as a single test	Introduce three new items that would group some of the tests covered under 66500 into three commonly requested panels. The three panels would cover: electrolytes, urea and creatinine (EUC), liver function tests (LFTs) and calcium, phosphate with albumin. Lipids tests will be taken out of the group and integrated into the HDL item. Acid phosphatase and globulin would be removed from this item. Neonatal bilirubin would be added to this item as a single test for infants.	The tests would be grouped into panels that usefully reflect clinical practice. Lipids tests would be removed from this item, as they will be covered under other items. Some other tests that no longer have clinical utility will be deleted. GPs will be educated about the changes to item 66500 and about appropriate collection and transport of samples, particularly for glucose tests.	To align testing with current clinical requesting practice, rather than billing system, and to allow better MBS data to be collected about tests used in Australia.
66503	2 tests described in item 66500	Change to clinically relevant groupings	Panels would usefully reflect clinical practice	To align testing with current clinical practice.
66506	3 tests described in item 66500	Change to clinically relevant groupings	Panels would usefully reflect clinical practice	To align testing with current clinical practice.
66509	4 tests described in item 66500	Change to clinically relevant groupings	Panels would usefully reflect clinical practice	To align testing with current clinical practice.
66512	5 or more tests described in item 66500	Change to clinically relevant groupings	Panels would usefully reflect clinical practice	To align testing with current clinical practice.

Proposed new items

Item	What it does	Committee recommendation	What would be different	Why
New item	Urea, electrolytes, creatinine panel, that includes tests for: • bicarbonate • sodium • potassium • urea • creatinine • chloride	Create a new item that groups relevant tests as a minimum panel	Only adjustment of billing with requesting practice.	Reflects better clinical practice and allows better tracking of use.
New item	Liver function test panel that includes tests for: • alanine aminotransferase • albumin • alkaline phosphatase • bilirubin (total) • gamma glutamyl transferase • total protein	Create a new item that groups relevant tests as a minimum panel	Only adjustment of billing with requesting practice.	Reflects better clinical practice and allows better tracking of use.
New item	Calcium and phosphate tests including tests for: • calcium' • phosphate • albumin	Create a new item that groups relevant tests as a minimum panel	Only adjustment of billing with requesting practice.	Reflects better clinical practice and allows better tracking of use.

Item	What it does	Committee recommendation	What would be different	Why
66500	Single tests for: • ammonia • amylase • C-reactive protein • creatine kinase • glucose • lipase • magnesium • urate • neonatal bilirubin • lactate dehydrogenase • chloride • aspartate aminotransferase	Leaves single tests as items to be added to panels where necessary	Not different	

Recommendation 2: Amniotic fluid: item 66749

Item	What it does	Committee recommendation	What would be different	Why
66749	Measures lung maturity of the unborn.	Delete this item from the MBS	This test would no longer be available on the MBS.	The test is rarely used, and all at one site in Victoria. It has little clinical utility and quality is difficult to maintain at low volume.

Recommendation 3: Antenatal testing for chromosomal abnormalities in pregnancy: items 66750 and 66751

Item	What it does	Committee recommendation	What would be different	Why
66750	Helps detect congenital malformations in the foetus before birth	Change item descriptor to stipulate test is performed as first trimester screening test.	This test would be performed with nuchal translucency scanning in trimester 1 as part of routine screening.	To bill appropriately in first trimester testing.
66751	Helps detect congenital malformations in the foetus before birth	Change item descriptor to stipulate test is performed as second trimester screening test, when patient has NOT had first trimester screening.	This item would only be used, without nuchal translucency scanning, when first trimester screening has been missed.	To bill appropriately in second trimester testing.

Recommendation 4: Cardiac or skeletal muscle damage: items 66518 and 66519

Item	What it does	Committee recommendation	What would be different	Why
66518	Detects cardiac damage	Change the wording of the item descriptor for item 66518 to remove creatine kinase isoenzymes and myoglobin.	Troponin is currently used by all laboratories in Australia for this purpose.	This item is out of date and needs updating. Troponin is a superior test to detect cardiac damage.
66519	Detects cardiac damage.	Change the wording of the item descriptor for item 66518 to remove creatine kinase isoenzymes and myoglobin.	Troponin is currently used by all laboratories in Australia for this purpose.	This item is out of date. Troponin is a superior test to detect cardiac damage.

Recommendation 5: Quantitation of HDL-cholesterol: item 66536

Item	What it does	Committee recommendation	What would be different	Why
66536	Measures HDL cholesterol, triglycerides, total cholesterol, LDL-cholesterol, non HDL-cholesterol	Create new item for lipids that includes cholesterol and triglycerides testing from item 66500 into this new item.	All lipid testing would be grouped together and a HDL would be done on every lipid request.	Inclusion of HDL in every lipid request gives better information to the requesting doctor and is recommended by international bodies.
Ladder item (subject to MSAC assessment	Measures HDL cholesterol, triglycerides, total cholesterol, LDL-cholesterol, non HDL-cholesterol and ApoB in patients with hypertriglyceridaemia	Add test for ApoB	Special testing for hypertriglyceridaemia patients	LDL cholesterol testing may be inaccurate in these patient and ApoB provides better risk information.
Ladder item (subject to MSAC assessment	Measures HDL cholesterol, triglycerides, total cholesterol, LDL-cholesterol, non HDL-cholesterol and LP(a) in patients on PCSK9 inhibitors and on nicotinic acid	Add test for Lipoprotein (a)	Special testing for patients on PCSK9 inhibitors or nicotinic acid	Because testing of LP(a) provides additional risk information for heart attacks and may help management in these patients.

Recommendation 6: Quantitation of disaccharides: item 66680

Item	What it does	Committee recommendation	What would be different	Why
66680	Measures lactase deficiency in malabsorption.	Change item descriptor to stipulate that the test should only be used in patients who cannot operate the hydrogen breath test	Instead of a test on an intestinal biopsy a breath test after lactose is suggested.	The test is limited to patients who cannot have the less invasive test first (mainly children).

Recommendation 7: Quantitation of faecal fat: item 66674

Item	What it does	Committee recommendation	What would be different	Why
66674	Measures faecal fat or breath hydrogen to detect malabsorption	Add extra wording to the item descriptor to include monosaccharides, faecal elastase in the investigation of pancreatic insufficiency, and methane.	The test would include additional features and provide useful information for a larger number of patients.	To bring test in line with clinical knowledge and practice.

Recommendation 8: Vitamins B1, B3, B6 or C

Item	What it does	Committee recommendation	What would be different	Why
66605	Measures vitamins B1, B2, B3, B6 or C in blood, urine or other body fluid - 1 or more tests	No change		
66606	A test described in item 66605 if rendered by a receiving APP - 1 or more tests(Item is subject to rule 18 and 25)	No change		

Recommendation 9: Drugs of abuse: items 66623, 66626

Item	What it does	Committee recommendation	What would be different	Why
66623	Measures levels of drugs of abuse, or of toxic chemicals in blood, urine or other body fluids, (excluding performance improving substances in sports, or monitoring of patients in drug abuse treatment programs).	No change	.	
66626	Measures levels of drugs of abuse or therapeutic drugs in blood, urine or other body fluids in people in drug abuse treatment programs, (excluding surveillance of sports people for performance improving substances).	No change		

Recommendation 10: Therapeutic drug monitoring: items 66800, 66803, 66804, 66805, 66806

Item	What it does	Committee recommendation	What would be different	Why
66800	Quantitation in blood, urine or other body fluid by any method (except reagent tablet or reagent strip) of a range of therapeutic drugs – 1 test (subject to rule 6)	Removal of -disopyramide, ethosuximide, lignocaine, netilmicin, procainamide, quinidine, salicylate from item descriptor, leaving antibiotics: amikacin, gentamicin, tobramycin, vancomycin; antiepileptic drugs: carbamazepine, phenytoin, phenobarbitone, primidone, valproate; digoxin, ethanol, lithium, paracetamol, theophylline.	Removal of some drugs from list nominated for testing for therapeutic monitoring.	These drugs are no longer or very rarely measured, because they are not used, or drug monitoring is not helpful.
66803	2 tests described in item 66800 (subject to rule 6)	As above		
66804	A test described in item 66800 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)	As above		

Item	What it does	Committee recommendation	What would be different	Why
66805	A test described in item 66800 other than that described in 66804, if rendered by a receiving APP - each test to a maximum of 2 tests (Item is subject to rule 6 and 18)	As above		
66806	3 tests described in item 66800 (Item is subject to rule 6)	As above		

Recommendation 11: Special therapeutic drug monitoring: items 66812, 66815, 66816, 66817

Item	What it does	Committee recommendation	What would be different	Why
66812	Quantitation, not elsewhere described in this Table by any method or methods, in blood, urine or other body fluid, of a drug being used therapeutically	No change	.	
66815	2 tests described in item 66812	No change		
66816	A test described in item 66812 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		
66817	A test described in item 66812, other than that described in 66816, if rendered by a receiving APP - to a maximum of 1 test (Item is subject to rule 6 and 18)	No change		

Recommendation 12: Caeruloplasmin, haptoglobins, or prealbumin: Item 66632

Item	What it does	Committee recommendation	What would be different	Why
66632	Measures caeruloplasmin, haptoglobins, or prealbumin in serum, urine or other body fluids - 1 or more tests	No change	.	

Recommendation 13: Alpha-1-antitrypsin: items 66635, 66638, and 66639

Item	What it does	Committee recommendation	What would be different	Why
66635	Alpha-1-antitrypsin - quantitation in serum, urine or other body fluid - 1 or more tests	No change	.	
66638	Isoelectric focussing or similar methods for determination of alpha-1-antitrypsin phenotype in serum - 1 or more tests	Require abnormal alpha-1-antitrypsin levels or a family history of alpha-1-antitrypsin deficiency for the phenotype testing	The specialist test would only be done, if there is an appropriate indication for it.	An abnormal spike of requests in one state only was observed. The change will allow the test to be done, when appropriate.
66639	A test described in item 66638 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	Require abnormal alpha-1-antitrypsin levels or a family history of alpha-1-antitrypsin deficiency for the phenotype testing		

Recommendation 14: Electrophoresis of serum isoenzymes: items 66641 and 66642

Item	What it does	Committee recommendation	What would be different	Why
66641	Detects isoenzymes of lactate dehydrogenase and alkaline phosphatase as markers of haemolysis and myocardial infarction	Remove lactate dehydrogenase isoenzymes	This item would no longer measure lactate dehydrogenase isoenzymes	There are now better markers for these conditions and the test no longer has clinical utility.
66642	A test described in item 66641 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	Remove lactate dehydrogenase isoenzymes	This item would no longer measure lactate dehydrogenase isoenzymes	There are now better markers for these conditions and the test no longer has clinical utility.

Recommendation 15: C1 inhibitor levels: items 66644, 66647

Item	What it does	Committee recommendation	What would be different	Why
66644	Measures C-1 esterase inhibitor	No change	.	
66647	Functional assay of C-1 esterase inhibitor.	No change		

Recommendation 16: Angiotensin converting enzyme: item 66758

Item	What it does	Committee recommendation	What would be different	Why
66758	Measures angiotensin converting enzyme, or cholinesterase	No change	.	

Recommendation 17: Immunology items: 71057, 71058, 71059, 71060, 71062, 71064, 71066, 71068, 71069, 71071, 71072, 71073, 71074, 71075, 71076, 71077, 71200

Item	What it does	Committee recommendation	What would be different	Why
71057	Electrophoresis, quantitative and qualitative, of serum, urine or other body fluid all collected within a 28-day period, to demonstrate: (a) protein classes; or (b) presence and amount of paraprotein; including the preliminary quantitation of total protein, albumin and globulin - 1 specimen type	No change	.	
71058	Examination as described in item 71057 of 2 or more specimen types	No change		
71059	Immunofixation or immunoelectrophoresis or isoelectric focusing of:(a) urine for detection of Bence Jones proteins; or(b) serum, plasma or other body fluid; and characterisation of a paraprotein or cryoglobulin -examination of 1 specimen type (eg. serum, urine or CSF)	No change		
71060	Examination as described in item 71059 of 2 or more specimen types	No change		
71062	Electrophoresis and immunofixation or immunoelectrophoresis or isoelectric focussing of CSF for the detection of oligoclonal bands and including if required electrophoresis of the patient's serum for comparison purposes - 1 or more tests	No change		
71064	Detection and quantitation of cryoglobulins or cryofibrinogen - 1 or more tests	Increase fee to reflect costs of transport and 'hot box' collection.	Adjustment of fee	Recognition of the cost of collection and transport for this specialised test.

Item	What it does	Committee recommendation	What would be different	Why
71066	Quantitation of total immunoglobulin A by any method in serum, urine or other body fluid – 1 test	Remove the wording 'urine or other body fluid'	To be measured in blood only.	The test is useless if done in urine or other body fluids apart from serum.
71068	Quantitation of total immunoglobulin G by any method in serum, urine or other body fluid - 1 test	Remove the wording 'urine or other body fluid'	To be measured in blood only.	The test is useless if done in urine or other body fluids apart from serum.
71069	2 tests described in items 71066, 71068, 71072 or 71074	No change		
71071	3 or more tests described in items 71066, 71068, 71072 or 71074	No change		
71072	Quantitation of total immunoglobulin M by any method in serum, urine or other body fluid - 1 test	Remove the wording 'urine or other body fluid'	To be measured in blood only.	The test is useless if done in urine or other body fluids apart from serum.
71073	Quantitation of all 4 immunoglobulin G subclasses	No change		
71074	Quantitation of total immunoglobulin D by any method in serum, urine or other body fluid - 1 test	Remove the wording 'urine or other body fluid'	To be measured in blood only.	The test is useless if done in urine or other body fluids apart from serum.
71075	Quantitation of immunoglobulin E (total), (Ig E) 1 test. (Item is subject to rule 25)	Consolidate 71077 into this item at fee for 71077	Only one item for the two items before	Simplification of the table
71076	A test described in item 71073 if rendered by a receiving APP - 1 test(Item is subject to rule 18)	No change		
71077	Quantitation of immunoglobulin E (total) (Ig E) in the follow up of a patient with proven immunoglobulin-E-secreting myeloma, proven congenital immunodeficiency or proven allergic bronchopulmonary aspergillosis, 1 test. (Item is subject to rule 25)	Consolidate into item 71075 at same fee as 71077.	Only one item for the two items before	Simplification of the table

Item	What it does	Committee recommendation	What would be different	Why
71200	Detection and quantitation, if present, of free kappa and lambda light chains in serum for the diagnosis or monitoring of amyloidosis, myeloma or plasma cell dyscrasias.	Add including the wording: 'this test is not to be used for the diagnosis or monitoring of lymphoma'.	Clarification of when the test is done.	The test is not helpful in lymphoma but is occasionally requested.
New item		Create a new item for cyclic citrullinated peptide antigens with the following wording: Investigation for rheumatoid arthritis: citrullinated peptide antibodies. This new item should be restricted to 4 tests within a 12-month period.	New item	Recognition of a better new test in patients with rheumatoid arthritis.

Recommendation 18: Thyroid antibodies

Item	What it does	Committee recommendation	What would be different	Why
71165	Measures 1 antibody to range of tissue antigens	Remove thyroid antibodies from this item	This item cannot be used for thyroid antibody testing	Separating thyroid from other tests allows for clearer data collection and billing
71166	Measures 2 antibodies to range of tissue antigens	As above	As above	Separating thyroid from other tests allows for clearer data collection and billing
71167	Measures 3 antibodies to range of tissue antigens	As above	As above	Separating thyroid from other tests allows for clearer data collection and billing
71168	Measures 4 or more antibodies to range of tissue antigens	As above	As above	Separating thyroid from other tests allows for clearer data collection and billing
71171	Measures thyroid peroxidase antibody. To a maximum of 2 within in a 12-month period (Item is subject to rule 25)	Remove thyroid antibodies from tests covered under items 71165-68, and create new thyroid antibodies items as follows (71171-74).	Items made specific to thyroid antibodies and numbers of tests limited to what is clinically necessary	Separating thyroid from other tests allows for clearer data collection and billing. The largest number of autoantibody tests are done for thyroid disease. There is no need to test more often as levels rarely change over 3 months.

Item	What it does	Committee recommendation	What would be different	Why
71165	Measures 1 antibody to range of tissue antigens	Remove thyroid antibodies from this item	This item cannot be used for thyroid antibody testing	Separating thyroid from other tests allows for clearer data collection and billing
71166	Measures 2 antibodies to range of tissue antigens	As above	As above	Separating thyroid from other tests allows for clearer data collection and billing
71167	Measures 3 antibodies to range of tissue antigens	As above	As above	Separating thyroid from other tests allows for clearer data collection and billing
71168	Measures 4 or more antibodies to range of tissue antigens	As above	As above	Separating thyroid from other tests allows for clearer data collection and billing
71172	Measures two antibodies: thyroid peroxidase antibody and thyroid receptor antibody (TRAB) or thyroid stimulating antibodies (TSI) for the differential diagnosis of hyperthyroidism. To a maximum of 1 in a 12-month period (Item is subject to rule 25)	New item	New item with use only in hyperthyroidism.	Allows differentiation of causes of hyperthyroidism, which affects therapy.
71173	Measures thyroid receptor antibody (TRAB) or thyroid stimulating antibodies (TSI) for diagnosis and monitoring of patients with previously diagnosed Graves' disease. To a maximum of 4 tests in a 12-month period (Item is subject to rule 25)	New item	Item for specific antibody testing in patients with Graves' disease.	Allows early identification of patients at high risk of recurrent hyperthyroidism.
71174	Tests for thyroglobulin as well as thyroglobulin antibody for monitoring of patients with thyroid cancer. To a maximum of 2 of this item in a 12-month period (Item is subject to rule 25).	New item	New item to be used only in patients with thyroid cancer.	Allows better follow up of patients with thyroid cancer. Thyroglobulin should only be measured in patients after thyroid cancer has been removed as a follow up marker. The antibody to thyroglobulin gives additional information as in some people it is responsible for giving false results of the tumour follow-up marker thyroglobulin.

Recommendation 19: Lead: items 66665, 66666

Item	What it does	Committee recommendation	What would be different	Why
66665	Measures lead in blood or urine (other than for occupational health screening purposes) to a maximum of 3 tests in a 6-month period - each test	No change	.	
66666	A test described in item 66665 if rendered by a receiving APP - 1 or more tests (Item is subject to rule 18)	No change		

Recommendation 20: Zinc, aluminium, arsenic, beryllium, cadmium, chromium, gold, mercury, nickel, strontium, copper and iron: items 66667, 66671, 66825, 66826, 66827, 66828, 66831, 66832

Item	What it does	Committee recommendation	What would be different	Why
66667	Measures serum zinc in a patient receiving intravenous alimentation - each test	No change	.	
66671	Measures serum aluminium in a patient in a renal dialysis program - each test	No change		
66825	Measures aluminium (except if item 66671 applies), arsenic, beryllium, cadmium, chromium, gold, mercury, nickel, or strontium, in blood, urine or other body fluid or tissue - 1 test. To a maximum of 3 of this item in a 6-month period (Item is subject to rules 6, 22 and 25)	No change		
66826	A test described in item 66825 if rendered by a receiving APP where no tests have been rendered by the referring APP - 1 test(Item is subject to rules 6, 18, 22 and 25)	No change		
66827	A test described in item 66825, other than that described in 66826, if rendered by a receiving APP to a maximum of 1 test(Item is subject to rules 6, 18, 22 and 25)	No change		

Item	What it does	Committee recommendation	What would be different	Why
66828	Measures aluminium (except if item 66671 applies), arsenic, beryllium, cadmium, chromium, gold, mercury, nickel, or strontium, in blood, urine or other body fluid or tissue - 2 or more tests. to a maximum of 3 of this item in a 6-month period (Item is subject to rules 6, 22 and 25)	No change		
66831	Measures copper or iron in liver tissue biopsy	No change		
66832	A test described in item 66831 if rendered by a receiving app (item is subject to rule 18a and 22)	No change		

Recommendation 21: Copper, manganese, selenium or zinc: items 66819, 66820, 66821, 66822

Item	What it does	Committee recommendation	What would be different	Why
66819	Measures copper, manganese, selenium, or zinc (except if item 66667 applies), in blood, urine or other body fluid - 1 test (Item is subject to rules 6, 22 and 25)	Provide clinical guidance on when copper and zinc testing is useful.	Extra information in the item descriptor will help guide doctors when to order this test.	Will help doctors decide when this test is useful in patients.
66820	A test described in item 66819 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, 18, 22 and 25)			
66821	A test described in item 66819 other than that described in 66820 if rendered by a receiving APP to a maximum of 1 test (Item is subject to rules 6, 18, 22 and 25)			
66822	Measures copper, manganese, selenium, or zinc (except if item 66667 applies), in blood, urine or other body fluid - 2 or more tests. (Item is subject to rules 6, 22 and 25)	Provide clinical guidance on when copper and zinc testing is useful.		

Recommendation 22: Salivary hormones: items 66711, 66712, 66714, 66715

Item	What it does	Committee recommendation	What would be different	Why
66711	Measures cortisol in saliva for: (a) the investigation of Cushing's syndrome; or (b) the management of children with congenital adrenal hyperplasia (Item is subject to rule 6)	No change		
66712	Two tests described in item 66711 (Item is subject to rule 6)	No change		
66714	A test described in item 66711, if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP (Item is subject to rules 6 and 18)	No change		
66715	Tests described in item 66711, other than that described in 66714, if rendered by a receiving APP, each test to a maximum of 1 test (Item is subject to rules 6 and 18)	Delete this item		Rarely used

Recommendation 23: Porphyrin testing: items 66782–66792

Item	What it does	Committee recommendation	What would be different	Why
66782	Porphyrins or porphyrins precursors - detection in plasma, red cells, urine or faeces - 1 or more tests	No change	.	
66783	A test described in item 66782 if rendered by a receiving APP - 1 or more tests(Item is subject to rule 18)	Delete this item	Item removed	The screening test should not be referred, but the proper test with quantitation should be done.
66785	Porphyrins or porphyrins precursors - quantitation in plasma, red cells, urine or faeces - 1 test (Item is subject to rule 6)	No change		
66788	Porphyrins or porphyrins precursors - quantitation in plasma, red cells, urine or faeces - 2 or more tests (Item is subject to rule 6)	No change		

Item	What it does	Committee recommendation	What would be different	Why
66789	A test described in item 66785 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		
66790	A test described in item 66785 other than that described in 66789, if rendered by a receiving APP - to a maximum of 1 test(Item is subject to rule 6 and 18)	Increase schedule fee to the fee for 66789		
66791	Porphyrin biosynthetic enzymes - measurement of activity in blood cells or other tissues - 1 or more tests	Delete this item		
66792	A test described in item 66791 if rendered by a receiving APP - 1 or more tests(Item is subject to rule 18)	Delete this item		

Recommendation 24: Amino acid quantitation: items 66756, 66757

Item	What it does	Committee recommendation	What would be different	Why
66756	Quantitation of 10 or more amino acids for the diagnosis of inborn errors of metabolism - up to 4 tests in a 12-month period on specimens of plasma, CSF and urine.	Consolidate items 66756 and 66757 into a single item, with reworded item descriptor.	Combine the 2 items.	Simplify the schedule.
66757	Quantitation of 10 or more amino acids for monitoring of previously diagnosed inborn errors of metabolism in 1 tissue type.	As above.		

Recommendation 25: Collagen breakdown products: items 66773, 66776

Item	What it does	Committee recommendation	What would be different	Why
66773	Measures products of collagen breakdown or formation for the monitoring of patients with proven low bone mineral density, and if performed, a service described in item 66752 - 1 or more tests	Limit testing to 2 tests within a 12-month period.		No clinical need to test more often.
66776	Measures products of collagen breakdown or formation for the monitoring of patients with metabolic bone disease or Paget's disease of bone, and if performed, a service described in item 66752 - 1 or more tests	Limit testing to 2 tests within a 12-month period.		No clinical need to test more often.

Recommendation 26: Adrenaline, 5HIAA, metanephrins: items 66779, 66780

Item	What it does	Committee recommendation	What would be different	Why
66779	Adrenaline, noradrenaline, dopamine, histamine, hydroxyindoleacetic acid (5HIAA), hydroxymethoxymandelic acid (HMMA), homovanillic acid (HVA), metanephrines, methoxyhydroxyphenylethylene glycol (MHPG), phenylacetic acid (PAA)or serotonin quantitation - 1 or more tests	Remove HMMA, MHPG and phenylacetic acid. Split item 66779 into two items, based on clinical differences: first item: catecholamines and metanephrines in 24-hour urine samples or as plasma free metanephrines second item: 5HIAA and serotonin tests (which are important in the diagnosis of carcinoid tumours). See below. Add explanatory note re dopamine measurement.	This Item will be tests for catecholamines and metanephrines to help diagnose or monitor certain types of tumours.	Modernisation of the test descriptor to recognise changes in technology and clarify the descriptor.
66780	A test described in item 66779 if rendered by a receiving APP – 1 or more tests(Item is subject to rule 18)	As above		
New item	5HIAA or serotonin quantitation in 24-hour urine	Create new item as described in item 66779	This item will contain tests for serotonin and its metabolites to help diagnose or monitor certain types of tumours.	

Recommendation 27: Enzymes in solid tissue: item 66683

Item	What it does	Committee recommendation	What would be different	Why
66683	Measures enzymes in solid tissue.	Delete this item	This item will no longer be available on the MBS.	It is very rarely used.

Recommendation 28: Tumour marker items: item 66650, 66651, 66652, 66653, 66629

Item	What it does	Committee recommendation	What would be different	Why
66650	Alpha-fetoprotein, CA-15.3 antigen (CA15.3), CA-125 antigen (CA125), CA-19.9 antigen (CA19.9), cancer-associated serum antigen (CASA), carcinoembryonic antigen (CEA), human chorionic gonadotrophin (HCG), neuron specific enolase (NSE), thyroglobulin in serum or other body fluid, in the monitoring of malignancy or in the detection or monitoring of hepatic tumours, gestational trophoblastic disease or germ cell tumour - quantitation - 1 test	Change the item descriptors to be specific for different tumour markers	Very clearly defined descriptors for individual tumour markers	To optimise the use of these items as a follow-up tool in patients with tumours. There is evidence that they are used inappropriately and this can be detrimental to patients.
66651	A test described in item 66650 if rendered by a receiving APP, where no tests in the item have been rendered by the referring APP - 1 test			
66652	A test described in item 66650 if rendered by a receiving APP - other than that described in 66651, if rendered by a receiving APP, 1 test			
66653	2 or more tests described in item 66650			
66629	Beta-2-microglobulin - quantitation in serum, urine or other body fluids - 1 or more tests			