
**Medicare Benefits Schedule Review
Taskforce**

**First Report from the Pathology
Clinical Committee –
Endocrine Tests**

2017

Important note

The views and recommendations in this review 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; and

△ Government.

Stakeholders should provide comment on the recommendations via the online consultation tool.

Confidentiality of comments:

If you want 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 The Taskforce will also seek to identify any services that may be unnecessary, outdated or potentially unsafe.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 Reports from Clinical Committees and stakeholder feedback before making recommendations to the Minister for Health, for consideration by Government.

The Chemical Working Group (the Working Group) is one of six clinical Working Groups established to support the work of the Pathology Clinical Committee (the Committee). The Committee was established in 2016 to make recommendations to the Taskforce on the review of MBS items in its area of responsibility, based on rapid evidence review and clinical expertise. The Taskforce asked the Committee to review chemical pathology testing.

1.1 Key recommendations

The recommendations of the Committee based on advice from the Working Group on endocrine tests are that two items be deleted, one added, 19 changed and 10 items remain unchanged. The Working Group is yet to review three items: Hormones and other tests (item 66686) and Adrenaline and other tests (items 66779 and 66780). Major changes to items are listed below; the remainders are found in the body of this report.

△ **Thyroid stimulating hormone (TSH) and thyroid function test (TFT) items**

TSH tests and TFTs: items 66716, 66719, 66722–5, 66728, 66731 and 66734

The Committee recommends that, in accordance with Choosing Wisely recommendations of the Royal Australian College of General Practitioners (RACGP) and international guidelines, TSH should not be used as a screening test in asymptomatic patients. The explanatory notes for TSH should note this and provide advice about the indications for testing and repeat testing.

The item descriptor and explanatory notes for TFTs should be amended to enable pathologist-determinable (or requested) testing of TFTs when the most recently performed TSH is abnormal.

The TFTs item should be further amended to reflect that another indication for TFTs is in circumstances that make TSH testing of thyroid function unreliable. Advice about these circumstances is now set out in the explanatory notes.

The Committee recommends adding a new item for TFTs to include all three tests: TSH, free thyroxine and free T3, as this is clinically valuable and provides additional information in a subgroup of patients with markedly suppressed TSH.

△ Oral glucose tolerance test (OGTT) and oral glucose challenge test (OGCT) items

The Committee recommends the obsolete item 66545 for OGTT be deleted to improve clinical quality. The item descriptor and explanatory notes of item 66542 should be revised to allow testing for patients when glycated haemoglobin (HbA1c) measurement is unreliable (recognising that for most patients HbA1c is the preferred test).

△ Quantitation of glycated haemoglobin

The Committee recommends item 66841 be changed to include specific indications for asymptomatic patients tested for diabetes mellitus in the explanatory notes. The maximum number of permissible tests under item 66841 should be increased to two per year to reflect current guidelines.

△ Quantitation of fructosamine

The Committee recommends the item descriptor for item 66557 be changed to stipulate that the test is only conducted when HbA1c is unreliable. The Committee also recommends that explanatory notes be added to specify the clinical circumstances in which testing is appropriate.

△ Microalbumin

The Committee recommends that clinical requirements for testing be included in the explanatory notes for item 66560 and that testing is restricted to four times within a 12-month period. The Committee also recommended changing the name of the item descriptor to albumin: creatinine ratio.

△ Electrophoresis of serum

The Committee recommends deleting the obsolete item 66539 to modernise the MBS.

1.2 Consumer engagement

The Committee believes it is important to find out from consumers if they will be helped or disadvantaged by the recommendations – and how, and why. After public consultation the Committee will assess the advice from consumers and decide whether any changes are needed to the recommendations.

The Committee will then send the recommendations to the Taskforce. The Taskforce will consider the recommendations as well as the information provided by consumers to make sure all the important concerns are addressed. The Taskforce will then provide the recommendations to government.

- △ The Committee brought together practitioners with experience in, and commitment to, the care of people with clinical diseases, to examine how well the description of Medicare items match current clinical practice and meet the needs of Australians. Consumer representatives were on the Committee and in every Working Group.
- △ There is a list of all the reviewed items, written in plain English, in Appendix B – Summary for consumers.
- △ Changes have been recommended for some items that are no longer up to date. Some items are no longer used, and some should not be used because clinical best-practice has changed since they were originally described. These items have been recommended for deletion.
- △ Most of the work conducted by the Committee focused on clinical issues and the provision of clinical services. As a result, the consumer representative relied frequently on the advice of the clinicians regarding how consumers would be affected.
- △ The consumer representative used the following framework to assess recommendations:
 - **Safety:** None of the recommendations negatively affect 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 reduce the effectiveness of chemical pathology services. The Committee did recommend that the Medical Services Advisory Committee (MSAC) consider allowing GPs to order TFTs comprising TSH, free thyroxine and free T3 in patients with suppressed TSH to assess the risk of ongoing medical condition and diagnose other medical conditions. .
 - **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 that enables all Australian residents (and some overseas visitors) to have access to a wide range of health services and medicines at little or no cost.

Introduced in 1984, Medicare has three components:

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

What is the Medicare Benefits Schedule (MBS)?

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

2.2 What is the MBS Review Taskforce?

The Government established the MBS Review Taskforce (the Taskforce) as an advisory body to review all of the 5,700 MBS items to ensure they are aligned with contemporary clinical evidence and practice and improve health outcomes for patients. The Taskforce will also modernise the MBS by identifying any services that may be unnecessary, outdated or potentially unsafe. The Review is clinician-led, and there are no targets for savings attached to the Review.

What are the goals of the Taskforce?

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

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

services that have proven benefit and are underused, particularly for patients who cannot readily access those services currently.

2.3 The Taskforce's approach

The Taskforce is reviewing the existing MBS items, with a primary focus on ensuring that individual items and usage meet the definition of best practice.

Within the Taskforce's brief there is considerable scope to review and advise on all aspects that would contribute to a modern, transparent and responsive system. This includes not only making recommendations about new items or services being added to the MBS, but also about a MBS structure that could better accommodate changing health service models.

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

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

As the Review is to be clinician led, the Taskforce has decided that the detailed review of MBS items should be done by clinical committees. The committees are broad based in their membership and members have been appointed in their individual capacity, not as representatives of any organisation. This draft report details the work done by the specific clinical committee and describes the committee's recommendations and their rationale.

The draft report does not represent the final position of the committee. A consultation process will inform recommendations of the committee and assist it in finalising its report to the Taskforce.

After consultation the committee will provide its final advice to the Taskforce. The Taskforce will consider the Review Report from the clinical committees and stakeholder feedback before making recommendations to the Minister for consideration by Government.

2.4 Prioritisation process

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 has needed to develop a workplan and assign priorities, keeping in mind the objectives of the Review.

With a focus on improving the clinical value of MBS services, the clinical committees have taken account of factors including the volume of services, service patterns and growth and variation in the per capita use of services, to prioritise their work. In addition to MBS data, important resources for the Taskforce and the Clinical Committees have included:

- △ The Choosing Wisely recommendations, both from Australian and internationally¹⁻³
- △ The National Institute for Health and Care Excellence (NICE UK) Do Not Do recommendations and clinical guidance⁴
- △ Other literature on low-value care, including Elshaug et al's (2012) *Medical Journal of Australia* article on potentially low-value health services⁵

- △ The Australian Commission on Safety and Quality in Health Care's (ACSQHC) *Atlas of Healthcare Variation*.⁶

3. About 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.

3.1 Pathology Clinical Committee members

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 (i.e. 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.

Table 1: Pathology Clinical Committee Members

Name	Position/organisation	Declared conflict of interest
Associate Professor Peter Stewart	Royal Prince Alfred Hospital (Public)	None
Professor Rita Horvath	South Eastern Area Laboratory Services (Public)	None
Dr Debra Norris	QML Pathology (Primary)	None
Dr Michael Harrison	Sullivan Nicolaides Pathology (Sonic)	None
Associate Professor Ken Sikaris	Melbourne Pathology (Sonic)	None
Dr Melody Caramins	Specialist Diagnostic Services (Primary)	None
Dr John Rowell	Royal Brisbane & Women's Hospital	None
Professor Dominic Mallon	PathWest	None
Dr Peter Roberts	Ryde Hospital (AESM)	None
Associate Professor Anthony Landgren	Australian Clinical Labs	None

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
Dr Gary Lum	Department of Health Medical Advisor	None
Ms Valerie Hanrahan	MBS Review Representative Consumer Consumers Health Forum	None
Dr Robyn Lindner	National Prescribing Service	None

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. Their recommendations were endorsed by the Pathology Clinical Committee to go out for public comment before MBS Taskforce consideration.

The Chemical Working Group consists of nine 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	Is the main biller of the tests at the Alfred, 100% of the proceeds are donated to the public hospital.
Dr Lawrie Bott	Pathologist, Sonic Healthcare, Hobart	Provider of MBS-funded services reviewed by this Committee.
Dr David Deam	Chemical Pathologist, Australian Clinical Labs	Provider of MBS-funded services reviewed by this Committee.
Dr Alan McNeil	Chemical Pathologist, Dorevitch Pathology, Melbourne	Nil
Dr Trina Gregory	Clinical Director, Watson General Practice, ACT	Requester of pathology
Ms Helen Maxwell-Wright	MBS Review Representative Consumer Director, Maxwell-Wright Associates	Nil

3.3 Conflicts of interest

All members of the Taskforce, Clinical Committees and Working Groups are asked to declare any conflicts of interest at the start of their involvement and reminded to update their declarations periodically.

4. Areas of responsibility of the Pathology Clinical Committee

The review process of the services covered in the report commenced with review by the Endocrinology Clinical Committee of 60 endocrine-related items on the Medicare Benefits Schedule (MBS). The Endocrinology Clinical Committee made recommendations to the Taskforce and relevant committees, based on rapid evidence review and clinical expertise.

Of these 60 items, 43 were related to endocrine pathology tests. The review of these 43 items was performed from a requesting clinician's perspective and were provided as advice to the Pathology Clinical Committee and its Chemical Working Group

The Chemical Working Group reviewed the Endocrinology Clinical Committee report on the 43 items relating to endocrine pathology tests and made recommendations to the Pathology Clinical Committee. This review was from a chemical pathology perspective with input from a GP who is a permanent member of the group. Subsequently the recommendations were discussed with the Endocrinology Clinical Committee. This report presents the Pathology Clinical Committee recommendations, with reference to the Endocrinology Clinical Committee report that was made available to the Pathology Clinical Committee for review and discussion before making recommendations.

A list of the Endocrinology Clinical Committee recommendations can be found in Appendix A of this report for comparison with the recommendations proposed by the Pathology Clinical Committee.

The 43 endocrine-related pathology test items include thyroid function testing, diabetes-related testing, and other hormone testing. In the 2014/15 financial year these items accounted for about 12.6 million services and \$324 million in benefits. Over the past 5 years, service volumes have increased by 6.1 per cent per year, and benefits have increased by 6.3 per cent per year. This growth is largely explained by an increase in the number of services per capita (Figure 1). TSH quantitation, diabetes-related items and TFTs account for most of the total services (Figure 2).

Figure 1. Drivers of growth in utilisation of endocrine-related pathology test items, 2010–15 financial year.

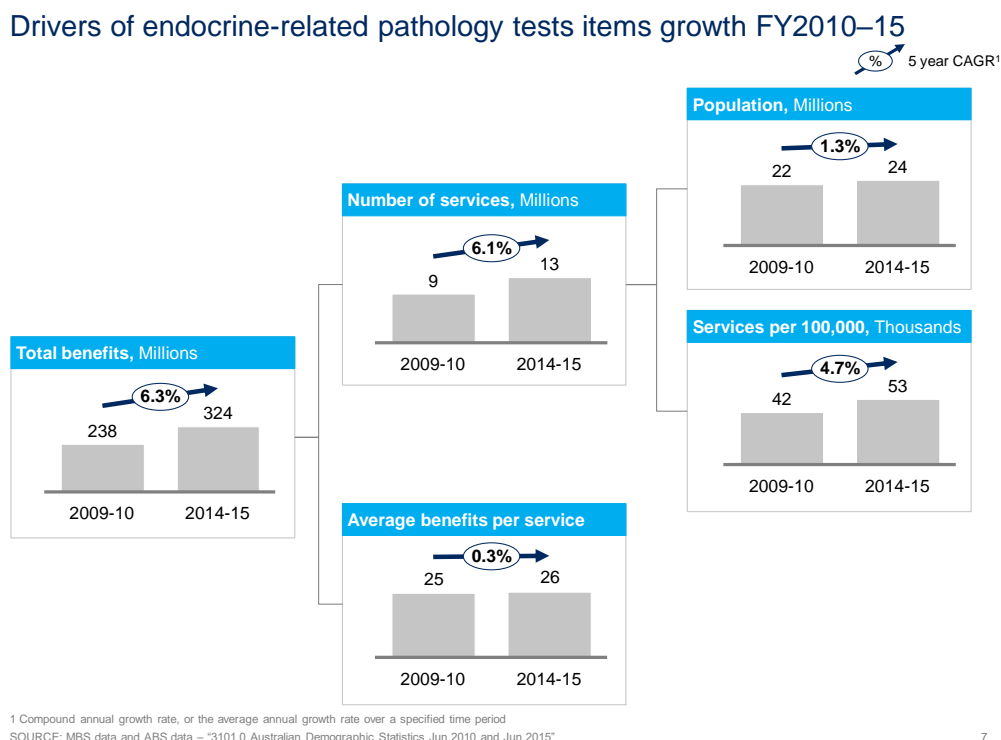


Figure 2. Endocrine-related pathology tests item groups by service volume, 2014–15.

Endocrine related pathology tests item groups ordered by service volume

Endocrine related pathology tests items - grouped items by total number of services FY2014-15 Service volume, Thousands	Percent of total services	Services 5 year CAGR	Benefits (2014-15) \$ Millions
TSH tests (66716 & 66722-66734)	41.6%	4.4%	136.7
Diabetes-related items (66542-8, 66551-4 & 66841, 66557, 66560)	23.2%	4.6%	47.1
TFT (66719)	17.4%	11.1%	66.5
Quantitation of hormones or binding proteins (66695-66707)	10.1%	7.0%	50.5
Thyroid antibodies (71165-71170)	3.8%	11.1%	18.6
Quantitation of collagen breakdown or formation (66773-66776)	0.5%	13.3%	1.5
Adrenaline and other tests (66779-66780)	0.5%	5.7%	2.2
1,25-dihydroxyvitamin D (61473-61713)	0.1%	N/A	0.3
Multiple hormones (66686)	0.0%	7.5%	0.2
Quantitation in Soliva of cortisol (66711-66715)	0.0%	42.3%	0.1
Electrophoresis of serum 66539	0.0%	3.8%	0.0

SOURCE: MBS data

Source: Department of Health, unpublished data, date of processing, accessed on 10 October 2016

5. Recommendations for endocrine-related pathology tests

5.1 Thyroid stimulating hormone (TSH) tests and thyroid function tests (TFTs)

TSH tests and TFTs: items 66716, 66719, 66722–5, 66728, 66731 and 66734

In the 2014–15 financial year about one in four Australians (5.7 million patients) had either a TSH test or a TFT.⁷ A total of 7.6 million tests were charged to Medicare over the course of the year (this excludes TSH tests and TFTs that are coned out and tests done for public hospital patients). This figure has grown by an average of 6.1 per cent per year over the last 5 years.

Benefits paid for these items totalled \$203 million in the 2014–15 financial year. This figure has grown by an average of 6.2 per cent per year over the last 5 years and accounts for around 1 per cent of the total MBS expenditure.⁸ This growth is largely explained by increase in the number of patients being tested, which has grown by an average of 5.7 per cent per year over the past 5 years⁹ (compared with population growth of 1.3 per cent per year).¹⁰

Service volumes in this group are concentrated in two large items: TSH quantitation (item 66716) and TFTs (item 66719). The total services for these items 66716 and 66719 have grown by 4.3 and 11.1 per cent, respectively, per year over the last 5 years.⁸

5.1.1 TSH test: Items 66716, 66722–5, 66728, 66731 and 66734

Table 3: Item introduction table for items 66716, 66722–5, 66728, 66731 and 66734

Item	Descriptor [date last amended]	Schedule fee	Services FY2014/15	Benefits FY2014/15	Services 5-year annual avg. growth
66716	TSH quantitation. [1998]	\$25.05	4,642,841	\$99,063,014	4.3%
66722	TSH quantitation described in item 66716 and 1 test described in item 66695. (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.) [1998]	\$37.90	257,252	\$8,302,767	6.8%
66723	Tests described in item 66722, that is, TSH quantitation and 1 test described in 66695, 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.) [2007]	\$37.90	17	\$548	–6.7%
66724	Tests described in item 66722, if rendered by a receiving APP, other than that described in	\$13.15	32	\$357	–45.1%

Item	Descriptor [date last amended]	Schedule fee	Services FY2014/15	Benefits FY2014/15	Services 5-year annual avg. growth
	66723. It is to include a quantitation of TSH – each test to a maximum of 4 tests described in item 66695. (Item is subject to rule 6 and 18.) [2007]				
66725	TSH quantitation described in item 66716 and 2 tests described in item 66695. (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs the only 3 tests specified on the request form or performs 3 tests and refers the rest to the laboratory of a separate APA.) (Item is subject to rule 6.) [1998]	\$51.05	108,605	\$4,727,365	3.6%
66728	TSH quantitation described in item 66716 and 3 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.) [1998]	\$64.20	88,184	\$4,836,010	2.1%
66731	TSH quantitation described in item 66716 and 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 5 tests specified on the request form or performs 5 tests and refers the rest to the laboratory of a separate APA.) (Item is subject to rule 6.) [1998]	\$77.40	104,774	\$6,924,385	3.4%
66734	TSH quantitation described in item 66716 and 5 tests described in item 66695. (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 6 or more tests specified on the request form.) (Item is subject to rule 6.) [1998]	\$90.55	166,829	\$12,895,377	7.1%

Source: Department of Human Services, published data, date of processing.

The following observations have been made with regard to TSH tests:

- △ There is significant use of TSH items. In the 2014–15 financial year about one in five Australians (4.6 million patients)⁷ had a TSH test, amounting to a total of 5.4 million tests.⁸ Thirty-eight per cent of patients had a repeat TSH test (item 66716) within 12 months of their first test in 2014.¹¹ As a result of these high service volumes, around \$111 million was

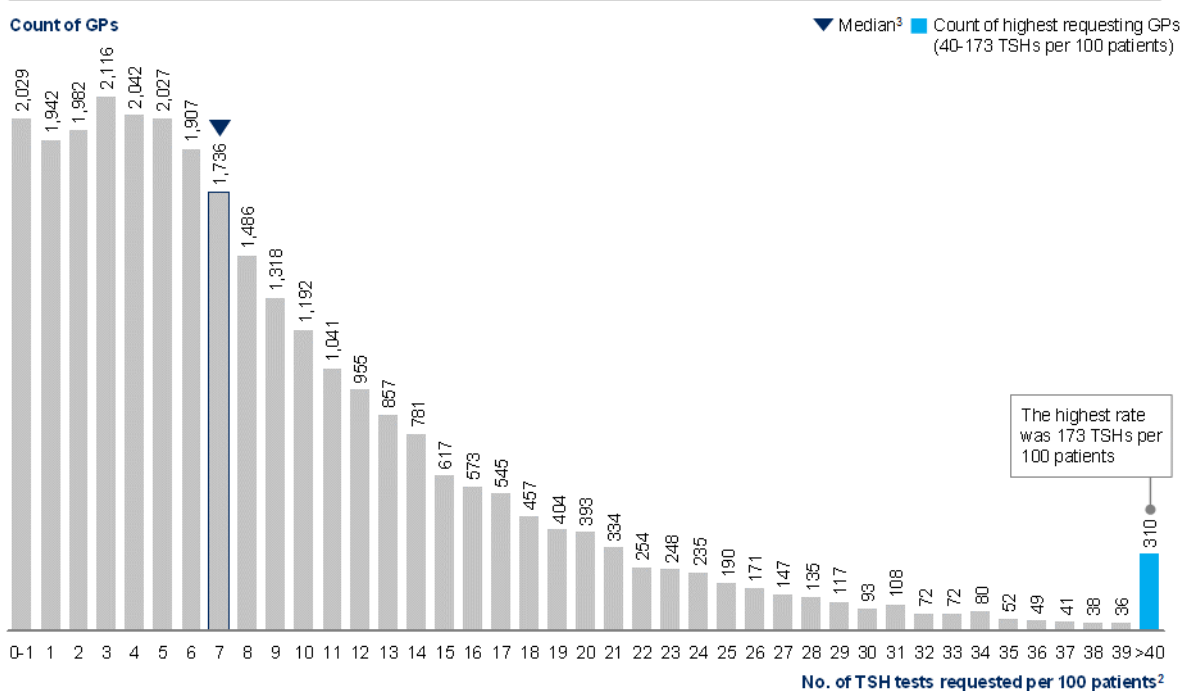
paid in benefits for TSH tests – 0.55 per cent of total MBS expenditure. This figure included benefits paid for item 66716 (\$99 million) as well as benefits paid for other item numbers containing TSH tests (applying only the 66716 fee for a TSH test).⁸

- △ There is considerable variation in patterns of use among requesters, which suggests that standardising practice may benefit patients. In the 2014–15 financial year about 20 per cent of requesting doctors accounted for two-thirds of 66716 tests.⁸ GPs are critical partners in optimising and standardising practice, as they request around 90 per cent of TSH tests. An analysis of GP requesting patterns shows that there is a long tail of GPs who request far more TSH tests per 100 patients than their peers. For example, a group of about 310 GPs requested 40–173 TSH tests per 100 patients in FY 2014/15, compared with a median of 7.31 (Figure 3).¹²

Figure 3: Rates of TSH tests requested per 100 patients, 2014–15.

There is a long tail of GPs requesting a high rate of TSH tests per 100 patients

Count of GPs by TSH test requests per 100 patients
FY2014-15, total no. of GPs = 29,1821¹



(1) GPs with less than 100 consults and 50 patients in FY2014/15 were excluded to reduce the chance of mis-allocation of provider speciality and bias caused by a small sample of patients.
(2) Numbers were rounded down to the lower number. (3) The median was 7.31 TSH tests per 100 patients.
SOURCE: MBS data – Q20354_02

Source: Department of Health, unpublished data, date of processing, accessed on 10 October 2016

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Change all item descriptors (66716–66734) to preclude testing in asymptomatic patients and patients with non-specific symptoms, specifying the following indications for testing:
 - The patient has known thyroid or pituitary disease.
 - There is clinical suspicion of thyroid dysfunction.
 - The patient is undergoing thyroid hormone replacement therapy and needs to be monitored.

- The patient is pregnant or planning pregnancy, and testing is clinically indicated.
- △ Add the following explanatory notes (explanatory notes are not currently provided):
 - Repeat testing should not be conducted on patients within 12 months of a normal TSH without a change in their underlying thyroid condition or their thyroid hormone replacement treatment.
- △ Develop an education strategy to support this change. Recommended measures include working with NPS MedicineWise to promote awareness, using tools such as its NPS MedicineWise bulletin. This should inform requesters of the changes and the appropriate use of guidelines for testing, and should emphasise the important requirement to include clinical information on all request forms. NPS MedicineWise’s appropriate use guidelines should include what is written in the explanatory notes above. Producers of consumer literature should align their recommendations for doctors with this behavioural change.
- △ Engage NPS MedicineWise to develop a specific audit and feedback activity after the MBS changes have been implemented to complement other education activities. This would show requesters how many tests they are requesting relative to their peers, and could be implemented after item descriptor changes have had time to take effect. This activity should focus on doctors with higher requesting rates.
- △ Actively monitor the impact of the changes on service patterns and volumes. If anticipated impacts do not occur, consider a combination of Medicare compliance audits and/or sending letters and making phone calls to: (i) doctors with high requesting rates, using requests per consultation or patients seen as a guiding metric to identify outlier practices; and (ii) pathology practices to determine compliance with item requirements.

Recommendation 1

The Pathology Clinical Committee provides the following advice and recommendations.

- △ The Pathology Clinical Committee agrees that TSH should not be used as a screening test in asymptomatic patients, as recommended by the RACGP Choosing Wisely guidelines and international guidelines.
- △ The Pathology Clinical Committee generally supports the Endocrinology Clinical Committee’s recommendations regarding the appropriate indications for TSH testing and the limits on repeat testing, with modifications as follows.
- △ The Pathology Clinical Committee recommends changing ‘non-specific symptoms’ to ‘unrelated symptoms’ noting that ‘non-specific’ could be misunderstood to include symptoms such as fatigue or weight gain which may well be appropriate indications for testing. ‘Unrelated’ would refer to symptoms that are not associated with thyroid disease.
- △ The Pathology Clinical Committee recommends broadening the Endocrinology Clinical Committee’s proposals to allow testing in asymptomatic patients who are pregnant or at elevated risk of thyroid disease, including patients with type 1 diabetes mellitus.
- △ The Pathology Clinical Committee does not support including clinical indications in the item descriptor but instead recommends that clinical advice be included in explanatory notes. It

notes that, following discussion, the Endocrinology Clinical Committee supports this approach.

- △ The Pathology Clinical Committee recommends that the explanatory note for TSH testing should state that testing is appropriate in the following circumstances:
 - The patient has known thyroid disease.
 - There is clinical suspicion of thyroid dysfunction.
 - The patient is currently receiving thyroid hormone replacement therapy and needs to be monitored.
 - The patient is pregnant or planning pregnancy, and testing is clinically indicated.
 - The patient has an autoimmune condition (e.g. type 1 diabetes mellitus or adrenal insufficiency).
 - The patient is taking medication known to affect thyroid function (e.g., lithium or amiodarone).
- △ In agreement with the Endocrinology Clinical Committee, the Committee does not recommend that there should be a limit on the annual number of TSHs performed, but recommends that repeat testing should not be conducted on patients within 12 months of a normal TSH without a change in their underlying thyroid condition or their thyroid hormone replacement treatment. It recommended that this advice should be included in an explanatory note.
 - Repeat testing should not be conducted within 12 months of a normal TSH without a change in the patient’s underlying condition or their thyroid hormone replacement treatment.
- △ The Pathology Clinical Committee supports the Endocrinology Clinical Committee recommendation for a proposed education program, supported by NPS MedicineWise, on the clinical appropriateness of TSH testing. The proposed education program would inform requesters of the appropriate use of guidelines for testing, and should emphasise the important requirement to include clinical information on all request forms. NPS MedicineWise’s appropriate use guidelines should include the content of the explanatory notes above. Consumer products should align the recommendations for doctors with this behavioural change.

Rationale 1

The Pathology Clinical Committee recommendation that TSH not be used as a screening test aligns with the RACGP Choosing Wisely recommendations.

There was considerable discussion in the Pathology Clinical Committee around the proposal that item descriptors be amended to reflect agreed indications for testing. It was agreed that the increased testing is based on an increase in requesting and the best way to address this is by seeking to improve the quality of requesting, particularly in primary care settings, through education of the requesting clinicians.

A change in descriptor puts the onus of compliance on the laboratories. Given that up to 30–50 per cent of clinical requests have no relevant clinical notes on the question of thyroid disease (according to pathologists working in the private sector), it is difficult for the pathologists to ensure compliance.

Although the Pathology Clinical Committee were supportive of the need to improve the clinical value of testing, they were unable to support the recommendation to change the item descriptors to specify clinical indications, due to issues relating to governance and increased workload for pathology laboratories. Instead, the Committee proposes that there be guidance in the explanatory notes to promote the appropriate use of TSH testing.

The Pathology Clinical Committee was supportive of the Endocrinology Clinical Committee recommendation that some high-risk groups should have access to testing even when asymptomatic. These groups include pregnant women and those at elevated risk of thyroid disease (generally patients with autoimmune disease, and in particular type 1 diabetes mellitus). This approach is supported internationally.¹³

The Pathology Clinical Committee notes that 38 per cent of patients had a repeat TSH test (item 66716) within 12 months of their first test in 2014.¹¹ The Committee supports the Endocrinology Clinical Committee recommendation as outlined, which seeks to remind clinicians that repeat testing is generally not indicated within 12 months of a normal TSH result. Including such advice in explanatory notes allows for repeat testing when it is appropriate and clinically indicated, noting that for relatively few patients, multiple tests can be indicated over short time period.

The Pathology Clinical Committee recommends amendments to item 66716 as follows.

Table 4: Current and proposed new item descriptor for item 66716

Current item descriptor	Proposed new item descriptor
TSH quantitation	<p>TSH quantitation</p> <p>Explanatory notes</p> <p>TSH testing should not be performed as a screening test in asymptomatic patients. Indications for testing with TSH are:</p> <ul style="list-style-type: none"> – The patient has known thyroid disease. – There is clinical suspicion of thyroid dysfunction. – The patient is currently receiving thyroid hormone replacement therapy and needs to be monitored. – The patient is pregnant or planning pregnancy, and testing is clinically indicated. – The patient is at elevated risk because of an autoimmune condition (e.g. type 1 diabetes mellitus or adrenal insufficiency). – The patient is taking medication known to affect thyroid function (e.g. lithium or amiodarone). <p>Repeat testing should not be conducted within 12 months of a normal TSH without a new clinical suspicion of thyroid dysfunction or a change in the patient’s underlying condition or their thyroid hormone replacement treatment.</p>

5.1.2 TFTs: Item 66719

Table 5: Item introduction table for item 66719

Item number	66719
Descriptor [date last amended]	Thyroid function tests (comprising the service described in item 66716 and 1 or more of the following tests – free thyroxine, free T3, for a patient, if at least 1 of the following conditions is satisfied: (a) the patient has an abnormal level of tsh; (b) the tests are performed: (i) for the purpose of monitoring thyroid disease in the patient; or (ii) to investigate the sick euthyroid syndrome if the patient is an admitted patient; or (iii) to investigate dementia or psychiatric illness of the patient; or (iv) to investigate amenorrhoea or infertility of the patient; (c) the medical practitioner who requested the tests suspects the patient has a pituitary dysfunction; (d) the patient is on drugs that interfere with thyroid hormone metabolism or function. (Item is subject to rule 9.) [2008]
Schedule fee	\$34.80
Volume of services FY2014/15	2,250,306
Total benefits paid FY2014/15	\$66,534,461
Services 5 year (FY2009/10–FY2014/15) annual average growth (CAGR)	11.1%

Source: Department of Human Services, published data, date of processing.

The following observations have been made with regard to TFTs:

- △ During the last 5 years use of TFTs has grown by an average of 11 per cent per year.⁸ In the 2014–15 financial year about 1 in 16 Australians (1.4 million patients) had a TFT, amounting to a total of 2.3 million tests. This growth is driven by increases in the number of patients tested (which is growing by 11.8 per cent per year), rather than increased tests per patient (which is declining at –0.7 per cent per year).⁷ Around 57 per cent of patients had a repeat TFT within 12 months of their first test in 2014.¹¹
- △ Twenty per cent of requesting doctors accounted for two-thirds of all tests in the 2014–15 financial year. GPs requested 75 per cent of tests, reinforcing that they are important partners in optimising and standardising practice.⁸
- △ It is possible that the clinical indications described in the current item descriptor do not adequately explain the volume of TFTs performed. It was noted that around 750,000 patients were dispensed PBS-listed thyroid replacement medication in the 2014–15 financial year,¹⁴ and these patients may have had multiple TFTs. Furthermore, an unknown number of TFTs were undertaken to investigate other indications listed in the item descriptor, such as dementia or psychiatric illness. Although the use of TFTs may be consistent with current item descriptors, which also allow TFTs for patients with

abnormal TSH tests and those with known thyroid disease, it is possible that a significant number of TFTs were being requested when a TSH test would be more suitable.

- △ MBS data demonstrates that 380,000 patients (26 per cent) received a separate TSH test in the 12 months preceding a TFT in FY2014/15.¹⁵ The ECC had noted that an abnormal TSH test is an appropriate indication for a TFT, but suggested that it is often inefficient for patients to have a second distinctive test performed when the indication for TFT is an abnormal TSH test.

Advice from the Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Change the TFT item descriptor to reflect the most clinically relevant indications for testing, which includes removing the following: 'To investigate the sick euthyroid syndrome if the patient is an admitted patient; or (iii) to investigate dementia or psychiatric illness of the patient.'
- △ Expand the current descriptor to discourage the use of TFTs for monitoring thyroid hormone replacement therapy. The proposed addition is as follows: 'For monitoring of thyroid replacement therapy where hypothyroidism is due to pituitary disease.'
- △ Change the rules for this item to make it a pathology-determinable test. This would allow a pathologist to conduct a TFT without further instruction from the requesting doctor if a patient has a significantly abnormal TSH test. An abnormal TSH test that automatically prompts testing of FT3 and FT4 should be defined as follows: 'a TSH quantitation of < 0.2 or > 5 mIU/L. When this occurs and TFTs are conducted, the pathologist should bill for TFT item 66719 alone.'
- △ Include education on the proper use of TFTs, and the use of audit and feedback, following the education strategy described in Section 4.2.1.
- △ Perform Medicare compliance audits on high-volume requesters and pathology practices and/or contact them by letter or telephone, following the principles outlined in Section 4.2.1. The change to pathology-determinable testing may require particular scrutiny.

Recommendation 2

The Pathology Clinical Committee provides the following advice and recommendations.

- △ The Pathology Clinical Committee supports the Endocrinology Clinical Committee recommendation on the removal of the wording '(ii) to investigate the sick euthyroid syndrome if the patient is an admitted patient; or (iii) to investigate dementia or psychiatric illness of the patient' from the current item descriptor of 66719.
- △ The Pathology Clinical Committee agrees with the Endocrinology Clinical Committee recommendation to add new wording of 'For monitoring of thyroid replacement therapy where hypothyroidism is due to pituitary disease.' in the explanatory notes, not the item descriptor as suggested by the Endocrinology Clinical Committee, as there is already mention of this situation in the descriptor.
- △ The Pathology Clinical Committee agrees that the use of TFT for monitoring thyroid hormone replacement therapy should be discouraged and that TSH should be used instead in most cases. This suggestion is based on the concern that there are cases of normal TSH tests

where fT4 and/or fT3 tests will provide additional clinical information, especially in patients taking non-traditional thyroid hormone replacement (thyroid extract or T3).

- △ The Pathology Clinical Committee supports an education program aimed at requesters of TFTs as a way to discourage use in patients taking thyroid replacement therapy. The education program should include consumers.
- △ The Pathology Clinical Committee supports the proposal to change fT4 and fT3 testing to be a pathologist-determinable test after an abnormal TSH test result.

The Pathology Clinical Committee recommends amendments to item 66719 as follows.

Table 6: Current and proposed new item descriptor for item 66719

Current item descriptor	Proposed new item descriptor
<p>Thyroid function tests (comprising the service described in item 66716 and 1 or more of the following tests – free thyroxine, free t3, for a patient, if at least 1 of the following conditions is satisfied: (a) the patient has an abnormal level of TSH; (b) the tests are performed: (i) for the purpose of monitoring thyroid disease in the patient; or (ii) to investigate the sick euthyroid syndrome if the patient is an admitted patient; or (iii) to investigate dementia or psychiatric illness of the patient; or (iv) to investigate amenorrhoea or infertility of the patient; (c) the medical practitioner who requested the tests suspects the patient has a pituitary dysfunction; (d) the patient is on drugs that interfere with thyroid hormone metabolism or function. (Item is subject to rule 9.)</p>	<p>Thyroid function tests (comprising the service described in item 66716 and 1 of the following tests – free thyroxine or free T3, for a patient, if at least 1 of the following conditions is satisfied: (a) the patient has an abnormal level of TSH on this test or the most recently available test; (b) when TSH may be an unreliable indicator of thyroid function (Item is subject to rule 9.)</p> <p>Explanatory notes</p> <p>TFTs can be pathologist-determinable when, after a request for TSH or TFT, an abnormal TSH is detected as part of this service. TFTs can also be performed when requested in response to the most recent TSH being abnormal.</p> <p>TFTs are an appropriate initial test when TSH alone may be an unreliable indicator of thyroid function, including:</p> <ol style="list-style-type: none"> 1. investigation of suspected pituitary dysfunction 2. investigation of amenorrhoea or infertility 3. monitoring of thyroid hormone replacement in patients with known pituitary dysfunction. 4. monitoring of some patients in the initial management of thyrotoxicosis 5. monitoring of patients with hypothyroidism who have documented intolerance or resistance to thyroxine. <p>For monitoring thyroid hormone replacement therapy TSH is usually the best test, but occasionally FT4 or FT3 can add information (e.g. in patients on T3 or thyroid extract).</p>

Rationale 2

There is universal agreement that in severe illness both TSH and fT4 can be abnormal. There is no advantage to patients to start with TFT testing instead of a single TSH test. In the so-called 'sick euthyroid state', abnormal TFT results are due to the patient's illness and will resolve after resolution of the non-thyroidal illness without thyroid-specific intervention.

Similarly, there is no clinical reason to require TFTs for patients with mental illness, as it is only in pituitary disease that the TSH test alone can be misleading.

In patients with hypothyroidism, TSH is the most valid test for the monitoring of thyroid hormone replacement therapy. TFTs might be misleading, as fT4 can be elevated, especially if the patient has recently taken the thyroxine supplementation. Therefore use of TFTs should be discouraged and TSH should be used instead in most cases.

The main benefit of education programs aimed at requesters on use of TFTs is to discourage use in patients taking thyroid replacement therapy. The education program should also include consumers.

The recommendation is that the new proposed wording: 'For monitoring of thyroid replacement therapy when hypothyroidism is due to pituitary disease' be included in the explanatory notes as opposed to the item descriptor as recommended by the Endocrinology Clinical Committee. In pituitary disease, TSH may be misleading despite the patient experiencing hypothyroidism. Therefore in this clinical setting TFT is the appropriate test.

The frequency of abnormal fT4 and fT3 levels is increased in patients with TSH outside the reference range, based on information from unpublished data and a recommendation from the chair of the endocrine testing subcommittee of the Endocrinology Clinical Committee.

When the initial TSH is outside the reference range, two scenarios are possible. In patients with suppressed levels of TSH, fT4 and fT3 can provide additional information about the degree of hyperthyroidism, while in patients with elevated TSH, fT4 can also provide additional information. In patients with mildly elevated TSH, the most helpful test is anti-TPO antibodies, as presence of these predicts future development of overt hypothyroidism.

About 25 per cent of requests have no additional clinical information on the request form about the type of test the laboratory needs to perform.

5.1.3 Proposed new item for TFTs

Recommendation 3

The Pathology Clinical Committee provides the following advice and recommendations.

- △ The Pathology Clinical Committee recommends adding a new item including the measurement of TSH, fT4 and fT3 in patients with totally suppressed TSH (< 0.05 mIU/L). This recognises that for most patients with TFT tests there is no indication to measure fT3, but for some with suppressed TSH the fT3 will offer additional information about the severity and prognosis of their hyperthyroidism and identify patients with T3-toxicosis.

Table 7: Proposed new item descriptor

New item descriptor
Thyroid function tests comprising TSH, free thyroxine and free T3, for a patient, if the following conditions are satisfied: (a) the patient has a suppressed level of TSH (to 0.05 mIU or less) on this occasion; and (b) TSH suppression is not due to thyroid treatment with the aim to suppress TSH.
Explanatory notes
When TSH is suppressed, free T3 can give helpful information on the severity of hyperthyroidism or can identify T3 toxicosis, when free thyroxine can be normal and only free T3 is elevated.
Many patients with a history of thyroid cancer are treated with thyroxine, and the thyroxine dose is aimed at suppressing TSH. Free T3 measurement is not indicated in these patients.

Rationale 3

Measurement of fT3 is currently not separately remunerated in the table. fT3 is the active form of the thyroid hormone and transmits its metabolic effects.¹⁶

While TSH and fT4 measurements suffice in most clinical scenarios, in clinical situations when the patient is hyperthyroid with a suppressed TSH, fT3 can add valuable information. In these situations an fT3 will add information about the rate of conversion from fT4, which allows clinicians to assess risk of ongoing disease; it will also diagnose patients with isolated T3 toxicosis, who have normal fT4 with suppressed TSH, but elevated fT3.

This should be limited to patients with suppressed TSH (< 0.05 mIU/L). A <0.05 mIU/L cut-off was selected based on unpublished laboratory data. Below this level the frequency of abnormal fT3 increased markedly. There was general agreement in the group that clinically valuable tests should be incentivised. The introduction of this item number is likely to increase MBS expenditure, with an estimated utilisation of 350,000 tests per year.

Further rationale: repeat TSH tests and TFTs

There was initial concern about repeat testing rates for both tests, and the Endocrinology Clinical Committee considered including a restriction in the item descriptor – specifically, a maximum of six tests within 12 months. Some of the considerations were as follows:

- △ Patients without thyroid or pituitary disease who have a normal TSH test do not require further testing unless clinical circumstances change.
- △ Patients who have unstable disease, particularly those with thyrotoxicosis, may need frequent testing.
- △ Patients who are taking thyroid replacement therapy may also require repeat testing, and the indications for whether a TSH test or TFT is most appropriate are outlined in the recommendations above.

However, MBS data showed that repeat testing resulting in more than six tests in 12 months did not account for a significant volume of tests: 0.04 per cent of TSH 66716 patients (about 1500) had more than six TSH tests, on average, within 12 months of their first test in 2014;¹¹ and 1.4 per cent of TFT 66719 patients (about 19,000) had more than six TFTs, on average, within 12 months of their first test in 2014.¹¹

As patients with repeat TFTs would include patients with new-onset hyperthyroidism, this group includes a significant population in which the tests are requested appropriately. The Endocrinology Clinical Committee therefore concluded that it was not necessary to restrict the maximum number of tests to six. However, it noted that guidelines should be provided specifying that a TSH test with normal results should generally preclude follow-up TSH tests for the next 12 months, and that this guidance should be provided in educational initiatives via NPS MedicineWise.

5.2 Diabetes-related items: Items 66542, 66545, 66548, 66551, 66554, 66557, 66841 and 66560

Table 8: Item introduction table for items 66542, 66545, 66548, 66551, 66554, 66557, 66841 and 66560

Item	Descriptor [date last amended]	Schedule fee	Services FY2014/15	Benefits FY2014/15	Services 5-year annual avg. growth
66542	Oral glucose tolerance test for the diagnosis of diabetes mellitus that includes: (a) administration of glucose; (b) at least 2 measurements of blood glucose; and if performed (c) any test described in item 66695. [1998]	\$18.95	292,924	\$4,737,344	-0.2%
66545	Oral glucose challenge test in pregnancy for the detection of gestational diabetes that includes: (a) administration of glucose; and (b) 1 or 2 measurements of blood glucose; and (c) (if performed) any test in item 66695. [1998]	\$15.80	49,327	\$684,953	-19.3%
66548	Oral glucose tolerance test in pregnancy for the diagnosis of gestational diabetes that includes: (a) administration of glucose; and (b) at least 3 measurements of blood glucose; and (c) any test in item 66695 (if performed). [1998]	\$19.90	138,051	\$2,378,743	31.7%
66551	Quantitation of glycated haemoglobin performed in the management of established diabetes – (item is subject to rule 25). [1998]	\$16.80	1,138,075	\$16,251,094	2.3%

Item	Descriptor [date last amended]	Schedule fee	Services FY2014/15	Benefits FY2014/15	Services 5-year annual avg. growth
66554	Quantitation of glycated haemoglobin performed in the management of pre-existing diabetes where the patient is pregnant – including a service in item 66551 (if performed). (Item is subject to rule 25.) [1998]	\$16.80	11,615	\$167,040	23.0%
66557	Quantitation of fructosamine performed in the management of established diabetes – each test to a maximum of 4 tests in a 12-month period. [1998]	\$9.70	14,741	\$121,415	-2.8%
66841	Quantitation of HbA1c (glycated haemoglobin) performed for the diagnosis of diabetes in asymptomatic patients at high risk. (Item is subject to rule 25.) [2014]	\$16.80	122,097	\$1,738,994	N/A
66560	Microalbumin – quantitation in urine. [1998]	\$20.10	1,228,232	\$21,032,232	6.9%

Source: Department of Human Services, published data, date of processing.

5.2.1 Oral glucose tolerance and challenge tests: Items 66542, 66545 and 66548

The following observations have been made in regards to OGTT tests:

- △ In the 2014–15 financial year a large number of OGTT diagnostic tests were performed on non-pregnant patients (292,000, or 61 per cent of OGTTs). While this figure has remained fairly constant looking at 2009–2015, declining by an average of only 0.2 per cent per year, it declined by 7 per cent in 2014–15 compared with 2013–14, and a further 14 per cent in 2015–16 compared with 2014–15 (251,250 tests).⁸

The overall use of OGTTs should continue to decrease, given that HbA1c measurement is a more reliable test and simpler to perform. The large number of OGTT tests is most likely explained by low-value over testing, particularly in non-pregnant patients who do not have a clinical indication for the test and should undergo HbA1c measurement instead.¹⁷⁻¹⁹ The changes are designed to remind requesters and pathologists that for most patients HbA1c is the preferred diagnostic test. Given the inconvenience of the OGTT, there is an expectation that the number will rapidly decline in coming years.

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Delete item 66545 and consolidate item 66548 under item 66542.

- △ Change the item descriptor for item 66542 to include pregnant patients, and highlight that it should be used when measurement of HbA1c is unreliable. The proposed item descriptor for item 66542 is as follows: ‘Oral glucose tolerance test (OGTT) for the diagnosis of diabetes mellitus in patients who are pregnant or in whom measurement of HbA1c is unreliable. The OGTT includes: (a) administration of glucose; and (b) at least two measurements of blood glucose; and (c) (if performed) any test described in item 66695.’
- △ Add explanatory notes for item 66542 to provide guidance on when an OGTT is appropriate. (Explanatory notes are not currently provided for this item.) The proposed explanatory notes are as follows: ‘OGTT in non-pregnant patients is indicated when diabetes is suspected despite a non-diagnostic HbA1c OR when HbA1c measurement is unreliable. Conditions that may make HbA1c measurement unreliable include haemoglobinopathies, iron-deficiency anaemia and severe illnesses that may shorten red cell lifespan, such as chronic renal impairment.’ Women with a history of gestational diabetes are recommended to have an OGTT 6–12 weeks postpartum.

Recommendation 4

The Pathology Clinical Committee provides the following advice and recommendations.

- △ The Pathology Clinical Committee supports the proposal to delete the oral glucose challenge test item 66545, as this test no longer has a place in practice. The Working Group suggested that requesters and providers be provided with an adequate warning and lead time before the change is implemented.
- △ The Pathology Clinical Committee recommends that item 66548 is not consolidated under item 66542, as proposed by the Endocrinology Clinical Committee. The Committee suggests keeping the items 66548 and 66542 separate. In pregnancy (item 66548) there is a requirement for three independent glucose levels, each of which can define gestational diabetes, while the glucose tolerance test in non-pregnant patients requires only two measurements with different cut-off levels (item 66542).
- △ The Pathology Clinical Committee supports the Endocrinology Clinical Committee recommendation that the descriptor for item 66542 be revised to include patients with conditions in which HbA1c measurement is unreliable.
- △ The Pathology Clinical Committee supports the Endocrinology Clinical Committee recommendation for complementary explanatory notes that provide more detail to requesters about the patient groups in which HbA1c may be unreliable.

Table 9: Current and proposed new item descriptor for item 66542

Current item descriptor	Proposed new item descriptor
<p>Oral glucose tolerance test for the diagnosis of diabetes mellitus that includes:</p> <p>(a) administration of glucose; and</p> <p>(b) at least 2 measurements of blood glucose; and</p> <p>(c) (if performed) any test described in item 66695.</p>	<p>Oral glucose tolerance test (OGTT) for the diagnosis of diabetes mellitus in patients in whom measurement of HbA1c is unreliable. The OGTT includes:</p> <p>(a) administration of glucose; and</p> <p>(b) at least two measurements of blood glucose; and</p> <p>(c) (if performed) any test described in item 66695.</p> <p>Explanatory note</p> <p>OGTT in non-pregnant patients is indicated when diabetes is suspected despite a non-diagnostic HbA1c or when HbA1c measurement is unreliable. Conditions that may make HbA1c measurement unreliable include haemoglobinopathies, iron-deficiency anaemia and illnesses that may shorten red cell lifespan, such as chronic renal impairment and haemolytic anaemia.</p>

Rationale 4

In pregnancy the glucose challenge test has been superseded by the full glucose tolerance test. This has been recommended by the Australian Diabetes in Pregnancy Society.²⁰

While there are still recommendations by the RACGP that women with a history of gestational diabetes have an OGTT 6–12 weeks postpartum,²¹ there is a recognition that a shift to HbA1c might improve adherence with testing.

5.2.2 Quantitation of glycated haemoglobin: Items 66551 and 66554

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Change the item descriptors to explicitly include the maximum number of tests permitted under rule 25, which is four tests in a 12-month period for item 66551 and six tests for pregnant patients under item 66554. For example, the proposed item descriptor for item 66551 is as follows: ‘Quantitation of glycated haemoglobin performed in the management of pre-existing diabetes; maximum four tests in a 12-month period (Item is subject to rule 25).’

Recommendation 5

The Pathology Clinical Committee provides the following advice and recommendations.

- △ The Pathology Clinical Committee supports the proposal to change the item descriptor for items 66551 and 66554 by adding rule 25 that limits the number of tests in a 12-month period to four and six tests, respectively.

Rationale 5

Rule 25 of the Health Insurance (Pathology Services Table) Regulation 2015, states that for any particular patient, item 66551 is used not more than four times in a 12-month period and item 66554 is used not more than six times in a 12-month period. The current item descriptor does not specify how many tests can be ordered in a 12-month period, and making this explicit in the item descriptor may assist requesters.

5.2.3 Quantitation of glycated haemoglobin: Item 66841

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Change the item descriptor to include specific indications for asymptomatic patients tested for diabetes mellitus, and change the maximum number of tests permitted in a 12-month period (under rule 25) to two, including this explicitly in the item descriptor. The proposed item descriptor is as follows:
 - Quantitation of HbA1c (glycated haemoglobin) performed for the diagnosis of diabetes mellitus in asymptomatic patients at high risk because of:
 - (i) a medical condition or ethnic background associated with high rates of diabetes mellitus, or
 - (ii) an Australian type 2 diabetes risk (AUSDRISK) score ≥ 12 .
 - Tests limited to one test per year if result is < 48 mmol/mol (6.5%). A second test can be ordered to confirm the diagnosis of diabetes if the initial test is ≥ 48 mmol/mol (6.5%). (Item is subject to rule 25; maximum two tests per year.)

Recommendation 6

The Pathology Clinical Committee provides the following advice and recommendations.

- △ The Pathology Clinical Committee supports the Endocrinology Clinical Committee proposal to change the number of available tests from one to two in a 12-month period when the test is used to confirm diagnosis when HbA1c is ≥ 48 mmol/mol (6.5%).
- △ The Pathology Clinical Committee recommends that the Endocrinology Clinical Committee proposal to change the item descriptor for item 66841 to include specific indications for asymptomatic patients tested for diabetes mellitus be moved to the explanatory notes. The proposed wording is:
 - Quantitation of HbA1c is indicated in patients with:

- (i) a medical condition or ethnic background associated with high rates of diabetes mellitus, or
 - (ii) an Australian type 2 diabetes risk (AUSDRISK) score ≥ 12 .
- △ The Pathology Clinical Committee supports an education program aimed at requesters to help with the implementation of the changes to the item descriptor.

Table 10: Current and proposed new item descriptor for item 66841

Current item descriptor	Proposed new item descriptor
<p>Quantitation of HbA1c (glycated haemoglobin) performed for the diagnosis of diabetes in asymptomatic patients at high risk. (Item is subject to rule 25.)</p>	<p>Quantitation of glycated haemoglobin (HbA1c) performed for the diagnosis of diabetes in asymptomatic patients at increased risk.</p> <p>Tests limited to one test per year if result is < 48 mmol/mol (6.5%). A second test can be performed for confirmation of the diagnosis of diabetes if the initial result is \geq 48 mmol/mol (6.5%). (Item is subject to rule 25; maximum two tests per year.)</p> <p>Explanatory note</p> <p>Quantitation of HbA1c is indicated in patients with:</p> <ul style="list-style-type: none"> (i) a medical condition or ethnic background associated with high rates of diabetes mellitus, or (ii) an Australian type 2 diabetes risk (AUSDRISK) score \geq 12.

Rationale 6

Currently, this item is restricted to one test in a 12-month period; this restriction is inconsistent with guidelines for diagnosing diabetes mellitus. The Australian Diabetes Society Position Statement 2015 states: ‘an HbA1c level \geq 48 mmol/mol (6.5 per cent) suggests that the patient has diabetes mellitus, and a confirmatory test should be performed on another day, ideally as soon as possible and before any lifestyle or pharmacological interventions are commenced’.¹⁹ The RACGP,²² the World Health Organisation²³ and the American Diabetes Association²⁴ provide the same advice.

The Australian Diabetes Society Position Statement (2015) also states: ‘There is an apparent conflict between these practice guidelines and the Medicare regulations (one diagnostic HbA1c test in a 12-month period). Medicare recognises a single elevated HbA1c measurement as establishing a diabetes diagnosis; this entitles the patient to four monitoring HbA1c tests in each subsequent 12-month period.’²⁵

The current MBS restriction requires the requesting health professional to state that a patient has an established diagnosis of diabetes for an asymptomatic patient with elevated HbA1c, when in fact the diagnosis is still to be established. This may have unintended consequences for insurance (e.g. for patients who are not found to have diabetes on this repeat testing).

It is acknowledged that there is inherent imprecision in pathology tests around any specified cut-off level, and that the implications of incorrect diagnosis are quite significant. To be sure of an established diagnosis rather than a suggested diagnosis, it therefore seems reasonable to allow for a confirmatory test to address any concerns of imprecision or error.

The item descriptor currently states 'diabetes' rather than 'diabetes mellitus.' HbA1c screening is not recommended for type 1 diabetes or gestational diabetes. It is acknowledged that other subtypes of diabetes exist.

5.2.4 Quantitation of fructosamine: Item 66557

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Change the item descriptor to highlight that the test should only be conducted when measurement of HbA1c is unreliable. The proposed item descriptor is as follows:
 - Quantitation of fructosamine performed in the management of established diabetes, when measurement of HbA1c is unreliable, to a maximum of four tests in a 12-month period.
- △ Add explanatory notes to guide clinicians in the appropriate use of the item. Explanatory notes are not currently provided for this item. The proposed explanatory notes are as follows:
 - HbA1c measurement is unreliable in non-pregnant patients with:
 - (i) a severe illness such as chronic renal impairment that may shorten the red cell lifespan or
 - (ii) a haemoglobinopathy.

Recommendation 7

The Pathology Clinical Committee provides the following advice and recommendations.

- △ The Pathology Clinical Committee supports the Endocrinology Clinical Committee proposal to change the item descriptor to stipulate the test only be conducted when HbA1c is unreliable. The proposed item descriptor wording is as follows:
 - Quantitation of fructosamine performed in the management of established diabetes, when measurement of HbA1c is unreliable, to a maximum of four tests in a 12-month period.
- △ The Pathology Clinical Committee supports the Endocrinology Clinical Committee proposal to add explanatory notes to the item descriptor to specify the clinical circumstances as follows:
 - HbA1c measurement is unreliable in patients with:
 - (i) a condition that will shorten the red cell lifespan or

- (ii) a haemoglobinopathy.
- △ The Pathology Clinical Committee proposed to remove the wording 'non-pregnant' from the explanatory notes suggested by the Endocrinology Clinical Committee, as HbA1c may also be unreliable in pregnancy.

Table 11: Current and proposed new item descriptor for item 66557

Current item descriptor	Proposed new item descriptor
<p>Quantitation of fructosamine performed in the management of established diabetes – each test to a maximum of 4 tests in a 12 month period.</p>	<p>Quantitation of fructosamine performed in the management of established diabetes, when measurement of HbA1c is unreliable, to a maximum of four tests in a 12-month period.</p> <p>Explanatory note</p> <p>HbA1c measurement is unreliable in patients with</p> <p>(i) a condition that will shorten the red cell lifespan or</p> <p>(ii) a haemoglobinopathy.’</p>

Rationale 7

The most reliable test for managing established diabetes is an HbA1c measurement. Relatively few fructosamine quantitation tests (14,741) were conducted in the 2014–15 financial year.⁸ There was concern that some patients may not be receiving the most reliable monitoring test for the management of their established diabetes. The easiest solution was to change the item descriptor and add explanatory notes to guide clinicians to use an HbA1c measurement instead, when appropriate. This aligns with other recommendations for diabetes-related items, outlined above.

5.2.5 Microalbumin: Item 66560

The following observations have been made with regard to microalbumin tests:

- △ The MBS data show an increased uptake of microalbumin testing, with 1.23 million services in the 2014–15 financial year and an annual growth rate of 6.9% over the last 5 years. Given that Australia has a million people with known diabetes, more than 30% of adult Australians have hypertension, and metabolic syndrome is increasingly frequent, there is little evidence of over-testing.
- △ Review of the geographic distribution of microalbumin testing shows a higher frequency of testing in very remote areas compared with cities (8,815 per 100,000 populations in very remote areas versus 4,743 per 100,000 population in the city). This is appropriate, as the frequency of diabetes and renal failure is markedly increased in Aboriginal and Torres Strait Islander people.

However, MBS data also suggests that the number of tests per patient in some people exceeds best practice: in the 2014–15 financial year, one per cent of patients had more than four tests. These figures have increased by an average of eight per cent and 17 per cent per year, respectively, over the last 5 years. In the same year, 65 patients had 20 or more tests. While very small, this figure has increased by an average of 25 per cent per year over the last five years.⁸

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Consider changing the item descriptor to incorporate the following suggestions:
 - Microalbumin – quantitation in urine. One test annually for:
 - (i) patients with type 1 diabetes, starting 5 years after diagnosis
 - (ii) patients with type 2 diabetes mellitus, from diagnosis
 - (iii) patients with hypertension or metabolic syndrome, from diagnosis.
 - In patients with previously established albuminuria (defined as a urinary albumin:creatinine ratio > 2.4 mg/mmol for men and > 3.4 mg/mmol for women) documented on a previous test and stated on the request form, up to a maximum of four tests per year for
 - (i) confirmation of albuminuria and
 - (ii) monitoring of progression of albuminuria.
- △ Note that these recommendations represent a diabetes and endocrine perspective, and other users such as nephrologists should be considered.

Recommendation 8

The Pathology Clinical Committee provides the following advice and recommendations.

- △ The Pathology Clinical Committee agrees with the clinical recommendations made by the Endocrinology Clinical Committee but suggest that these detailed clinical requirements be contained in the explanatory notes.
- △ The Pathology Clinical Committee suggests including 'renal disease' and that 'testing is restricted to four times within a 12-month period' is also contained within the notes.
- △ The Pathology Clinical Committee recommends that this item should be accompanied by an explanatory note as follows:
 - It is recommended that the following patients should be tested annually:
 - (i) patients with type 1 diabetes, starting 5 years after diagnosis
 - (ii) patients with type 2 diabetes mellitus, from diagnosis
 - (iii) patients with hypertension or metabolic syndrome, from diagnosis
 - (iv) patients with or at risk of renal disease.
 - In patients with previously established albuminuria (defined as a urinary albumin:creatinine ratio > 2.4 mg/mmol for men and > 3.4 mg/mmol for women) documented on a previous test and stated on the request form; up to a maximum of four tests per year may be indicated for confirmation of albuminuria and monitoring of progression of albuminuria.
- △ The Pathology Clinical Committee recommends changing the name of the item descriptor from microalbumin to albumin:creatinine ratio.

Table 12: Current and proposed new item descriptor for item 66560

Current item descriptor	Proposed new item descriptor
<p>Microalbumin – quantitation in urine.</p>	<p>Albumin:creatinine ratio (ACR) – quantitation in urine.</p> <p>Explanatory note</p> <p>The following patients should be tested annually:</p> <p>(i) patients with type 1 diabetes, starting 5 years after diagnosis</p> <p>(ii) patients with type 2 diabetes mellitus, from diagnosis</p> <p>(iii) patients with hypertension or metabolic syndrome, from diagnosis</p> <p>(iv) patients with or at risk of renal disease.</p> <p>Testing is restricted to four times within a 12-month period:</p> <ul style="list-style-type: none"> • in patients with previously established albuminuria (defined as a urinary albumin:creatinine ratio > 2.4 mg/mmol for men and > 3.4 mg/mmol for women) documented on a previous test and stated on the request form; up to a maximum of four tests per year may be indicated for confirmation of albuminuria and monitoring of progression of albuminuria.

Rationale 8

This test is primarily used for two clinical purposes: screening and diagnosis of patients who are at risk of developing albuminuria, and monitoring the progression of albuminuria.

The number of times a single patient is tested within a 12-month period depends on the purpose of the test. The position of the Committee is that the explanatory notes should include the appropriate indications for each test. These indications were determined based on the Committee’s clinical judgment and the relevant literature.²⁶⁻²⁸

The Pathology Clinical Committee also noted that this test was ordered by nephrologists and is also indicated in renal disease. The Committee recognised that the term ‘microalbumin’ is now an outdated term and that the preferred name is albumin:creatinine ratio, reflecting the measurement of albumin corrected for the excretion of creatinine in a random sample. It therefore suggested changing the name of the item descriptor to albumin:creatinine ratio. This also removes the link to absolute concentrations of albumin, which can range from very small amounts to grams per day.

5.3 Quantitation of hormones and hormone-binding proteins: Items 66695–8, 66701, 66704 and 66707

Table 13: Item introduction table for items 66695–8, 66701, 66704 and 66707

Item	Descriptor [date last amended]	Schedule fee	Services FY2014/15	Benefits FY2014/15	Services 5-year annual avg. growth
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.) [1998]	\$30.50	602,001	\$15,579,871	7.1%
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.) [2007]	\$30.50	15,160	\$390,842	0.0%
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.) [2007]	\$13.20	43,783	\$491,811	12.0%
66698	2 tests described in item 66695. (Item is subject to rule 6.) [1998]	\$43.70	171,416	\$6,368,414	5.3%
66701	3 tests described in item 66695. (Item is subject to rule 6.) [1998]	\$56.90	180,259	\$8,755,478	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	\$70.15	129,211	\$7,724,653	6.9%

Item	Descriptor [date last amended]	Schedule fee	Services FY2014/15	Benefits FY2014/15	Services 5-year annual avg. growth
	request form or performs 4 tests and refers the rest to the laboratory of a separate APA.) (Item is subject to rule 6.) [1998]				
66707	5 or more tests described in item 66695. (Item is subject to rule 6.) [1998]	\$83.35	157,655	\$11,191,602	9.8%

Source: Department of Human Services, published data, date of processing.

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Leave these items unchanged.

Recommendation 9

The Pathology Clinical Committee decided to review these items at a later stage and has put them on the work plan. No recommendations are made at this time.

5.4 Thyroid antibodies to tissue antigens: Items 71165–71170

Table 14: Item introduction table for items 71165–70

Item	Descriptor [date last amended]	Schedule fee	Services FY2014/15	Benefits FY2014/15	Services 5-year annual avg. growth
71165	Antibodies to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, salivary gland, skeletal muscle, skin basement membrane and intercellular substance, thyroglobulin, thyroid microsome or thyroid stimulating hormone receptor) – detection, including quantitation if required, of 1 antibody. (Item is subject to rule 6.) [2007]	\$34.55	128,207	\$3,790,200	10.0%
71166	Detection of 2 antibodies described in item 71165. (Item is subject to rule 6.) [2007]	\$47.45	287,101	\$11,658,177	11.3%

Item	Descriptor [date last amended]	Schedule fee	Services FY2014/15	Benefits FY2014/15	Services 5-year annual avg. growth
71167	Detection of 3 antibodies described in item 71165. (Item is subject to rule 6.) [2007]	\$60.30	40,198	\$2,072,476	16.2%
71168	Detection of 4 or more antibodies described in item 71165. (Item is subject to rule 6.) [2007]	\$73.15	6,596	\$408,989	18.5%
71169	A test described in item 71165, 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.) [2007]	\$34.55	18,588	\$544,709	13.7%
71170	Tests described in item 71165, other than that described in 71169, if rendered by a receiving APP – each test to a maximum of 3 tests. (Item is subject to rule 6 and 18.) [2007]	\$12.85	15,399	\$167,907	3.4%

Source: Department of Human Services, published data, date of processing.

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Remove the thyroid antibodies (thyroglobulin, thyroid microsome or thyroid stimulating hormone receptor) from the suite of tests currently covered under items 71165–71168 and create three new distinct thyroid antibodies items, proposed below:
- △ Item A: Thyroglobulin and thyroglobulin antibody (TgAb): for monitoring of patients with thyroid cancer.
- △ Item B: Thyroperoxidase antibody (TPOAb): for diagnosis of patients suspected to have autoimmune thyroid disease; if positive this test should not be repeated.
- △ Item C: TSH receptor antibody (TRAb or TSI): for diagnosis and monitoring of patients with Graves' disease. Up to four tests annually.

Recommendation 10

While supportive of the proposals of the Endocrinology Clinical Committee, the Pathology Clinical Committee is awaiting input from the Immunology Working Group before finalising its proposals for the testing for thyroid antibodies.

There are no recommendations on these items. The Pathology Clinical Committee will further consider thyroid antibodies at a later date.

5.5 Quantitation of products of collagen breakdown or formation: Items 66773 and 66776

Table 15: Item introduction table for items 66773 and 66776

Item	Descriptor [date last amended]	Schedule fee	Services FY2014/15	Benefits FY2014/15	Services 5-year annual avg. growth
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 ¹ is defined in the explanatory notes to Category 2 – Diagnostic Procedures and Investigations of the Medicare Benefits Schedule.) [1998]	\$24.65	43,017	\$906,370	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. [1998]	\$24.65	26,409	\$562,509	10.3%

Source: Department of Human Services, published data, date of processing.

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Leave these items unchanged.

Recommendation 11

The Pathology Clinical Committee provides the following advice and recommendation.

- △ The Pathology Clinical Committee supports the proposal to leave these items unchanged.

¹It was noted that this may be referred to as 'low bone mineral density' in the Schedule, section D1.19 pages 30 and 31, and may require the descriptor to be updated.

Rationale 11

The recommendation is based on the following observation. The MBS items provide clinically required tests, and the high growth rates in service volumes reflect the frequency of osteoporosis in the population and the recent introduction of medications used to treat bone-related disorders. These medications have a potent effect on bone turnover markers.²⁹ This recommendation is to encourage best practice within this area.

A restriction on the maximum number of tests per year was considered; however, there is no consensus within the published literature about the appropriate number of tests per year.³⁰ In the 2014–15 financial year, only 18 per cent and 13 per cent of patients had two or more tests under items 66773 and 66776, respectively.⁸

5.6 Adrenaline and other tests: Items 66779 and 66780

Table 16: Item introduction table for items 66779 and 66780

Item	Descriptor [date last amended]	Schedule fee	Services FY2014/15	Benefits FY2014/15	Services 5-year annual avg. growth
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. [1998]	\$39.95	42,115	\$1,448,373	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.) [2007]	\$39.95	22,010	\$745,570	8.2%

Source: Department of Human Services, published data, date of processing.

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Leave these items unchanged.

Recommendation 12

Quantitation of adrenal hormones will require review by the Committee and has been put on the work plan. No recommendations are made at this time.

5.7 1, 25-dihydroxyvitamin D quantification: Items 66835–7

Table 17: Item introduction table for items 66835–7

Item	Descriptor	Schedule fee	Services FY2014/15	Benefits FY2014/15	Services 5-year annual avg. growth
66835	1, 25-dihydroxyvitamin D – quantification in serum, if the request for the test is made by, or on advice of, the specialist or consultant physician managing the treatment of the patient. [2014]	\$ 39.05	7068	\$234,845	N/A
66836	1, 25-dihydroxyvitamin D – quantification in serum, if: (a) the patient has hypercalcaemia; and (b) the request for the test is made by a general practitioner managing the treatment of the patient. [2014]	\$ 39.05	67	\$2,155	N/A
66837	A test described in item 66835 or 66836 if rendered by a receiving APP. (Item is subject to rule 18.) [2014]	\$39.05	997	\$33,025	N/A

Source: Department of Human Services, published data, date of processing.

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Leave these items unchanged.

Recommendation 13

The Pathology Clinical Committee provides the following advice and recommendation.

- △ The Pathology Clinical Committee supports the Endocrinology Clinical Committee proposal to leave these items unchanged.

Rationale 13

These items were recently reviewed and changed within the MBS Schedule; they do not require further revision at this stage.

5.8 Hormone and other tests: Item 66686

Table 18: Item introduction table for item 66686

Item number	66686
Descriptor [date last amended]	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. [1998]
Schedule fee	\$50.65
Volume of services FY2014/15	4,555
Total benefits paid FY2014/15	\$196,662
Services 5-year (FY2009/10–FY2014/15) annual average growth (CAGR)	7.5%

Source: Department of Human Services, published data, date of processing.

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Leave this item unchanged.

Recommendation 14

The Pathology Clinical Committee provides the following advice and recommendation.

- △ The Pathology Clinical Committee supports the proposal to leave this item unchanged.

Rationale 14

- △ This item contains an unrelated bundle of tests; these tests are required and should remain unchanged on the MBS.

5.9 Quantification in saliva of cortisol: Items 66711–2 and 66714–5

Table 19: Item introduction table for items 66711–2 and 66714–5

Item	Descriptor	Schedule fee	Services FY2014/15	Benefits FY2014/15	Services 5-year annual avg. growth
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.) [2005]	\$30.15	2286	\$59,115	58.9%
66712	Two tests described in item 66711. (Item is subject to rule 6.) [2005]	\$43.05	201	\$7,330	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.) [2007]	\$30.15	194	\$4,967	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.) [2007]	\$12.85	151	\$1,720	2.0%

Source: Department of Human Services, published data, date of processing.

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Leave these items unchanged.

Recommendation 15

The Pathology Clinical Committee provides the following advice and recommendation.

- △ The Chemical Working Group supports the proposal to leave these items unchanged.

Rationale 15

These tests are clinically relevant and should remain unchanged from their current form in the MBS Schedule.

5.10 Electrophoresis of serum: Item 66539

Table 20: Item introduction table for item 66539

Item number	66539
Descriptor [date last amended]	Electrophoresis of serum for demonstration of lipoprotein subclasses, if the cholesterol is > 6.5 mmol/l and triglyceride >4.0 mmol/l or in the diagnosis of types iii and iv hyperlipidaemia. (Item is subject to rule 25.) [1998]
Schedule fee	\$30.60
Volume of services FY2014/15	559
Total benefits paid FY2014/15	\$15,251
Services 5-year (FY2009/10–FY2014/15) annual average growth (CAGR)	3.8%

Source: Department of Human Services, published data, date of processing.

Advice from Endocrinology Clinical Committee

The Endocrinology Clinical Committee proposed the following:

- △ Delete this item from the MBS.

Recommendation 16

The Pathology Clinical Committee provides the following advice and recommendations.

- △ The Pathology Clinical Committee supports the proposal to remove the item 66539.
- △ The Pathology Clinical Committee recommends a new item for the investigation of familial hypercholesterolaemia be introduced into the table. This test should be a genetic test, including mutations of the LDL-receptor gene, PCSK9 gene or mutations of the apolipoprotein B gene, and should be reviewed by the genetics committee, including appropriate indications for testing.
- △ The Committee recommends a new item for the investigation of markedly high mixed hyperlipidaemia, investigating apoE genotype, be introduced into the table subsequent to genetics committee suggestions.

Rationale 16

The Committee noted that electrophoresis of lipoprotein E is now superseded by genotyping. The Committee also considered that there will be a small group of patients with hyperlipidaemia who will not be diagnosed with genotyping. In addition apolipoprotein E (apo E4) predicts an increased risk of Alzheimer's disease. The evidence for a clinical benefit is not as strong as for the genetic testing for familial hypercholesterolaemia (see below) and is beyond the scope of the Committee's review of the MBS Schedule for chemical-pathology items.

There is no item in the MBS Schedule for genotyping for patients with familial hypercholesterolaemia, the most common autosomal dominant lipid disorder (frequency 1:200 to 1:400). There is strong evidence to support the addition of new items for investigation of lipid disorders by genetic testing in Australia; this is beyond the scope of the Committee's review of the MBS Schedule for chemical pathology items.

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7. Glossary

Term	Description
APA	Approved pathology authority.
APP	Approved pathology provider.
CAGR	Compound annual growth rate, or the average annual growth rate over a specified time period.
Change	Describes when the item and/or its services will be affected by the recommendations. This could result from a range of recommendations, such as: (i) specific recommendations that affect the services provided by changing item descriptors or explanatory notes, (ii) the consolidation of item numbers, and (iii) splitting item numbers (e.g. splitting the current services provided across two or more items).
Delete	Describes when an item is recommended for removal from the MBS and its services will no longer be provided under the MBS.
FY	Financial year
GP	General practitioner
HbA1c	Glycated haemoglobin
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	Use of MBS services for purposes other than those intended. This includes a range of behaviours, from failing to adhere to particular item descriptors or rules through to deliberate fraud.
Low-value care	Use of an intervention that evidence suggests confers little benefit or no benefit to patients; or when the risk of harm from the intervention exceeds the likely benefit; or, more broadly, when the added costs of the intervention do not provide proportional added benefits.
MBS	Medicare Benefits Schedule
MBS item	An administrative object listed in the MBS and used for the purposes of claiming and paying Medicare benefits, consisting of an item number, service descriptor and supporting information, schedule fee and Medicare benefits.

Term	Description
MBS service	The actual medical consultation, procedure or test to which the relevant MBS item refers.
MSAC	Medical Services Advisory Committee
Multiple services rules	A set of rules governing the amount of Medicare benefit payable for multiple services provided to a patient at the same attendance (same day).
New service	Describes when a new service has been recommended, with a new item number. In most circumstances these will need to go through MSAC. It is worth noting that implementation of the recommendation may result in more or fewer item numbers than specifically stated.
No change or unchanged	Describes when the services provided under these items will not be changed or affected by the recommendations. This does not rule out small changes in item descriptors (e.g. references to other items, which may have changed as a result of the MBS Review or prior reviews).
Obsolete services/items	Services that should no longer be performed, as they do not represent current clinical best practice and have been superseded by superior tests or procedures.
OGCT	Oral glucose challenge test
OGTT	Oral glucose tolerance test
Pathology episode coning	An arrangement governing the amount of Medicare benefit payable for multiple pathology services performed in a single patient episode. When more than three pathology services are requested by a GP in a patient episode, the benefits payable are equivalent to the sum of the benefits for the three items with the highest schedule fees.
PBS	Pharmaceutical Benefits Scheme
RACGP	Royal Australian College of General Practitioners
TFT	Thyroid function tests
The Taskforce	MBS Review Taskforce
TSH	Thyroid stimulating hormone

Appendix A Endocrine-related pathology test items– Recommendations list

Table A1: *Endocrine pathology MBS items considered by the committee*

Item	Current descriptor	Recommendation	Page reference
66539	Electrophoresis of serum for demonstration of lipoprotein subclasses, if the cholesterol is > 6.5 mmol/L and triglyceride >4.0 mmol/L or in the diagnosis of types iii and iv hyperlipidaemia – (Item is subject to rule 25).	Delete	51
66542	Oral glucose tolerance test for the diagnosis of diabetes mellitus that includes: (a) administration of glucose; (b) at least 2 measurements of blood glucose; and if performed (c) any test described in item 66695.	Change	30
66545	Oral glucose challenge test in pregnancy for the detection of gestational diabetes that includes: (a) administration of glucose; and (b) 1 or 2 measurements of blood glucose; and (c) (if performed) any test in item 66695.	Delete	31
66548	Oral glucose tolerance test in pregnancy for the diagnosis of gestational diabetes that includes:	Change	31
66551	Quantitation of glycated haemoglobin performed in the management of established diabetes – (item is subject to rule 25).	Change	32
66554	Quantitation of glycated haemoglobin performed in the management of pre-existing diabetes where the patient is pregnant – including a service in item 66551 (if performed) – (Item is subject to rule 25).	Change	32
66557	Quantitation of fructosamine performed in the management of established diabetes – each test to a maximum of 4 tests in a 12 month period.	Change	36
66560	Microalbumin – quantitation in urine.	Change	38
66686	Performance of 1 or more of the following procedures: (a) growth hormone suppression by	No change	48

Item	Current descriptor	Recommendation	Page reference
	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.		
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.)	No change	42
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.)	Pending	42
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.)	Pending	42
66698	2 tests described in item 66695. (Item is subject to rule 6.)	Pending	42
66701	3 tests described in item 66695. (Item is subject to rule 6.)	Pending	42
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.)	Pending	42

Item	Current descriptor	Recommendation	Page reference
66707	5 or more tests described in item 66695. (Item is subject to rule 6.)	Pending	42
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.)	No change	49
66712	Two tests described in item 66711. (Item is subject to rule 6.)	No change	49
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.)	No change	49
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.)	No change	49
66716	TSH quantitation	Change	16
66719	Thyroid function tests (comprising the service described in item 66716 and 1 or more of the following tests – free thyroxine, free t3, for a patient, if at least 1 of the following conditions is satisfied: (a) the patient has an abnormal level of TSH; (b) the tests are performed: (i) for the purpose of monitoring thyroid disease in the patient; or (ii) to investigate the sick euthyroid syndrome if the patient is an admitted patient; or (iii) to investigate dementia or psychiatric illness of the patient; or (iv) to investigate amenorrhoea or infertility of the patient; (c) the medical practitioner who requested the tests suspects the patient has a pituitary dysfunction; (d) the patient is on drugs that interfere with thyroid hormone metabolism or function. (Item is subject to rule 9.)	Change	23
66722	TSH quantitation described in item 66716 and 1 test described in item 66695. (This fee applies where 1	Change	23

Item	Current descriptor	Recommendation	Page reference
	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.)		
66723	Tests described in item 66722, that is, TSH quantitation and 1 test described in 66695, 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.)	Change	23
66724	Tests described in item 66722, if rendered by a receiving APP, other than that described in 66723. It is to include a quantitation of TSH – each test to a maximum of 4 tests described in item 66695. (Item is subject to rule 6 and 18.)	Change	23
66725	TSH quantitation described in item 66716 and 2 tests described in item 66695. (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs the only 3 tests specified on the request form or performs 3 tests and refers the rest to the laboratory of a separate APA.) (Item is subject to rule 6.)	Change	23
66728	TSH quantitation described in item 66716 and 3 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.)	Change	23
66731	TSH quantitation described in item 66716 and 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 5 tests specified on the request form or performs 5 tests and refers the rest to the laboratory of a separate APA.) (Item is subject to rule 6.)	Change	23

Item	Current descriptor	Recommendation	Page reference
66734	TSH quantitation described in item 66716 and 5 tests described in item 66695. (This fee applies where 1 laboratory, or more than 1 laboratory belonging to the same APA, performs 6 or more tests specified on the request form.) (Item is subject to rule 6.)	Change	23
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.)	No change	45
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.	No change	45
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.	Pending	46
66780	A test described in item 66779 if rendered by a receiving APP – 1 or more tests. (Item is subject to rule 18.)	Pending	46
66835	1, 25-dihydroxyvitamin D – quantification in serum, if the request for the test is made by, or on advice of, the specialist or consultant physician managing the treatment of the patient.	No change	47
66836	1, 25-dihydroxyvitamin D—quantification in serum, if: (a) the patient has hypercalcaemia; and (b) the request for the test is made by a general practitioner managing the treatment of the patient.	No change	47

Item	Current descriptor	Recommendation	Page reference
66837	A test described in item 66835 or 66836 if rendered by a receiving APP. (Item is subject to rule 18.)	No change	47
66841	Quantitation of HbA1c (glycated haemoglobin) performed for the diagnosis of diabetes in asymptomatic patients at high risk. (Item is subject to rule 25.)	Change	33
71165	Antibodies to tissue antigens (acetylcholine receptor, adrenal cortex, heart, histone, insulin, insulin receptor, intrinsic factor, islet cell, lymphocyte, neuron, ovary, parathyroid, platelet, salivary gland, skeletal muscle, skin basement membrane and intercellular substance, thyroglobulin, thyroid microsome or thyroid stimulating hormone receptor) – detection, including quantitation if required, of 1 antibody. (Item is subject to rule 6.)	Pending	43
71166	Detection of 2 antibodies described in item 71165. (Item is subject to rule 6.)	Pending	43
71167	Detection of 3 antibodies described in item 71165. (Item is subject to rule 6.)	Pending	43
71168	Detection of 4 or more antibodies described in item 71165. (Item is subject to rule 6.)	Pending	43
71169	A test described in item 71165, 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.)	Pending	43

Appendix B Summary for consumers

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

Recommendation 1: TSH (thyroid-stimulating hormone)

Item	What it does	Committee recommendation	What would be different	Why
66716	Measures blood levels of the hormone that stimulates the thyroid gland, to assess thyroid disease.	Include guidance on when the test is appropriate for doctors to request.	The test would be avoided in patients who do not show thyroid disease symptoms, unless they are pregnant or at high risk of thyroid disease.	To align testing with current medical guidelines, such as the RACGP Choosing Wisely recommendations.

Recommendation 2: TFTs (thyroid function tests)

Item	What it does	Committee recommendation	What would be different	Why
66719	Measures blood levels of thyroid hormones to assess thyroid disease.	Include guidance on when the test is appropriate for doctors and pathologists to request.	The test would be avoided in patients when the results can be unreliable and misleading.	To align testing with current medical guidelines.

Recommendation 3: New item for TFTs

Item	What it does	Committee recommendation	What would be different	Why
New item	Measures all thyroid hormone levels.	Create a new item that includes the measurement of all thyroid hormone levels in patients with totally suppressed thyroid-stimulating hormone (TSH).	An additional test would be available that measures the levels of all thyroid hormones in patients with totally suppressed TSH.	For most patients TFT tests don't include testing all thyroid hormones, but for some with suppressed TSH the additional tests will offer more information about the severity and prognosis of their overactive thyroid and identify patients with toxic levels of thyroid hormones.

Recommendation 4: Oral glucose tolerance and challenge tests

Item	What it does	Committee recommendation	What would be different	Why
66545	Measures blood sugar levels to test for diabetes mellitus in pregnancy.	Remove this item from the MBS.	This item would no longer be available.	This item is out of date.
66542, 66548	Measures blood sugar levels to test for diabetes mellitus.	Include use in pregnant women and certain specific patient groups, plus guidance on who those specific patient groups are.	The test would be able to be done in pregnant and specific patient groups.	To align testing with current medical guidelines as recommended by the Australian Diabetes in Pregnancy Society.

Recommendation 5: Quantitation of glycated haemoglobin (how much oxygen-carrying protein in red blood cells is bound to sugar)

Item	What it does	Committee recommendation	What would be different	Why
66551	Measures blood sugar levels to test for diabetes mellitus.	Restrict to a maximum of four tests per year.	Test would be limited to four times per year per patient.	To align testing with the current Health Insurance Regulation 2015.
66554	Measures blood sugar levels to test for diabetes mellitus.	Restrict to a maximum of six tests per year.	The test would be limited to six times per year per patient.	To align testing with the current Health Insurance Regulation 2015.

Recommendation 6: Quantitation of glycated haemoglobin (how much oxygen-carrying protein in red blood cells is bound to sugar)

Item	What it does	Committee recommendation	What would be different	Why
66841	Measures blood sugar levels to test for diabetes mellitus.	Specify medical situations in which the test should be used. Increase the number of tests to a maximum of two per year.	The test would be prevented from being used to see if diabetes is present, except in pregnant women or people at high risk of thyroid disease.	To align the number of tests with current medical guidelines, such as the Australian Diabetes Society Position Statement 2015 as well as the RACGP, World Health Organisation and American Diabetes Association's advice.

Recommendation 7: Quantitation of fructosamine (blood fructose level)

Item	What it does	Committee recommendation	What would be different	Why
66557	Measures blood fructose (sugar) levels to test for diabetes mellitus.	Specify when the test should be used and provide guidance on appropriate use of this test.	Doctors will have clear guidance on when they can use this test. The test would only be used in appropriate medical situations.	The test may not have been used optimally.

Recommendation 8: Microalbumin (albumin is a protein that, when found in urine, indicates kidney damage due to diabetes)

Item	What it does	Committee recommendation	What would be different	Why
66560	Measures levels of albumin and creatinine in urine to test for diabetes mellitus.	Change the title of the test to albumin:creatinine ratio and specify medical situations in which the test is appropriate.	The Medical Benefits Schedule (MBS) would be updated to use more current medical terms. The test would only be used in appropriate medical situations.	To update the MBS and make it current.

Recommendation 9: Quantitation of hormones and hormone-binding proteins

Item	What it does	Committee recommendation	What would be different	Why
66695–66698, 66701, 66704, 66707	Measures the levels of various hormones (which regulate body functions) and the proteins that regulate their action.	To review these items at a later stage. No recommendations at this time.	No difference at this stage.	No recommendations made at this time.

Recommendation 10: Thyroid antibodies to tissue antigens

Item	What it does	Committee recommendation	What would be different	Why
71165–71170	Identifies thyroid cancer or immune response against the thyroid gland.	Awaiting input from the Immunology Working Group. No recommendations at this time.	No difference at this stage.	No recommendations made at this time.

Recommendation 11: Quantitation of products of collagen breakdown or formation

Item	What it does	Committee recommendation	What would be different	Why
66773, 66776	Measures bone density in patients with bone diseases.	Leave these items unchanged.	No difference.	These items are recommended to be left unchanged.

Recommendation 12: Adrenaline and other tests

Item	What it does	Committee recommendation	What would be different	Why
66779, 66780	Measures level of adrenal gland hormones.	Requires review by the Committee. No recommendations at this time.	No difference at this stage.	No recommendations made at this time.

Recommendation 13: 1, 25-dihydroxivitamin D quantification

Item	What it does	Committee recommendation	What would be different	Why
66835, 66836, 66837	Measures the amount of vitamin D in the blood.	Leave these items unchanged.	No difference.	These items were recently reviewed and changed within the MBS Schedule; they do not require further revision at this stage.

Recommendation 14: Hormones and other tests

Item	What it does	Committee recommendation	What would be different	Why
66686	Testing for irregular production of growth hormone, cortisol or chloride in sweat, indicating underlying diseases.	Leave these items unchanged.	No difference.	This item is recommended to be left unchanged.

Recommendation 15: Quantification in saliva of cortisol

Item	What it does	Committee recommendation	What would be different	Why
66711–66712, 66714–66715	Tests saliva for abnormally high or low cortisol levels that indicate underlying diseases	Leave these items unchanged.	No difference.	These items are recommended to be left unchanged.

Recommendation 16: Electrophoresis of serum

Item	What it does	Committee recommendation	What would be different	Why
66539	Tests for hereditary high cholesterol by measuring levels of cholesterol components.	Remove this item from the MBS.	This item would no longer be available.	This item is out of date and has been superseded by genetic testing.
New item	Tests for hereditary high cholesterol by checking for mutations in certain genes that produce components of the cholesterol system.	New genetic test for hereditary high cholesterol.	New test would replace existing outdated test.	To update the MBS and make it current.
New item	Tests for markedly high cholesterol level by checking for mutations in the gene that produces a key cholesterol component.	New genetic test for markedly high cholesterol.	New test would replace existing outdated test and has added benefit of predicting increased risk of Alzheimer's disease.	To update the MBS and make it current.