
Medicare Benefits Schedule Review Taskforce

Third report from the Pathology

Clinical Committee on Chemical

Pathology

February 2018

Important note

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

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

△ Stakeholder feedback.

Then

△ Consideration by the MBS Review Taskforce.

Then, *if endorsed*, consideration by

△ The Minister for Health.

△ The Government.

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

Confidentiality of comments:

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

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1. Executive summary

The Medicare Benefits Schedule (MBS) Review Taskforce (the Taskforce) is undertaking a program of work that considers how more than 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 The Taskforce will also seek to identify any services that may be unnecessary, outdated or potentially unsafe.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 is the third 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 developed for referral to other committees are presented in Section 5. A complete list of items, including the nature of the recommendations and the page number for each recommendation, can be found in Appendices A and B (in table summary form).

Recommendations for consultation

The Committee's recommendations for stakeholder consultation are:

- **that 1 item should be deleted from the MBS;**
- **2 items should be changed; and**
- **12 items should remain unchanged.**

Forty-three tests were reviewed in the first chemical working group report and 87 tests were reviewed in the second 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.

- △ **Faecal occult testing** – change the descriptor for item 66764 to stipulate the test should be performed using immunochemical tests and that inoculation should be done either by the patient or close to time of collection.

Recommendations for referral to other committees

The following tests were referred to the Diagnostic Medicine Clinical Committee for their consideration:

- △ **Vitamin D testing**
- △ **Iron studies** were referred after considerable discussion. The working group noted in their discussion that for pre-menopausal women, ferritin is the best test to identify iron deficiency, for other groups it recommended full iron studies.

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-served.
- △ **Best-practice health services.** One of the core objectives of the Review is to modernise the MBS, ensuring that individual items and their descriptors are consistent with contemporary best practice and the evidence base, where possible. Although the 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:

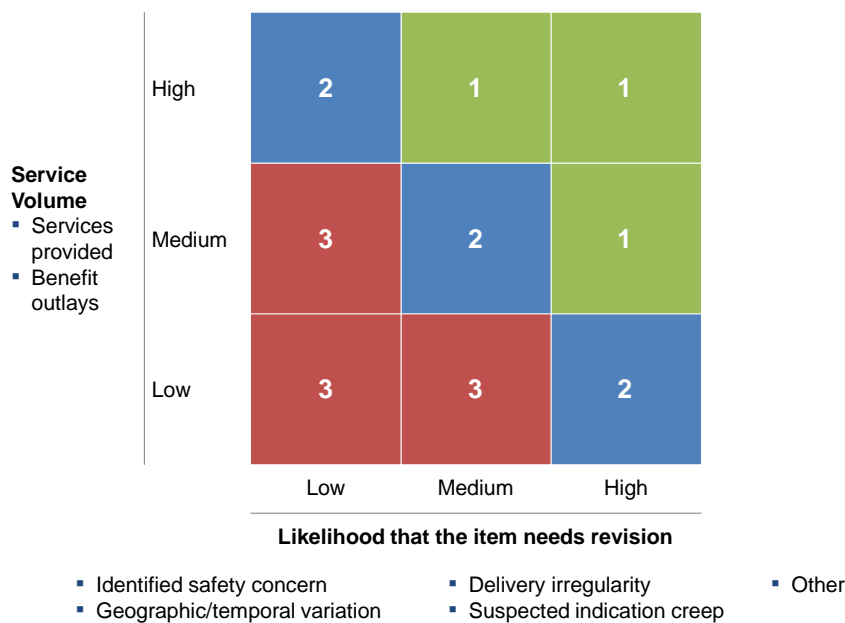
1. Develop an initial fact base for all items under consideration, drawing on the relevant data and literature.
2. Identify items that are obsolete, are of questionable clinical value, are misused and/or pose a risk to patient safety. This step includes prioritising items as 'priority 1,' 'priority 2' 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
Associate Professor Mary-Jo Waters	St Vincent's Pathology (CHA)	None

Name	Position/Organisation	Declared conflict of interest
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 public comment 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

Name	Position/organisation	Declared conflict of interest
Dr Lawrie Bott	Chief Medical Officer, Pathology, 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

3.4 Areas of responsibility of the Committee

The Committee was assigned 15 MBS chemical pathology items (MBS 2014-15). A complete list of these items can be found in Appendix A.

3.5 Summary of the Committee's review approach

The Committee completed the review of 15 chemical pathology items. Items associated with Vitamin D and iron testing were referred to the Diagnostic Medicine Clinical Committee.

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.

An inclusive set of 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 Urine and faeces-related tests: items 66764, 66767 and 66770

Table 3. Item introduction table for item 66764, 66767 and 66770

Item	Long item descriptor	Schedule Fee (\$)	Benefits FY2014-15	Services FY2014-15	Patient count 2014-15	5 year service change % (CAGR)
66764	Examination for faecal occult blood (including tests for haemoglobin and its derivatives in the faeces except by reagent strip or dip stick methods) with a maximum of 3 examinations on specimens collected on separate days in a 28 day period	8.90	\$373,583	49,642	44,085	-0.8%
66767	2 examinations described in item 66764 performed on separately collected and identified specimens	17.85	\$1,361,191	89,048	87,834	8.5%
66770	3 examinations described in item 66764 performed on separately collected and identified specimens	26.70	\$4,203,727	182,234	179,345	7.9%

4.1.1 Recommendation 1

The Committee proposes the following:

- △ change the item descriptor for items 66764 to stipulate that the test should be performed using immunochemical tests and that inoculation should be done either by the patient or close to time of collection.
- △ change the descriptor for item 66767 to reflect the changes to item 66764.
- △ leave item 66770 unchanged.
- △ develop an education and awareness program aimed at GPs to inform and encourage patients to inoculate their test samples at home.

4.1.2 Rationale 1

- △ Item 66764 is a test for faecal occult blood used to detect the early signs of bowel cancer by detecting minimal amounts of blood in bowel motions; items 66767 and 66770 are for 2 and 3 examinations as described in item 66764, respectively. There is quite marked state to state variation in the relative use of these items as disclosed below (see Figures 4, 5 and 6).

- △ MBS funded faecal occult blood testing is generally requested by GPs for patients who do not meet the criteria for the NBCSP, have elected not to participate in the NBCSP or who have symptoms that raise concern about occult blood loss. Use of these items for bowel cancer screening should decrease over time with the progressive roll out of the NBCSP
- △ The Committee proposed a new item descriptor for item 66764, to specify that the test should be performed using immunochemical testing. This is the preferred method with improved sensitivity and specificity for bleeding from the lower GI tract. The Committee further recommended additional wording in the item and advice in explanatory notes stating that home inoculation of samples by patients is preferred for a more accurate test result. This should be supported by an education program aimed at GPs, to inform and encourage patients to inoculate their samples at home. These changes are designed to align testing with the NBCSP and to improve test performance by specifying necessary elements of the collection and test analysis. At a practice level this is achieved by pathology practices providing to GPs the appropriate collection equipment.
- △ The Committee considered the clinical utility of two versus three tests specified in item 66764 and noted that while testing the third sample increases the sensitivity for the detection of bowel cancer, it also increases the rate of false-positive results. The Committee noted that the NBSP requires two samples but that the evidence used to inform the National Bowel Screening Program is 10 years old. In some other jurisdictions (notably the UK) only one sample is collected. Data provided from a private laboratory indicated that in two different regional settings 5 and 10% of samples with previously negative results showed a third positive sample. In light of the uncertain evidence and practice variation locally and internationally, the Committee recommends that the status quo continue and that laboratories and requestors be able to determine whether one, two or three tests are required.
- △ The Committee acknowledged that currently there is no education program for GPs on the appropriate use of the faecal occult blood test described in item 66764. It was also acknowledged that in patients with iron deficiency anaemia without another clinical explanation for blood loss best practice is to perform an upper and/or lower GI endoscopy even if the faecal occult blood test result is negative.
- △ In summary, the Committee recommends changing the wording of the item descriptor to specify the immunochemical method but withholds a recommendation on specifying testing two or three samples.

Figure 2. State variation for item 66764 (services per 100,000 people)

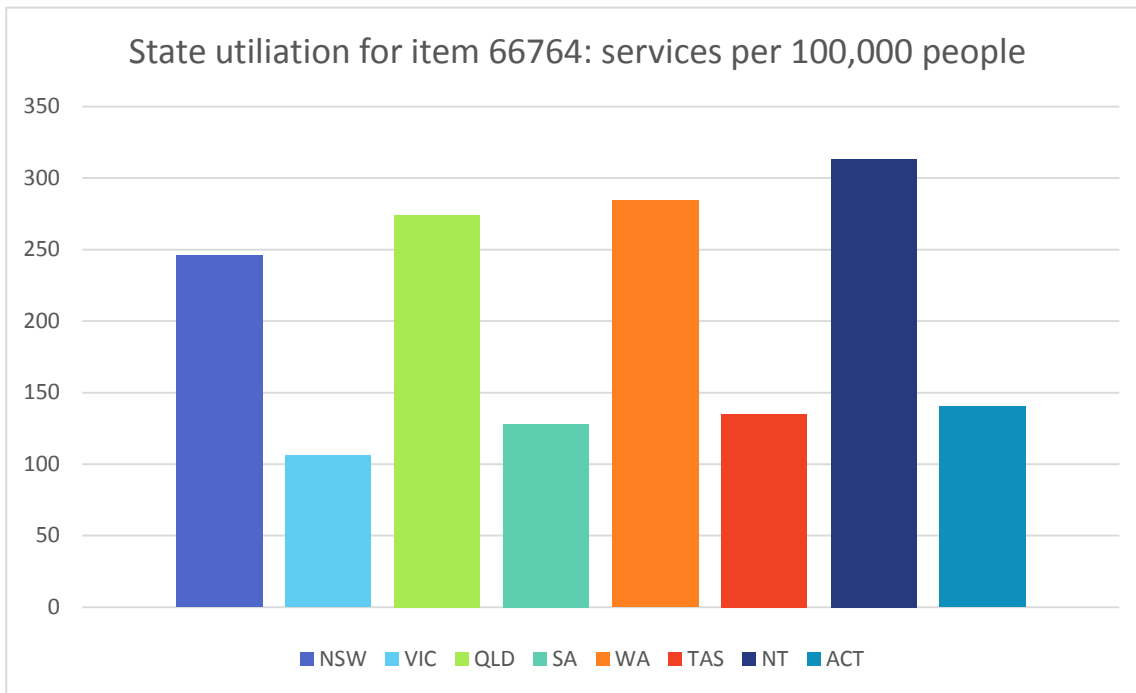


Figure 3. State utilisation for item 66767 (services per 100,000 people)

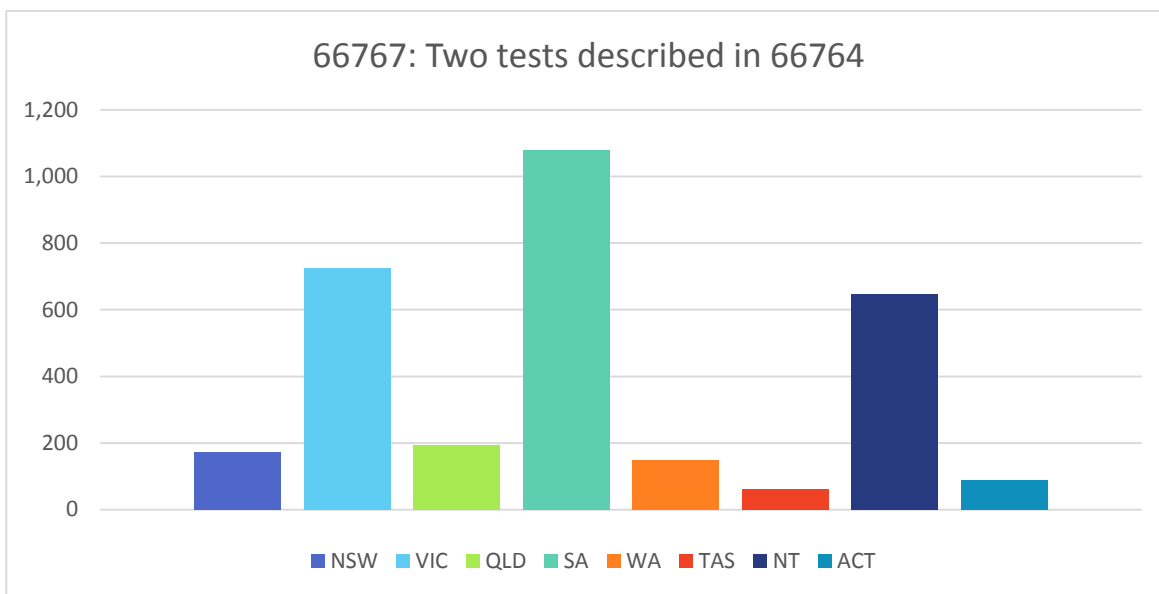


Figure 4. State variation for item 66770 (services per 100,000 people)

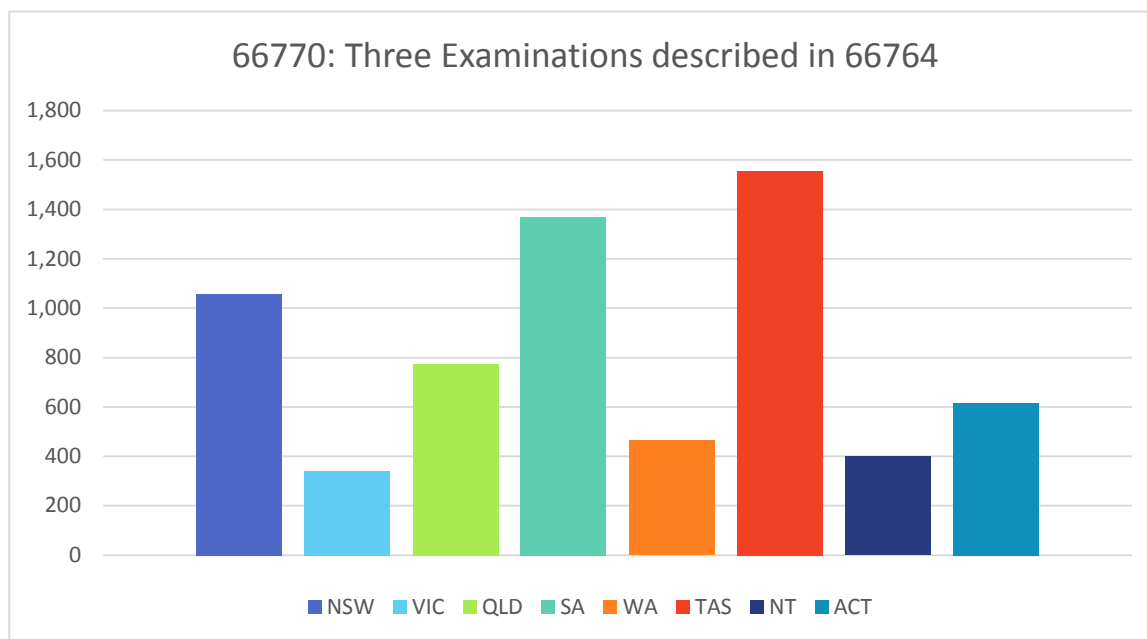


Table 4. Current and proposed new item descriptor for items 66764 and 66767

Item	Current item descriptor	Proposed item descriptor
66764	Examination for faecal occult blood (including tests for haemoglobin and its derivatives in the faeces except by reagent strip or dip stick methods) with a maximum of 3 examinations on specimens collected on separate days in a 28 day period	Examination for faecal occult blood using an immunochemical method with a maximum of 3 examinations on specimens collected on separate days in a 28 day period.
66767	2 examinations described in item 66764 performed on separately collected and identified specimens	2 specimens or 2 separate collections described in item 66764
66770	3 examinations described in item 66764 performed on separately collected and identified specimens	3 specimens or 3 separate collections described in item 66764

4.2 Hormones: items 66695, 66696, 66697, 66698, 66701, 66704, 66707, 66686

Table 5. Item introduction table for items 66695, 66696, 66697, 66698, 66701, 66704, 66707, 66686

Item	Long item descriptor	Schedule Fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5 year service change % (CAGR)
66695	Quantitation in blood or urine of hormones and hormone binding proteins - ACTH, aldosterone, androstenedione, C-peptide, calcitonin, cortisol, DHEAS, 11-deoxycortisol, dihydrotestosterone,	30.50	\$15,579,871	602,001	411,307	7.1%

	FSH, gastrin, glucagon, growth hormone, hydroxyprogesterone, insulin, LH, oestradiol, oestrone, progesterone, prolactin, PTH, renin, sex hormone binding globulin, somatomedin C(IGF-1), free or total testosterone, urine steroid fraction or fractions, vasoactive intestinal peptide, - 1 test (Item is subject to rule 6)					
66696	A test described in item 66695, if rendered by a receiving APP - where no tests in the item have been rendered by the referring APP (Item is subject to rule 6 and 18)	30.50	\$390,842	15,160	14,012	-4.6%
66697	Test described in item 66695, other than that described in 66696, if rendered by a receiving APP - each test to a maximum of 4 tests (Item is subject to rule 6 and 18)	13.20	\$491,811	43,783	23,709	12.0%
66698	2 tests described in item 66695 (Item is subject to rule 6)	43.70	\$6,368,414	171,416	133,827	5.3%
66701	3 tests described in item 66695 (Item is subject to rule 6)	56.90	\$8,755,478	180,259	121,553	5.9%
66704	4 tests described in item 66695 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs the only 4 tests specified on the request form or performs 4 tests and refers the rest to the laboratory of a separate APA) (Item is subject to rule 6)	70.15	\$7,724,653	129,211	108,069	6.9%
66707	5 or more tests described in item 66695 (Item is subject to rule 6)	83.35	\$11,191,602	157,655	137,289	9.8%
66686	Performance of 1 or more of the following procedures: (a) growth hormone suppression by glucose loading; (b) growth hormone stimulation by exercise; (c) dexamethasone suppression test; (d) sweat collection by iontophoresis for chloride analysis; (e) pharmacological stimulation of growth hormone	50.65	\$196,662	4,555	4,311	7.5%

4.2.1 Recommendation 2

- △ Leave item 66695 unchanged.
- △ The committee considered splitting item 66695 into the following groups:
 - Automated immunoassay: ACTH, C-peptide, cortisol, DHEAS, FSH, growth hormone, insulin, LH, oestradiol, progesterone, prolactin, PTH, sex hormone binding globulin, total testosterone
 - Specialised or manual immunoassay: aldosterone, renin, gastrin, 21-hydroxyprogesterone, oestrone, androstenedione, somatomedin C (IGF-1), calcitonin, 11-deoxycortisol, dihydrotestosterone, glucagon, VIP, vasopressin/ADH
 - Chromatography / mass spectrometry: urine steroid profile, DHT, androstenedione, low levels of testosterone or oestradiol with specific clinical indications
- △ Items 66695, 66696, 66697, 66698, 66701, 66704, 66707, 66686 cover tests used to detect more than 20 different hormones ranging from follicle stimulating hormone (FSH) to vasoactive intestinal peptide (VIP).
- △ These tests are mostly requested by GPs. There were no unusual features regarding the changes over time and the requesting patterns. One observation regarding this group of tests is that the fee does not take account of the variable complexity of testing. Testosterone for example can be measured using a high throughput immunoassay analyser, by manual radioimmunoassay or by tandem mass spectrometry. Tests like FSH are widely available and automated, whilst 11-deoxycortisol can only be measured in the most specialised laboratories.
- △ While reviewing this set of items, the Committee noted that clinical practice is diverging from the time when this group of tests was first added to the MBS Schedule. The Committee considered restructuring the item 66695 into appropriate groups (eg, manual versus automated) could improve the clinical value in terms GP requesting of this item.
- △ The Committee initially restructured the item into three tiers using the following reasoning: the first tier comprises commonly performed and automated tests, the second tier comprises tests that are not commonly performed or that are quite specialised, and the third tier lists tests that are done with chromatography/mass spectrometry. Hormones have not been separated into clinical categories. The Committee initially proposed that reimbursement should also be tiered relative to the difficulty of the test and recognises that the Pathology Business Group would have to review and propose a fee for the newly structured items.
- △ As oestradiol and testosterone can be done by immunoassay as well as by mass spectrometry. In most instances immunoassay measurement will be satisfactory, but occasionally there might be a specific indication to measure these hormones by mass spectrometry. This should be only done on request by a specialist endocrinologist and limited to once per year. It might be indicated in men with doubtful levels of testosterone before initiation of long-term testosterone supplementation or in women with the question of a virilising tumour of the ovary.

- △ Following extensive discussion and consultation with experts, the Committee agreed to leave item 66695 unchanged. While the hormone measurements can be split into different groups with different methodologies, the committee was unable to link specific clinical scenarios to particular methodologies (for example- Immunoassay might be the sufficiently sensitive technology for most measurements of testosterone, but in borderline cases LC-MSMS might provide more precise testing at a higher cost).

4.3 Salivary hormones: items 66711, 66712, 66714, 66715

Table 6. Item introduction table for items 66711, 66712, 66714, 66715

Item	Long item descriptor	Schedule Fee	Benefits FY 2014–15	Services FY 2014–15	Patient count 2014–15	5 year service change % (CAGR)
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	2,286	1,811	58.9%
66712	Two tests described in item 66711 (Item is subject to rule 6)	43.05	\$7,330	201	191	13.9%
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 rule 6 and 18)	30.15	\$4,967	194	179	62.7%
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 rule 6 and 18)	12.85	\$1,720	151	123	2.0%

4.3.1 Recommendation 3

The Committee proposes the following:

- △ Items 66711, 66712 and 66714 should remain unchanged.
 △ Delete item 66715.

4.3.2 Rationale 3

- △ Items 66711, 66712, 66714 and 66715 are tests used to detect salivary cortisol. The utilisation of items 66711, 66712 and 66714 is relatively low and is clinically appropriate. These tests are mainly requested by endocrinologists, and the clinical value of salivary cortisol in the investigation of Cushing's syndrome is recognised. Item 66715 is used in very remote areas where there is limited access to

blood testing, and the saliva test is used to measure transdermal progesterone. Additionally, the number of tests requested is relatively small.

△ The Committee recommended deleting item 66715 due to low utilisation.

Figure 5. State utilisation of item 66711: services per 100,000 people

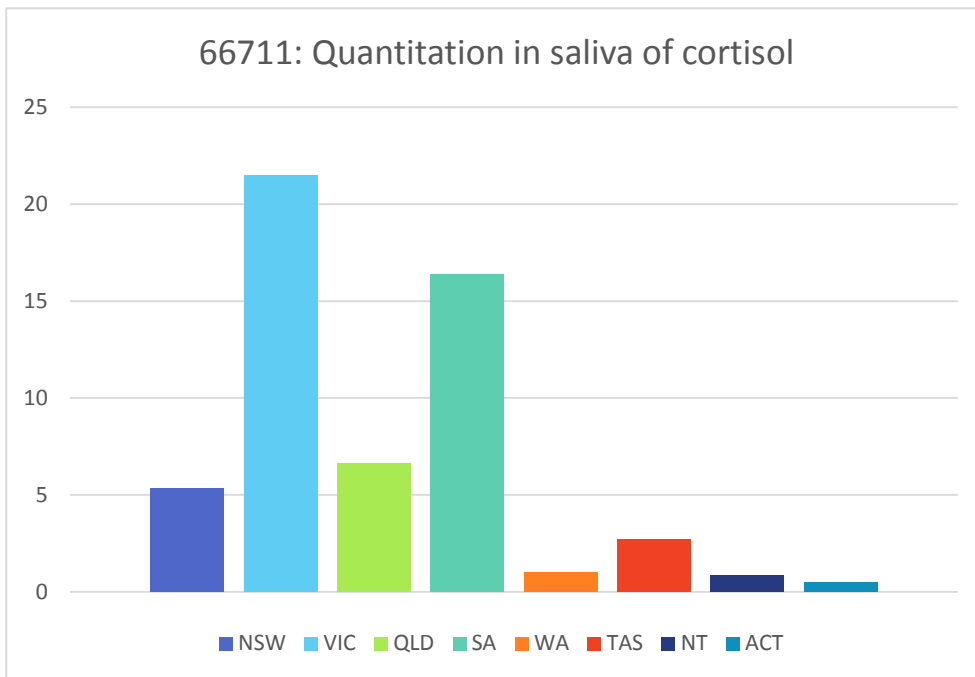
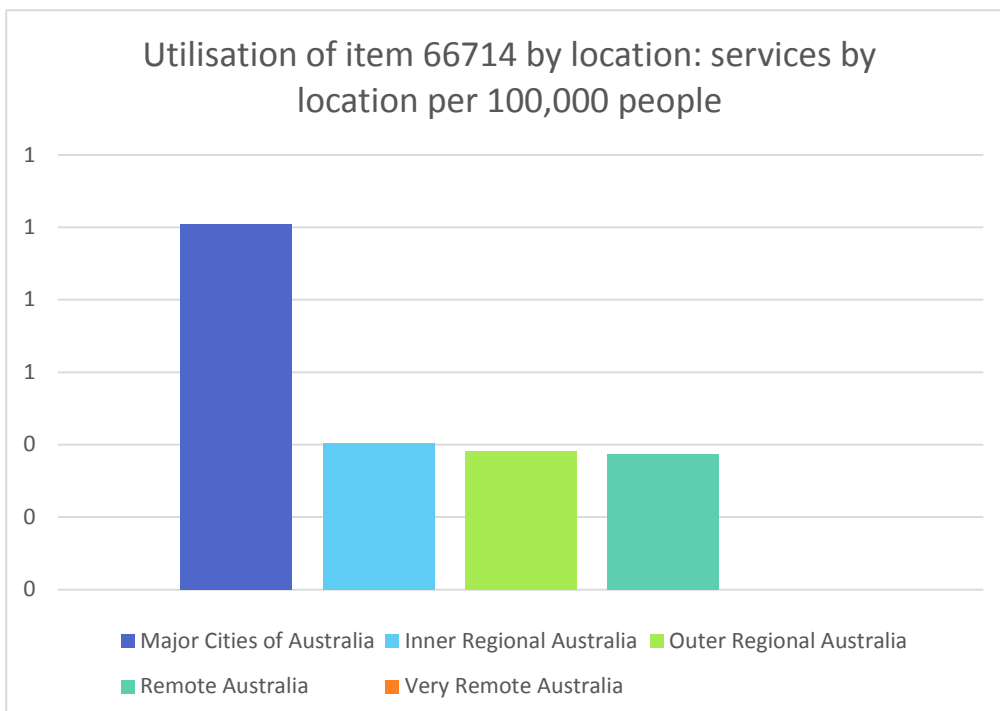


Figure 6. Utilisation of item 66714 services by locations per 100,000 people



5. Items with no changes

The Committee recommends that the MBS items listed in table 7 do not require amendment, as they are clinically appropriate.

Table 7. MBS items that do not require amendment

Item	Item descriptor	Schedule fee (\$)	Benefits (2014–15)
66770	3 examinations described in item 66764 performed on separately collected and identified specimens	26.70	\$4,203,727
66695	Quantitation in blood or urine of hormones and hormone binding proteins - ACTH, aldosterone, androstenedione, C-peptide, calcitonin, cortisol, DHEAS, 11-deoxycortisol, dihydrotestosterone, FSH, gastrin, glucagon, growth hormone, hydroxyprogesterone, insulin, LH, oestradiol, oestrone, progesterone, prolactin, PTH, renin, sex hormone binding globulin, somatomedin C(IGF-1), free or total testosterone, urine steroid fraction or fractions, vasoactive intestinal peptide, - 1 test (Item is subject to rule 6)	30.50	\$15,579,871
66696	A test described in item 66695, if rendered by a receiving APP - where no tests in the item have been rendered by the referring APP (Item is subject to rule 6 and 18)	30.50	\$390,842
66697	Test described in item 66695, other than that described in 66696, if rendered by a receiving APP - each test to a maximum of 4 tests (Item is subject to rule 6 and 18)	13.20	\$491,811
66698	2 tests described in item 66695 (Item is subject to rule 6)	43.70	\$6,368,414
66701	3 tests described in item 66695 (Item is subject to rule 6)	56.90	\$8,755,478
66704	4 tests described in item 66695 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs the only 4 tests specified on the request form or performs 4 tests and refers the rest to the laboratory of a separate APA) (Item is subject to rule 6)	70.15	\$7,725,653
66707	5 or more tests described in item 66695 (Item is subject to rule 6)	83.35	\$11,191,602
66686	Performance of 1 or more of the following procedures: (a) growth hormone suppression by glucose loading; (b) growth hormone stimulation by exercise; (c) dexamethasone suppression test; (d) sweat collection by iontophoresis for chloride analysis; (e) pharmacological stimulation of growth hormone	50.65	\$196,662
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 rule 6 and 18)	30.15	\$4,967

6. Items to be deleted

The following item is to be deleted from the MBS as utilisation of the item is minimal and no longer warrants listing on the pathology services table.

Table 8. MBS items recommended for deletion.

Item	Item descriptor	Schedule fee (\$)	Services (2014–15)
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 rule 6 and 18)	12.85	151

7. References

1. Elshaug AG, Watt AM, Mundy L, et al. Over 150 potentially low-value health care practices: an Australian study. *Med J Aust* 2012;197:556-60. <https://www.ncbi.nlm.nih.gov/pubmed/23163685>.

8. 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.
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

Recommendation 1: Testing to detect faecal occult blood: items 66764, 66767 and 66770

Item	What it does	Committee recommendation	What would be different	Why
66764	Examination for faecal occult blood (up to 3 examinations on specimens collected on separate days in a 28-day period)	Change the item descriptor for items 66764 to stipulate that the test should be performed using immunochemical tests and that inoculation should be done either by the patient or close to time of collection.	Test would be done differently, using the preferred methods with improved sensitivity and specificity. Patients would be encouraged to inoculate samples at home.	This would improve accuracy of results and align with National Bowel Screening program.
66767	2 examinations described in item 66764 performed on separately collected and identified specimens	Change the item descriptor for item 66767 to reflect changes to item 66764.	Test would be done differently, using the preferred methods with improved sensitivity and specificity. Patients would be encouraged to inoculate samples at home.	This would improve accuracy of results and align with National Bowel Screening program.
66770	3 examinations described in item 66764 performed on separately collected and identified specimens	Leave unchanged.	There will be no change.	

Recommendation 2: Miscellaneous hormones: items 66695, 66696, 66697, 66698, 66701, 66704, 66707, 66686

Item	What it does	Committee recommendation	What would be different	Why
66695	Quantitation in blood or urine of hormones and hormone binding proteins - ACTH, aldosterone, androstenedione, C-peptide, calcitonin, cortisol, DHEAS, 11-deoxycortisol, dihydrotestosterone, FSH, gastrin, glucagon, growth hormone, hydroxyprogesterone, insulin, LH, oestradiol, oestrone, progesterone, prolactin, PTH, renin, sex hormone binding globulin, somatomedin C(IGF-1), free or total testosterone, urine steroid fraction or fractions, vasoactive intestinal peptide, - 1 test (Item is subject to rule 6)	Leave unchanged	Different payment levels for different levels of complexity for specific hormones.	Allows better scaling of payment for tests of different complexities. Encourages pathology companies to invest in mass spectrometry technology with better results, if appropriate.

Item	What it does	Committee recommendation	What would be different	Why
66696	A test described in item 66695, 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)	As above		
66697	Test described in item 66695, other than that described in 66696, if rendered by a receiving APP - each test to a maximum of 4 tests (Item is subject to rules 6 and 18)	As above		
66698	2 tests described in item 66695 (Item is subject to rule 6)	As above		
66701	3 tests described in item 66695 (Item is subject to rule 6)	As above		
66704	4 tests described in item 66695 (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs the only 4 tests specified on the request form or performs 4 tests and refers the rest to the laboratory of a separate APA) (Item is subject to rule 6)	As above		
66707	5 or more tests described in item 66695 (Item is subject to rule 6)	As above		
66686	Performance of 1 or more of the following procedures: (a) growth hormone suppression by glucose loading; (b) growth hormone stimulation by exercise; (c) dexamethasone suppression test; (d) sweat collection by iontophoresis for chloride analysis; (e) pharmacological stimulation of growth hormone	As above		

Recommendation 3: Salivary hormones: items 66711, 66712, 66714, 66715

Item	What it does	Committee recommendation	What would be different	Why
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)	Leave unchanged.	There will be no difference.	Utilisation of these items is relatively low and clinically appropriate.

Item	What it does	Committee recommendation	What would be different	Why
66712	Two tests described in item 66711 (Item is subject to rule 6)	As above.		As above
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 rule 6 and 18)	As above.		As above.
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 rule 6 and 18)	Delete this item.	This item would no longer be available on the MBS.	The utilisation of this item no longer warrants the item being available on the MBS.

