
**Medicare Benefits Schedule Review
Taskforce**

**Report from the Pathology Clinical
Committee
(Tissue (Anatomical)
Pathology/Cytology)**

May 2017

Important note

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

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

△ Stakeholder feedback.

Then

△ Consideration by the MBS Review Taskforce.

Then, *if endorsed*, consideration by

△ The Minister for Health.

△ The Government.

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

Confidentiality of comments:

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

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1. Executive summary

The Medicare Benefits Schedule (MBS) Review Taskforce (the Taskforce) is undertaking a program of work that considers how more than 5700 items on the MBS can be aligned with contemporary clinical evidence and practice and improves 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 The Taskforce will also seek to identify any services that may be unnecessary, outdated or potentially unsafe.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 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 and then provide recommendations to the Taskforce in a Review Report. The Taskforce will consider the Review Report from Clinical Committees and stakeholder feedback before making recommendations to the Minister for consideration by Government.

1.1 MBS Review process

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

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

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

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

1.2 The Pathology Clinical Committee

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

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

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

The Anatomical and Cytology Working Group is one of six clinical working groups established to support the work of Pathology Clinical Committee (the Committee). The Committee was established in 2016 to make recommendations to the MBS Review 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 tissue (anatomical) and cytology pathology items as a priority review.

1.3 Recommendations

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

The Committee recommends that a number of items be significantly amended to ensure the clinical criteria are appropriate. Most of the changes are structural changes to the organisation of items, rather than changes to the items themselves.

Changes to the histopathology (tissue pathology) Complexity Levels Table

- △ 78 changes to the Complexity Table are recommended in order to provide equity of classification of comparable work.
- △ The mandatory use of structured reports for complexity 6 and 7 cancer cases is recommended.

The Complexity Table classifies tissue specimens into six complexity levels with different MBS rebates. Recommendations include:

- increasing or decreasing some complexity levels;
- splitting current listings to separate examinations of neoplastic lesions from other examinations;
- deleting some listings and pooling with other listings of similar types; and
- clarifying the requirements for certain specimen types.

These proposed changes are intended to provide equity between different organ systems and work of the same difficulty. To drive best practice, the use of structured reports has been mandated for complex cancer cases.

Item tiering and coning in tissue pathology services

- △ Removal of current tissue pathology item tiering is recommended, with a single item for specimens of each complexity level and a modified remuneration model.

Currently there are different tiered items for specimens of complexity levels 3 and 4, with reduced effective rebate per specimen with increasing numbers of specimens. There is no capacity to fund multiple specimens of complexity levels 2, 5, 6 or 7.

- △ Removal of Rule 13 is recommended, with alternate funding strategy proposed.

Rule 13 dictates that a billing code for a specimen of higher complexity overrides a billing code for lower-complexity item/s, unless the dollar value of a tiered lower-complexity item is greater.

There are no economies of scale in the processing and examination of tissue specimens, and the current coning rules are particularly inequitable for complex specimens. Funding strategies, including the 'Surgical' model (where the first item is rebated at 100%, the second at 50% and subsequent items at 25%), have been examined as an alternative to renegotiating the rebate for each item.

Item tiering and coning in cytology services

- △ Abolition of current item tiering is recommended, with a single item for each examination type.

- △ Removal of Rule 13 is recommended, with alternate funding strategy proposed.

Rule 13 dictates that a billing code for a specimen of higher complexity overrides a billing code for lower-complexity item/s, unless the dollar value of a tiered lower-complexity item is greater. As with tissue specimens, there are no economies of scale in the processing and examination of cytological specimens, and the current coning rules are particularly

inequitable for multiple fine-needle biopsy specimens. Funding strategies, including the 'Surgical' model (where the first item is rebated at 100%, the second at 50% and subsequent items at 25%), have been examined as an alternative to renegotiating the rebate for each item.

Alignment and coning of immunohistochemistry and immunocytochemistry items

- △ Alignment of immunohistochemistry and immunocytochemistry items by removal of the latter is recommended.
- △ Removal of tiering of immunohistochemistry items is recommended, with alternative strategy proposed.
- △ Retention of simple and complex immunohistochemistry items is recommended.
- △ Creation of a new item for chromogenic in situ hybridization item (exclusive of current in situ hybridization assays on the Genetics schedule) is recommended.

There is no necessity for separate immunocytochemistry items for the same test. Current complex tiering rules are inequitable and should be replaced by an alternative funding model.

Assays of different complexity involving immunohistochemical detection should be recognized. Detection of certain targets by in situ hybridization with chromogenic detection is required for tumour classification and should be recognized by a separate item in view of increased costs and complexity.

Electron microscope rebate

- △ An immediate increase in the rebate is recommended commensurate with the work involved. This specialised low-volume item has been markedly underfunded for many years to the detriment of electron microscopy services.

Frozen-section items

- △ Removal of current tiering for frozen-section examinations is recommended. The current tiering of frozen section rebates is inequitable and is impacting on the availability of the service.

Second-opinion items

- △ Splitting of the current items to differentiate between pathologist-initiated and non-pathologist-initiated requests is recommended.
- △ Minor changes to the item descriptor and explanatory notes are recommended. Current wording has caused confusion and poor uptake of the item. The recommended changes are to ensure that the items are used appropriately.

Pathologist-determinable items

- △ Clarification of the pathologist-determinable status of MBS items is recommended.
- △ Consideration of the current limitations to pathologist-determinable biomarker testing by MSAC is recommended.

The current inability of pathologists to cross-refer biomarker testing causes logistical problems and adversely affects timely testing. The pathologist-determinable status of items should be clearly indicated on the MBS.

1.4 Consumer engagement and impact

The Committee includes experienced and committed health practitioners and consumer representatives. This section summarises the report's key recommendations from a consumer

perspective. It aims to make it easier for health consumers and members of the general public to understand the report's recommendations.

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

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

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

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

The consumer representatives used the following framework to assess recommendations:

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

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

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

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

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

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

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

2. About the Medicare Benefits Schedule (MBS) Review

2.1 Medicare and the MBS

What is Medicare?

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

Introduced in 1984, Medicare has three components, being free public hospital services for public patients, subsidised drugs covered by the Pharmaceutical Benefits Scheme, and subsidised health professional services listed on the Medicare Benefits Schedule (MBS).

What is the Medicare Benefits Schedule (MBS)?

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

2.2 What is the MBS Review Taskforce?

The Government has established an MBS Review Taskforce (the Taskforce) to review all 5,700 MBS items to ensure they are aligned with contemporary clinical evidence and practice and improve health outcomes for patients.

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 where possible. Although the Medical Services Advisory Committee (MSAC) plays a crucial role in thoroughly evaluating new services, the vast majority of existing MBS items pre-date this process and have never been reviewed.
- △ **Value for the individual patient**—another core objective of the Review is to have a 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 provide advice on all aspects which 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 an MBS structure that could better accommodate changing health service models. The Taskforce has made a conscious decision to be ambitious in its approach and seize this unique opportunity to recommend changes to modernise the MBS on all levels, from the clinical detail of individual items, to administrative rules and mechanisms, to structural, whole-of-MBS issues. The Taskforce will also develop a mechanism for the ongoing review of the MBS once the current Review is concluded.

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

The Taskforce asked all committees to review MBS items using a framework based on Appropriate Use Criteria accepted by the Taskforce (Elshaug et al., 2012). The framework consists of seven steps:

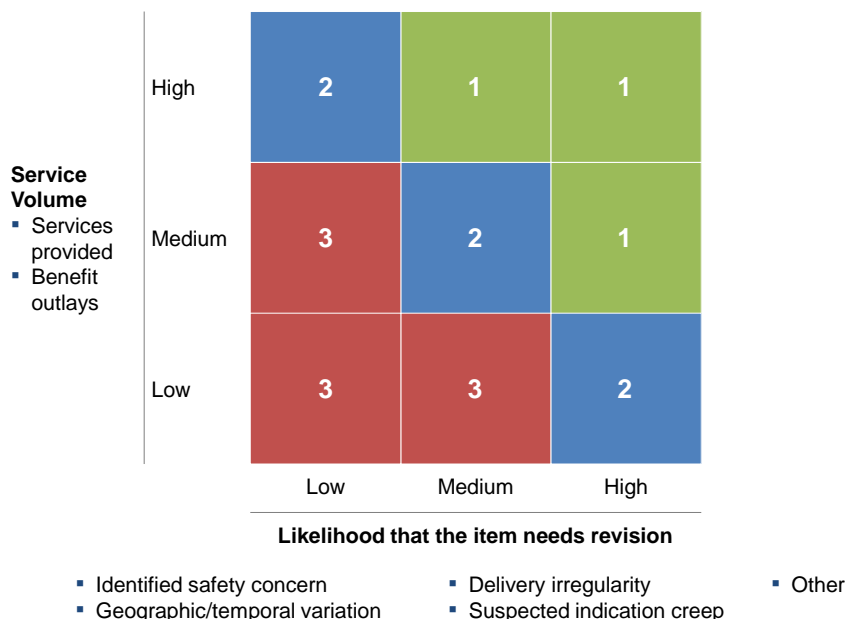
1. Develop an initial fact base for all items under consideration, drawing on the relevant data and literature.
2. Identify items that are obsolete, are of questionable clinical value, are misused and/or pose a risk to patient safety. This step includes prioritising items as 'priority 1,' 'priority 2'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

All MBS items will be reviewed during the course of the MBS Review. However, given the breadth of and timeframe for the Review, each Clinical Committee had to develop a work plan and assign priorities, keeping in mind the objectives of the Review. Committees used a robust prioritisation methodology to focus their attention and resources on the most important items requiring review. This was determined based on a combination of two standard metrics, derived from the appropriate use criteria (Elshaug et al, 2012):

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

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

Figure 1. Prioritisation matrix.



3. About the Pathology Clinical Committee

The Pathology Clinical Committee (the Committee) was established in 2016 to make recommendations to the MBS Review Taskforce on the review of MBS items within its remit, based on rapid evidence review and clinical expertise. The Taskforce has asked the Committee to review anatomical pathology and cytology items as a priority review.

3.1 Committee members

Table 1: Pathology Clinical Committee members

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

3.2 Anatomical and Cytology Working Group

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.

Table 2: Anatomical and Cytology Working Group members

Name	Position/organisation	Declared conflict of interest
Associate Professor Adrienne Morey	ACT Pathology (Public Sector): formerly SydPath, St Vincent's (Catholic)	Practising Anatomical Pathologist
Dr Nick Musgrave	Sullivan Nicolaides Pathology (Sonic)	Practising Anatomical Pathologist
Dr Chris Douglas	Histopath Specialist Pathology	Practising Anatomical Pathologist
Professor Yee Khong	SA Pathology	Practising Anatomical Pathologist
Professor Danform Lim	General Practitioner Representative	Nil relevant
Mr John Stubbs	Consumer consultant	Nil relevant

Conflicts of interest

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.

3.3 Areas of responsibility of the Committee

The Committee was assigned 43 MBS Tissue Pathology and Cytology items. A complete list of these items can be found in Appendix A.

3.4 Summary of the Committee's review approach

The Committee reviewed 43 Tissue Pathology and Cytology items on the MBS, and made recommendations to the Taskforce and relevant committees, based on rapid evidence review and clinical expertise.

The Committee also liaised with the Genetics Working Group on items with relevance to both groups (i.e. items relating to biomarker testing on tissue samples).

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

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

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

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

An inclusive set of stakeholders is now engaged in consultation on the recommendations resulting from this process, which are outlined in this report. Following this period of consultation, the Committee will consider stakeholder feedback before finalising the recommendations and presenting them to the Taskforce. The Taskforce will consider the report and stakeholder feedback before making recommendations to the Minister for Health for consideration by the Government.

4. Recommendations

The 43 Anatomical (Tissue) Pathology and Cytology-related pathology test items accounted for about 3.3 million and 2.1 million services, respectively, in the 2014–15 financial year, and \$291million and \$47 million in benefits. Substantial changes are currently under way in the Cytology sector due to changes in the National Cervical Screening Program.

Most of the Committee’s recommendations relate to revising the structure of the MBS for Histopathology (Tissue Pathology) and Cytology, currently complicated by inequitable tiering and coning rules. Background information on the status quo is therefore provided before a detailed discussion of the specific recommendations.

Background

The Tissue Pathology and Cytology services listed in the MBS (items 72813-72859 & 73043-73067) essentially consist of only two key procedures—histological examination (involving formalin-fixed paraffin embedded tissues) and cytological examination (involving dispersed cells fixed on slides), the latter being subdivided into gynaecological and non-gynaecological cytology.

A small number of additional items for ancillary investigations (frozen section, electron microscopy, immunohistochemistry/ immunocytochemistry) are also listed. Recently, items for second opinions in morphological pathology have also been added.

In Tissue Pathology, the multiplicity of current MBS items relate to examination of specimen types of different complexity (levels 2–7, as defined in the Complexity Table included at the end of the Pathology listing). In addition, complexity levels 3 and 4 include tiering related to the number of specimens (item for one specimen, item for 2–4 specimens, item for 5–7 specimens, etc.).

Superimposed over this is Rule 13, which dictates that a billing code for a specimen of higher complexity overrides (‘trumps’) a billing code for lower-complexity item/s, unless the dollar value of a tiered lower-complexity item is greater. The Cytology component of the MBS likewise includes a variety of items related to multiples of the basic types of examination.

This complicated system has numerous intrinsic flaws, and addressing these issues has been the main focus of the Anatomical Pathology/Cytology Working Group.

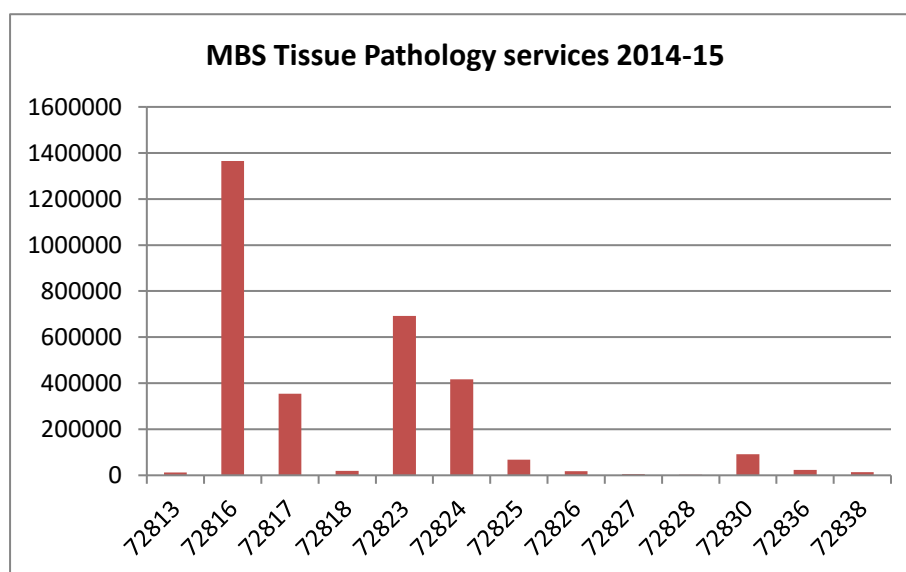
Tissue Pathology service data

Tissue Pathology item service data are shown in *Table 3* below and represented graphically in *Figure 2*. The majority of rebated specimens are simple single skin biopsies (level 3: 72816) and gastrointestinal biopsies (level 4: 72823, 72824, etc.).

Table 3: 2014/15 MBS Tissue Pathology item service /benefit data

Item number	Brief description	Total benefits paid 2014–15	Number of services 2014–15	% of total histology items	% specialist-ordered
72813	L2: 1+	\$690 034.65	12 105	0.4	61.3
72816	L3: 1	\$99 857 964.89	1364 447	44.3	23.9
72817	L3: 2–4	\$29 125 992.80	354 178	11.5	30
72818	L3: 5+	\$1 706 094.65	18 997	0.6	45.4
72823	L4: 1	\$54 375 409.43	691 687	22.5	68.8
72824	L4: 2–4	\$46 005 706.98	416 644	13.5	88.7
72825	L4: 2–7	\$9 441 084.85	67 847	2.2	96.6
72826	L4: 8–11	\$2 742 752.45	18 338	0.6	97.7
72827	L4: 12–17	\$804 795.45	4 988	0.2	98.3
72828	L4: 18+	\$414 761.50	2 431	0.1	94.1
72830	L5: 1+	\$20 102 689.29	91 527	3.0	71.6
72836	L6: 1+	\$7 372 039.32	23 468	0.8	98.3
72838	L7: 1+	\$4 870 472.80	13 882	0.5	99.5
		\$277 509 799.10	3 080 539		48.27

Figure 2. 2014/15 MBS Tissue Pathology item service data



To analyse the impact of Tissue Pathology item coning/ tiering on laboratories, and the impact of possible changes to the complexity table, coned and unconed data was collected from four separate laboratories (A–D), three teaching hospitals (two public and one Schedule 3) and a large state-wide private practice.

This data is not available via the DHS, as pre-coning takes place before submission of MBS claims. The data analysis is based on specimen type, diagnosis and nominal billings (according to MBS complexity and coning) rather than actual claims and, in the interests of simplicity, does not include additional items for ancillary investigations (immunohistochemistry, frozen sections, genetic testing, electron microscopy, etc.), autopsy-related testing and requests for second opinions. The parameters of the data collected are shown in *Table 4* below.

Table 4: Parameters of data collected from four independent laboratories

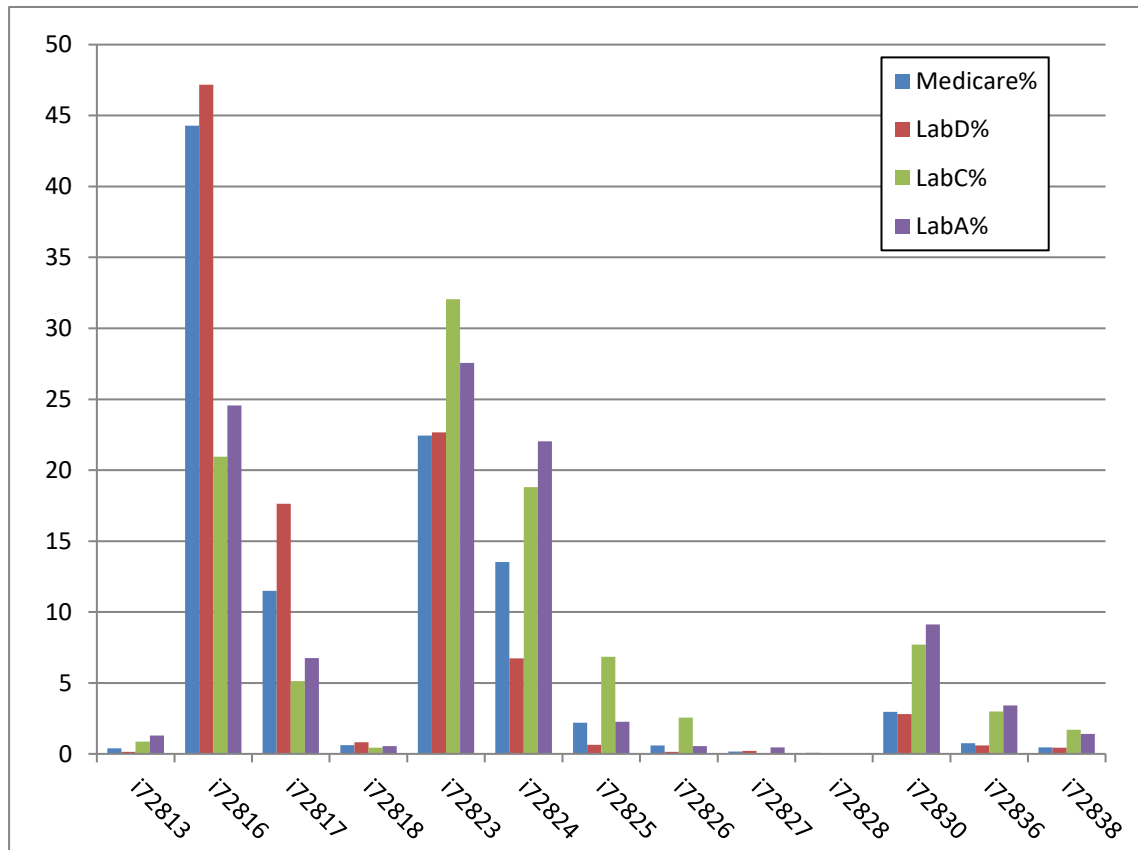
Lab	Status	Accessions [#] analysed	Specimens analysed	Time period
A	Metropolitan Schedule 3 teaching hospital with ~50% external private referrals	8 518	17 230	8 months, 2011
B	Metropolitan public teaching hospital*	673	1 722	2 weeks, July 16
C	Regional public teaching hospital with ~30% external private referrals	234	475	2 days, Nov 16
D	Large state-wide private laboratory with metropolitan, regional and rural referrals	11 118	16 971	1 week, Jan17

*Data from Laboratory B was presented in the form of a (prize winning) poster at the Royal College of Pathologists of Australasia (RCPA) Pathology Update (Buzacott, 2017) ⁱⁱ

[#] An Accession relates to all specimens received in a single patient episode (as part of a single request/referral)

The distribution (%) of coned item codes from three different laboratories compared with the aggregate MBS data (2014–15) is show in *Figure 3* below. Data collected over a week from the state-wide private laboratory (D) obviously most closely reflects the overall Medicare data.

Figure 3. Comparison of distribution of histology billing: overall Medicare (%) compared with Labs A, C and D. *



* Incomplete data available from Lab B not included.

Cytology Service Data

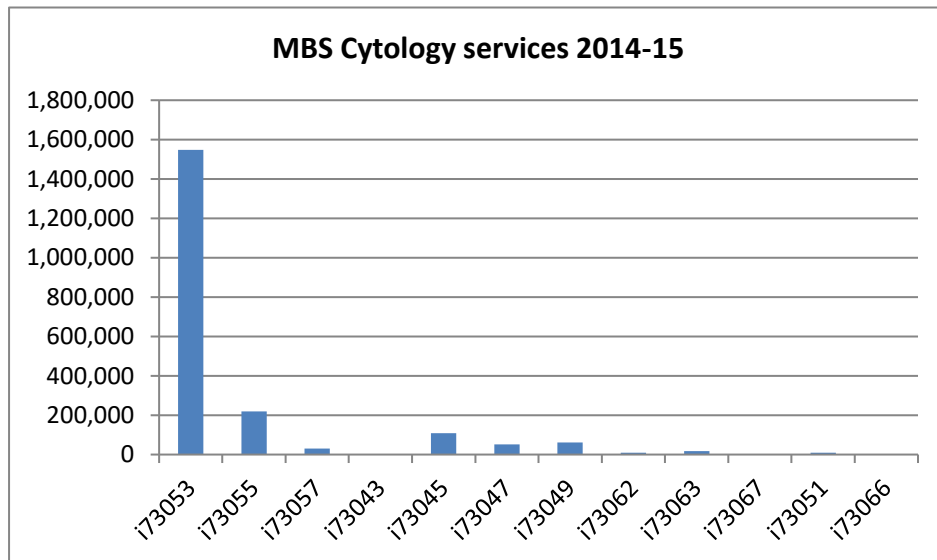
Cytology item service data is shown in *Table 5* below and represented graphically in *Figure 4*. The item numbers have been reordered to show logical relationships between items.

Table 5. 2014/15 MBS Cytology item service / benefit data

Item number	Summary item descriptor	MBS Fee	Total benefits paid 2014–15	Number of services 2014–15	Specialist-requested
73053	Cervical Pap	\$19.45	\$25 708 900	1 547 997	8.6%
73055	Cervical Pap - history or symptoms	\$19.45	\$3 644 749	219 364	26.1%
73057	Vaginal Pap	\$19.45	\$499 321	29 916	32.2%
73043	Mucosal smears, 1+ sites	\$22.85	\$44 691	2 272	38.3%
73045	Washing, brushing or fluid, 1+ sites	\$48.60	\$4 349 616	108 241	54.8%
73047	Series of 3 sputa or urines	\$94.70	\$4 242 812	52 240	48.6%
73049	Fine needle aspiration biopsy - 1 site	\$68.15	\$3 632 808	61 445	93.1%

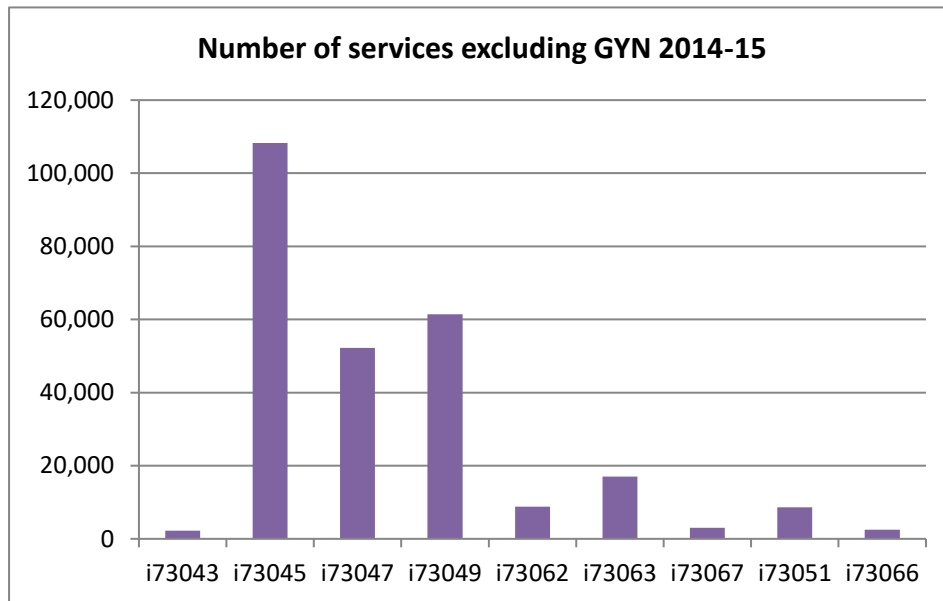
Item number	Summary item descriptor	MBS Fee	Total benefits paid 2014–15	Number of services 2014–15	Specialist-requested
73062	FNAB - 2+ sites	\$89.00	\$679 280	8 777	92.5%
73063	Attended FNAB - 1 site	\$99.35	\$1 446 665	17 044	94.3%
73067	Attended FNAB - 2+ sites	\$129.15	\$331 261	2 976	93.3%
73051	Pathologist attended FNAB - 1 site	\$170.35	\$1 269 004	8 617	76.8%
73066	Pathologist attended FNAB - 2+ sites	\$221.45	\$483 367	2 520	83.4%

Figure 4. 2014/15 MBS Cytology item service data



The majority of rebated specimens are cervical Pap smears (73053, 73055). Based on new evidence and better technology, the National Cervical Screening Program will change from 1 December 2017. The two yearly Pap test will be replaced by a five yearly cervical sample human papillomavirus (HPV) test. Given the changes underway in the National Cervical Screening Program, gynaecological cytology items (73053, 73055 and 73057) will not be further considered in this analysis or recommendations, as new items are being proposed and usage is uncertain. The usage of non-gynaecological cytology items is shown in *Figure 5*.

Figure 5. 2014/15 MBS Cytology item service data - excluding gynaecological items



Non-gynaecological cytology services are dominated by examination of fluids (73045/73047) and fine-needle aspiration biopsies (73049/73062) with relatively low numbers of the more expensive cytologist attended (73063/73067) and pathologist-attended (73051/73066) fine-needle aspiration biopsies. The vast majority of the higher complexity cytology items are specialist-requested.

As with Tissue Pathology items, non-gynaecological cytology items can be viewed as covering a number of different 'complexity' levels, with multipliers in place for more than one specimen at some of these levels. If ranked from lowest to highest complexity, the non-gynaecological items may be summarised as follows:

- 73043: A squamous mucosal/nipple smear, generally involving direct slide preparation with limited numbers of slides (although liquid-based cytology is required for anal smears).
- 73045: Washing/brushing or fluid examination, often requiring a spin-down of fluid to prepare multiple slides, and possibly a cell block preparation.
(73047: 'series of 3 urines or sputa')
- 73049: A fine-needle aspiration biopsy (possibly with multiple passes, and usually involving preparation of a paraffin cell block).
(73062: 'FNAB at 2+ sites')
- 73063: A fine-needle aspiration biopsy, attended by a cytologist (possibly off site) to assess adequacy of the sample and triage for other tests (such as flow cytometry) where required.
(73067: 'Attended FNAB at 2+ sites').
- 73051: A fine-needle aspiration biopsy, attended by a pathologist to give rapid on-site diagnosis (similar to a frozen section).
(73066: 'Pathologist-attended FNAB at 2+ sites').

There is no rebate for the preparation of a cytology cell block (a 'clot' of cells embedded in paraffin) unless it is utilised for immunocytochemical stains. Issues relating to cytology immunocytochemistry items are considered further below in Section 4.4.

4.1 Proposed changes to the Histopathology Complexity Levels table

Introduction

Tissue Pathology (Histology) specimens are classified (and rebated) according to complexity as currently defined in the Histopathology Complexity Levels Table published at the end of the Pathology Services (Category 6) of the MBS.

The Committee notes that these specimen complexity categories not only relate to MBS billing but are also used by an increasing number of laboratories for allocation of workload and workforce planning, thus appropriate classification of specimens is required for a variety of reasons, not limited to the reimbursement of MBS pathology services.

The recommendations below aim to provide equity between different organ systems for similar work, and for work of similar difficulty (laboratory and diagnostic) across systems. The necessity for additional special stains in specimens of a certain type has been highlighted, along with the suggested requirement for use of a Structured Report in complex malignancies.

Recommendations

The Committee proposes the following:

- △ 78 changes to the Complexity Table to provide equity of classification of comparable work.
- △ The mandatory use of Structured Reports for complexity 6 and 7 cancer cases.
- △ The inclusion of special stains as part of the specimen description is recommended when the use of such stains is expected practice.

The rationale for each change is summarised in the rightmost column of *Table 6*. Specimens for which no change is recommended have not been included in the table.

Table 6. Proposed changes to the Complexity Table

Specimen type	Complexity level	Proposed change	Rationale
Adrenal resection, neoplasm	5	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice
Anus, all specimens not otherwise specified	3	Raise complexity level to 4	Alignment. Distinction from rectal biopsy (L4) inconsistent. Many biopsies straddle junction; often significant issue regarding dysplasia/koilocytosis to resolve
Anus, neoplasm, radical resection	6	Add ' <i>with Structured Report</i> ' <i>[not yet in development]</i>	Alignment. Drive best practice
Appendix	3	Split into <i>appendix, neoplasm</i> (level 5) and <i>appendix, NOS</i> (remain level 3)	Alignment. Appendiceal tumour (eg, carcinoid) will require additional blocks and assessment of margins, as per other gastrointestinal tract tumours
Artery, biopsy	4	Split into <i>artery, assessment for arteritis with special stains</i> (level 5)	Alignment. Assessment for temporal arteritis involves sections at multiple levels as

Specimen type	Complexity level	Proposed change	Rationale
		and <i>artery, biopsy NOS</i> (remain level 4)	well as special stains for elastin; urgent and time consuming
Bile duct, resection, all types	6	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice
Bone, biopsy, curettings or fragments - lesion	5	Add ' <i>or neoplasm</i> ' to wording	Clarification
Bone, resection, neoplasm - all sites and types	6	Add ' <i>with Structured Report</i> ' <i>[not yet in development]</i>	Alignment. Drive best practice
Bone marrow, biopsy	4	Split into <i>bone marrow biopsy for haemopoietic malignancy</i> (level 5) and <i>bone marrow biopsy, NOS</i> (remain level 4)	Alignment. Other haematopoietic malignancy biopsies are L5; bone biopsy for lesion is also L5
Brain neoplasm, resection - cerebello-pontine angle	4	Delete (include under Brain or meninges, resection – neoplasm)	Alignment. Currently CPA biopsy is L5 but resection L4. Illogical to separate from other tumours of meninges and brain
Brain or meninges, not neoplasm - temporal lobe	6	Delete <i>not neoplasm</i> and add ' <i>for epilepsy</i> '	Clarification. Detailed assessment is required for epilepsy
Brain or meninges, resection - neoplasm (intracranial)	5	Raise complexity level to 6. Add ' <i>with Structured Report</i> '	Alignment. Brain tumours require detailed assessment with structured report and tiered diagnosis including consideration of molecular profile
Breast - excision biopsy, guidewire localisation - non-palpable lesion	6	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice
Breast, excision biopsy, or radical resection, malignant neoplasm or atypical proliferative disease - all specimen types	6	Raise complexity level to 7 Add ' <i>with Structured Report</i> '	Alignment. Number of blocks, assessment of margins & amount of diagnostic work in mastectomy is equivalent to wide local excision; often multifocal disease
Breast – microdochectomy	6	Reduce complexity level to 5	Downgrade. Involved work not commensurate with level 6
Breast, orientated wide local excision for carcinoma, with margin assessment	7	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice
Eye, conjunctiva - biopsy or pterygium	3	Split into: <i>eye, conjunctiva -pterygium</i> (level 3) and	Alignment. Conjunctival biopsies other than pterygia

Specimen type	Complexity level	Proposed change	Rationale
		<i>eye, conjunctiva - biopsy NOS (level 4)</i>	are complex; often melanocytic lesions or atypical lymphocytic infiltrates
Foetus with dissection	6	Raise complexity level to 7	Alignment. Highly complex cases requiring additional investigations (X-ray, photography) as well as detailed measurements, dissection, histology, correlation with microbiology and genetics
Foreskin - new born	2	Delete	Replaced. See below
Foreskin - not new born	3	Delete <i>not new born</i> and split into: <i>foreskin, inflammatory dermatosis with special stains (level 5)</i> and <i>foreskin, NOS (level 3)</i>	Clarification. Issue is not age of patient but presence of inflammatory condition requiring detailed examination
Gallbladder	3	Split into: <i>gallbladder, neoplasm (level 5)</i> and <i>gallbladder, NOS (level 3)</i>	Alignment. Equate with other GIT malignancies requiring detailed examination and margins
Gallbladder and portal hepatis - radical resection	6	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice
Heart - not otherwise specified	5	Split into: <i>heart, biopsy including transplant with special stains (level 5)</i> and <i>heart - neoplasm with Structured Report (level 6)</i>	Alignment. Differentiate neoplasm from medical biopsy. Drive best practice
Kidney, biopsy including transplant	5	Split into: <i>kidney, medical biopsy including transplant, with special stains (level 6)</i> and <i>kidney, biopsy, neoplasm (level 5)</i>	Alignment. Medical renal biopsy is highly complex and very time consuming with multiple special stains, immunofluorescence stains, electron microscopy and clinical correlation; often urgent.
Kidney, partial or total nephrectomy or nephroureterectomy - neoplasm	6	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice
Large bowel, colostomy - stoma	3	Raise complexity level to 4	Alignment. Equate with other GIT biopsies; examination for residual / inflammatory disease required
Large bowel (including rectum), biopsy, for confirmation or	5	Raise complexity level to 6 Add ' <i>with special stains</i> '	Alignment. Includes up to 60 levels with enzyme stains; very time consuming to analyse

Specimen type	Complexity level	Proposed change	Rationale
exclusion of Hirschsprung's disease			
Large bowel (including rectum), segmental resection - neoplasm	6	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice
Larynx, partial or total resection	5	Raise complexity level to 6 Add ' <i>with Structured Report</i> ' <i>[in development]</i>	Alignment. Inconsistent that complex laryngeal resection for malignancy with margin assessment only L5
Larynx, resection with nodes or pharynx or both	6	Raise complexity level to 7 Add ' <i>with Structured Report</i> ' <i>[in development]</i>	Alignment. Highly complex dissection with margins, particularly if pharynx and nodes involved, at least equivalent to wide local excision of breast
Liver - total or subtotal hepatectomy - neoplasm	6	Add ' <i>with Structured Report</i> ' <i>[in development]</i>	Alignment. Drive best practice
Liver - all specimens not otherwise specified	5	Split into: <i>liver, biopsy for inflammatory disease with special stains</i> (level 5) and <i>liver, biopsy for neoplasia</i> (level 5) , and <i>liver, NOS</i> (level 5)	Clarification. Currently all indications lumped together; in other organs neoplasia is separated, even if complexity is similar
Lung, needle or transbronchial biopsy	4	Split into: <i>lung, needle or transbronchial biopsy, assessment of transplant rejection or inflammatory disease</i> (level 5) and <i>lung, needle or transbronchial biopsy, neoplasm</i> (level 5)	Alignment. Currently inconsistent that heart transplant biopsy is L5 but lung transplant is L4 (equal or greater work). Currently inconsistent that lung biopsy for neoplasm is L4 but liver biopsy (including for neoplasm) is L5; requires tumour classification and detailed molecular work-up for biomarkers
Lung, resection - neoplasm	6	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice
Lymph node, biopsy - all sites	4	Split into: <i>lymph node, biopsy or sampling NOS</i> (level 4) and <i>lymph node biopsy, sentinel node biopsy</i> (level 5)	Alignment. Sentinel node biopsy requires multiple levels, detailed examination, correlation with immunostains
Lymph node, biopsy – for lymphoma or lymphoproliferative disorder	5	Raise complexity level to 6 Add ' <i>with Structured Report</i> '	Alignment. Lymphoma diagnosis and classification is highly complex with necessity to correlate with numerous immunostains, flow/genetics

Specimen type	Complexity level	Proposed change	Rationale
			results and creation of structured report
Lymph node, regional resection - all sites	5	Change to: <i>lymph node, regional dissection – all sites</i> (level 5)	Clarification. Lymph node regional dissection has more specific meaning than resection
Oesophagus, partial or total resection	6	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice
Pancreas, subtotal or total with or without splenectomy	6	Raise complexity level to 7 Add ' <i>with Structured Report</i> '	Alignment. Highly complex dissection with margins, at least equivalent to WLE breast
Penisectomy with node dissection	5	Raise complexity level to 6	Alignment. Additional node dissection should be remunerated appropriately
Penisectomy - simple	4	Split into: <i>penisectomy, neoplasm</i> (level 5) and <i>penisectomy, other</i> (4)	Alignment. If neoplastic, detailed examination with margins required
[new listing] Pharynx, biopsy	—	Complexity level 4	Clarification/alignment. No current listing for pharynx; make comparable with other head and neck biopsies
[new listing] Pharynx, resection without node dissection	—	Complexity level 5	Clarification/ alignment. No current listing for pharyngectomy; complex dissection with margins, equivalence to other sites
[new listing] Pharynx, resection with node dissection <i>with Structured Report</i>	—	Complexity level 6 <i>[in development]</i>	Clarification/ alignment. Complex dissection with margins and nodes, equivalence to other sites
Pituitary neoplasm	4	Raise complexity level to 5	Alignment. Should be equivalent to other endocrine neoplasms; correlation with special stains and immunostains required
Placenta - not third trimester	4	Delete	Clarification. Trimester not the critical determinant
Placenta - third trimester, abnormal pregnancy or delivery	4	Remove <i>third trimester</i> wording; split into <i>placenta, abnormal pregnancy or delivery</i> (level 5) and <i>placenta, stillbirth</i> (level 6)	Alignment. Complex examination with multiple blocks, particularly so in the case of stillbirth; correlation with microbiological and genetic assays required
[new listing] Pleura - pleurectomy for neoplasia with Structured Report	—	Complexity level 5	Clarification. Current item does not include extensive pleural resections for mesothelioma

Specimen type	Complexity level	Proposed change	Rationale
Prostate, radical resection	6	Delete	Clarification. Superseded by updated listing for radical prostatectomy
Prostate, radical prostatectomy or cystoprostatectomy for carcinoma	7	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice
Salivary gland, neoplasm - all sites	5	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice
Skin, biopsy - blistering skin diseases	4	Delete	Clarification. Combine with inflammatory dermatosis
Skin, biopsy - inflammatory dermatosis	4	Add ' <i>or blistering skin disease, excluding secondary inflammation in a simple skin lesion, with special stains</i> ' Raise complexity level to 5	Alignment. Vastly more time consuming than GIT biopsy (L4); special stains/IF required. Clarification of excluded secondary inflammation included.
Skin, resection of malignant melanoma or melanoma in situ	5	Add ' <i>with margin assessment and Structured Report</i> '	Clarification. Drive best practice
Small bowel, diverticulum	3	Raise complexity level to 4	Alignment. Equivalence to other GIT biopsies, assessment of heterotopia
Small bowel, resection - neoplasm	6	Add ' <i>with Structured Report</i> ' <i>[not yet in development]</i>	Alignment. Drive best practice
[New listing] Small bowel, stoma	—	Complexity level 4	Alignment. Equate to colostomy; currently small bowel resection (L5) being wrongly used as no item for small bowel stoma
Soft tissue, lipoma and variants	3	Delete the wording <i>and variants</i> Add wording <i>NOS and angiolipoma</i> Keep complexity level 3	Clarification. Atypical variants of lipoma can be diagnostically very challenging; to be included with soft tissue, neoplasm
Soft tissue, infiltrative lesion, extensive resections at least 5cm in maximal diameter	6	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice

Specimen type	Complexity level	Proposed change	Rationale
Soft tissue, neoplasm, not lipoma - all specimens	5	Delete wording ' <i>not lipoma</i> ' Replace wording with ' <i>excluding lipoma NOS/angiolipoma</i> ' Keep complexity level 5	Clarification. Atypical variants of lipoma can be diagnostically very challenging, similar to other soft tissue neoplasms
Stomach, resection, neoplasm – all specimens	6	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice
Testis and adjacent structures, neoplasm with or without nodes	5	Raise complexity level to 6 Add ' <i>with Structured Report</i> '	Alignment. Complex dissection with margins and nodes, equivalence to other sites
Testis and adjacent structures, vas deferens sterilisation	2	Delete wording <i>testis and adjacent structures</i> Keep complexity level 2	Clarification. Should just list under Vas deferens, currently confusing location under testis
Thymus - not otherwise specified	5	Split into: <i>Thymus, total or partial resection for neoplasm, with Structured Report (level 6)</i> and <i>thymus, not otherwise specified (level 4)</i>	Clarification. Differentiate resection for neoplasm (requiring margins, classification) from incidental specimen.
Thyroid - all specimens	5	Delete wording ' <i>all specimens</i> ' Split into: <i>thyroid, total or partial resection for neoplasm with Structured Report (level 6)</i> and <i>thyroid, not otherwise specified (level 5)</i>	Clarification/alignment. Currently single listing for all thyroid specimens illogical; neoplasms require complete embedding with detailed margin assessment
Tongue, biopsy	4	Add wording ' <i>or local excision of lesion</i> ' Keep complexity level 4	Clarification. Differentiate resection of small benign lesion (i.e. polyp) from resection for malignancy
Tongue or tonsil, neoplasm local	5	Delete wording ' <i>neoplasm local</i> ' Add wording ' <i>local resection of malignant neoplasm with Structured Report</i> ' Keep complexity level 5	Clarification. Differentiate resection of small benign lesion (i.e. polyp) from resection for malignancy
Urinary bladder, partial or total with or without prostatectomy	6	Add ' <i>with Structured Report</i> '	Alignment. Drive best practice

Specimen type	Complexity level	Proposed change	Rationale
Uterus, cervix, curettings or biopsy	4	Change wording to <i>'uterine cervix, curetting or biopsy including polyp'</i> Keep complexity level 4	Clarification/alignment. Listing currently confusing. Polyp should be included rather than separate
Uterus, cervix cone, biopsy (including LLETZ or LEEP biopsy)	5	Change wording <i>'uterus, cervix'</i> to <i>'uterine cervix, cone biopsy (including LLETZ or LEEP biopsy)'</i> . Keep complexity level 5	Clarification
Uterus, endocervix, polyp	3	Delete	Clarification. Include under Uterine cervix, curetting or biopsy including polyp; polyp in isolation unlikely and confusing
Uterus, endometrium, polyp	3	Change wording to <i>'uterus, endometrium, biopsy or polyp'</i> Complexity level to 4	Clarification/alignment. Appropriate to have item for endometrial examination (\pm polyp) separate from examination of whole uterus
Uterus, with or without adnexa, malignant neoplasm - all specimen types not otherwise specified	6	Add <i>'with Structured Report'</i>	Alignment. Drive best practice
Uterus, with or without adnexa, neoplasm, Wertheim's or pelvic clearance	6	Add <i>'with Structured Report'</i>	Alignment. Drive best practice
Uterus and/or cervix - all specimens not otherwise specified	4	Split into: <i>'uterus and/or cervix, resection with or without adnexa'</i> (complexity level to 5) and <i>uterus and/or cervix, all specimens not otherwise specified</i> (level 4)	Alignment. Current rebate for examining cervix, uterus, tubes and ovaries (at least 7 blocks) vastly underfunded
Vaginal mucosa, incidental	3	Delete	Clarification. Incidental sampling of vaginal mucosa unlikely
Vulval (sic), subtotal or total with or without nodes	6	Change wording to: <i>Vulva, subtotal or total vulvectomy with or without nodes, with Structured Report</i>	Clarification and Alignment. Drive best practice

Rationale

- △ The Committee identified numerous inconsistencies in the Complexity Table, with work of similar complexity being differently remunerated, and work of vastly different complexity being similarly remunerated. Most of the proposed changes relate to obvious anomalies. For example, currently examination of a cervix, uterus, both fallopian tubes and both ovaries

(which requires careful dissection, 7–10 blocks/slides and commensurate time to review them) is currently rebated at Level 4, the same level as a single gastrointestinal biopsy or orientated skin biopsy. The examination of a lung core biopsy for lung transplant rejection is currently level 4 while examination of a cardiac biopsy for heart transplant rejection is level 5. Equity between organ systems has been addressed in the Committee's recommendations for similar work of similar complexity.

- △ Most of the proposed changes reflect increases in complexity level, while a few represent decreases (e.g. breast microdochectomy from level 6 to level 5). In most cases the increase in complexity is also associated a specified requirement for additional special stains to be performed or a Structured Report to be included.
- △ The necessity for additional special stains in certain types of specimens has never been explicitly recognised in the complexity table, despite these being an integral component of the diagnostic process. Rather than propose the addition of a specific item for special stains (as is the case in the USA), the Committee proposes making the necessity for special stains in certain types of specimens more explicit.
- △ Structured reporting has been widely demonstrated as improving the completeness and quality of data in pathology reports and therefore ensuring improved outcomes for cancer patients.
 - The Commonwealth Government has recognised its importance by the funding of the *National Structured Pathology Reporting of Cancer (NSPRC) Project*ⁱⁱⁱ since 2007, which has provided cancer reporting protocols freely available through the RCPA website.
 - Level 3 reporting is defined as data entry in a structured format, with SPR-protocol-compliant content, but does not enforce higher levels of data storage, coding or Health level 7 (HL7) messaging.^{iv} Level 3 reporting can be achieved with current Laboratory Information Systems (LIS) and is therefore attainable without further capital investment.
 - The National Pathology Accreditation Advisory Council (NPAAC) has recognised the importance of structured reporting, with NPAAC's *Requirements for Medical Pathology Services* document (2nd Edition released for public comment June 2017) stating that: 'CC8.2(ii) Structured reporting must be used where appropriate'.
 - While efforts continue via the *National Structured Pathology Reporting of Cancer Project* (overseen by the RCPA) to increase the suite of published protocols, the Committee suggests that the addition of a requirement for use of a Structured Report to qualify for MBS funding for high-complexity items presents an opportunity to drive best practice in pathology reporting.
 - All but a few of the current or proposed level 6 and 7 specimens have Structured Report Protocols either already available or in development.
- △ Some of the changes relate to necessity to split current listings to separate examination of a neoplastic lesion from other examinations of the same organ (for instance in thyroid, where all specimens are currently level 5).
- △ Some specimen listings have been deleted and pooled with others of the same type (cerebellopontine angle brain tumours with other brain tumours).
- △ Items related to the examination of placentas from abnormal deliveries and examination of stillborn babies < 20 weeks' gestation have been the subject of particularly detailed review:
 - The Committee recommends that examination of the placenta when clinically necessary (i.e. in an abnormal gestation), in the absence of foetal demise, should be increased from level 4 to level 5 on the basis of the complexity of dissection, the number of blocks required (usually > 5), the time taken to examine the sections and the level of detail required in the report required. Feedback along these lines was provided by numerous pathologists.
 - The Committee recommends that examination of the placenta of a stillborn baby (when no examination of the foetus/baby is conducted) be increased to level 6, in view of the additional level of detail and special stains required. Estimates of the reporting time involved indicate it is commensurate with examination of a substantial neoplastic resection.
 - The Committee recommends that the item for examination and dissection of a stillborn baby of < 20 weeks' gestation (with ancillary studies as required along with examination of the placenta) be increased to level 7. This still falls short of reflecting the complexity and

effort required in such cases, which usually involve X-ray, photography, detailed measurements as well as dissection and histology, along with correlation with genetic tests and microbiology.

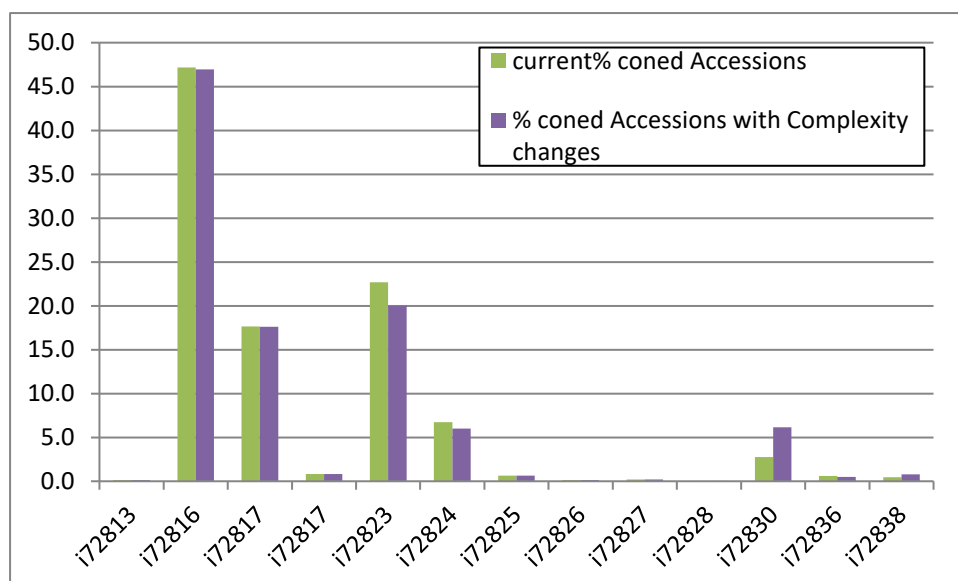
- The Committee considers that the issue of remuneration for autopsies on babies of > 20 weeks' gestation necessarily falls outside the scope of the MBS review (such remuneration being explicitly excluded under MBS rules). However, the Committee suggests that the issue be addressed via appropriate RCPA committees/Working Groups, with a view to defining the existing (variable) state-based funding available and working toward a national approach to this very important issue.

Data modelling

Details of specimen type/s within each accession was available from laboratory D (11118 accessions, 16971 specimens) collected over a 1-week period in January 2017. Medicare data for the period 2014–15 indicated that a total of 3,080,539 histology services were rebated, thus this data from Laboratory D represents a sample equating to around 0.36% of the expected Australian annual total.

The proposed changes in the complexity table were modelled after sorting by specimen type, with maintenance of current tiering and coning rules. The overall effects of the proposed complexity changes on the distribution of complexity for this laboratory is shown in *Figure 6*: the most obvious change is a small reduction in level 4 items and increase in level 5 due to changes in classification for inflammatory dermatoses and hysterectomy specimens.

Figure 6. Laboratory D data showing change in case distribution before and after proposed complexity changes.



Financial modelling of the effects of these changes on billing was also performed using data from Laboratory D. The effect was similar if coned billings (utilising the current tiering and coning rules) and unconed billings were considered. The increase in nominal billings is expressed as a percentage of the current billings (*Table 7*).

Table 7. Effect of proposed complexity changes on nominal MBS billings (Laboratory D)

	Number of specimens	Number of accessions	% billing change with proposed complexity changes
Lab D: unconed data	16 971	—	6.60%

Lab D: coned data	—	11 118	6.29%
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4.2 Coning in Tissue Pathology core items

Introduction

Currently there is no capacity to fund multiple specimens of complexity levels 2, 5, 6 or 7. There are different tiered items for multiple specimens of complexity levels 3 and 4, with reduced effective rebate per specimen with increasing numbers of specimens. Superimposed on these within-level cones is Rule 13, which dictates that a billing code for a specimen of higher complexity overrides a billing code for lower-complexity item/s, unless the dollar value of a tiered lower-complexity item is greater.

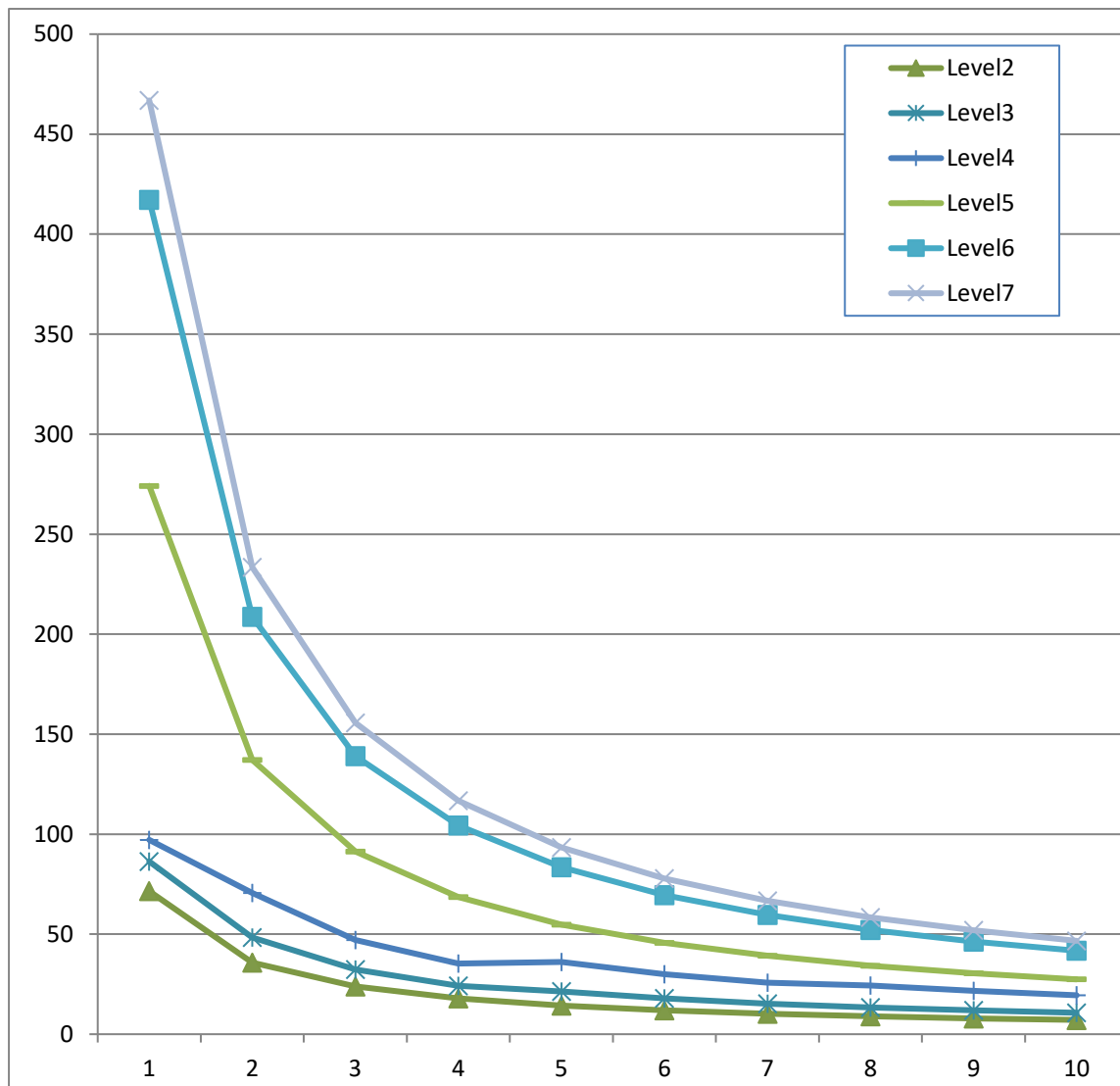
Recommendations

- △ Remove all within-level coning/tiering, having a single item for each Histology complexity:
 - minor rewording of Histology items: 72813, 72816, 72823, 72830, 72836, 72838
 - removal of Histology items: 72817, 72818, 72824, 72825, 72826, 72827, 72828.
- △ Remove Rule 13 to remove all between-level coning for Histology (adjust explanatory notes).
- △ Rather than renegotiate the rebate for each item (assuming simple removal of coning is deemed financially unacceptable), consider the adoption of an alternative 'Surgical' model of reimbursement for histology core items, providing 100% rebate for the most expensive item, 50% rebate for the next most expensive item and 25% rebate for each subsequent item thereafter.

Rationale

- △ If coning is anything other than a cost-constraining exercise, it presumably is supposed to reflect economies of scale in the provision of work. There are no significant economies of scale in Tissue Pathology. Every single specimen must be individually macroscopically assessed (cut-up), processed, cut and stained, microscopically assessed and reported as if it were received as a single specimen. A minor economy of scale is present in the data entry effort required for multiple specimens from a single patient, but this is insignificant in comparison to the effort involved in the laboratory processing and pathologist reporting. The current coning rules are particularly inequitable for complex specimens.
- △ Depending on the practice type, at least 40% of Tissue Pathology specimens come via Specialist request (rather the GP request). The overall percentage of Specialist requests evident in the 2014–15 MBS data was 48.27% (see *Table 3* above). Coning in other areas of pathology is limited to specimens referred by GPs. Not only does this differential coning not occur in Tissue Pathology, all specimen requests are similarly coned, regardless of requester Specialist status.
- △ Coning in other areas of pathology is designed to limit unnecessary testing (particularly when certain tests are pathologist-determinable). In Tissue Pathology, unnecessary testing is highly unlikely to occur, as clinicians do not perform unnecessary biopsies or excision and patients will not consent to unnecessary surgical intervention to provide additional specimens.
- △ There is no particular logic to the current tiered item structure within complexity levels. In addition to there being no capacity to bill for more than one level 2 histology specimen (such as vasectomy, which is rarely unilateral), there are no tiers for multiple specimens of levels 5, 6 and 7 complexity, despite these being the most difficult and time-consuming specimens. Thus a double mastectomy for bilateral breast cancer is rebated the same as a single mastectomy (level 6), despite requiring twice the work.
- △ The incrementally smaller rebate for each additional specimen at a given complexity level is shown in *Figure 7* below. For example, if one level 6 specimen is received, it attracts \$417.20. However, if two level 6 specimens are received, the rebate is unchanged, thus each specimen is effectively remunerated at \$208.60. If 3 level 6 specimens are received the effective remuneration per specimen is only \$139.06, and so on. Examination of high-complexity specimens is therefore a loss-making exercise.

Figure 7. Current effective rebate per specimen if additional histology specimens are received at each complexity level.



- △ At present Rule 13 requires that a specimen of higher complexity ‘trumps’ all specimens of lower complexity with respect to the rebate, except if the dollar value of a higher-tier lower-complexity item is greater (which rarely happens). Thus a single orientated skin biopsy (level 4) trumps up to five unorientated skin biopsies (level 3) received on the same request, and only the single level 4 biopsy is remunerated. Likewise an orientated wide local excision of a breast tumour (level 7) trumps the associated axillary node dissection (level 5), which is not remunerated, regardless of the work involved.
- △ Attempts to compare and manage laboratory Anatomical Pathologist workload based on coned MBS data have repeatedly been found to be inequitable. Labs have used other measures such as block or slide numbers and workload points allocated according to complexity of each individual specimen. This is obviously necessary because real work effort is not reflected in the coned MBS histology data.
- △ If Tissue Pathology laboratories are unable to demonstrate financial viability, this potentially impacts on staffing, hence on workload, and subsequently on turn-around times and quality (a stressed and overloaded workforce is more likely to make diagnostic errors). Laboratories must allocate resources across each of the Pathology disciplines in a financially sustainable way to remain viable.
- △ There is currently a serious issue of understaffing within Tissue Pathology laboratories, resulting in significant delays in the preparation of histopathology slides and the preparation of histopathology reports. This is resulting in increasing turnaround times for results.

The issue of staff shortages results from an immediate lack of funding for additional staff but also a workforce shortage of histopathology scientific and technical staff due to the inability to attract people to the career.

The staff shortages also include histopathology typists. Delays in Histopathology reports result in delays in instituting treatments and management plans including the scheduling of surgical procedures and the initiation of appropriate chemotherapy for the treatment of cancer.

△ Workloads for histopathologists in some laboratories have reached very high levels and there is an immediate risk of histopathologists working at unsafe levels, with the increased risk of diagnostic errors. These errors may lead to either an unnecessary operation or, in the case of a false negative diagnosis, the undertreatment of malignancies.

△ There is evidently an immediate histopathology workforce shortage within many areas of Australia. This has led to many histopathologists working well past normal retirement age* and at times this has led to unsafe practice (as evidenced by recent reports of systemic errors within some jurisdictions).

The lack of adequate histopathology workforce relates to both insufficient resourcing to allow for increased training numbers but also an inability to attract sufficient numbers of qualified medical graduates to the field.

△ If the processing and reporting of high-complexity items is particularly under-remunerated, this introduces perverse incentives to maximise (or exclusively focus on) the reporting of simple specimens where there is less inequity of rebate. This in turn affects the diversity and balance of pathology practices, and may affect the availability of more complex diagnostic services across locations.

It has already resulted in the consolidation of pathology practices into larger centralised practices, where Tissue Pathology is necessarily cross-subsidised by other disciplines. As Pathology rebates have been reduced by about 50% in real terms since 2000, the ability to cross-subsidise loss-making fields within Pathology has diminished.

△ A shortage of histopathologists and technicians (particularly in regional centres) has meant that in some centres intraoperative histopathological examination of tissue specimens (frozen sections) can no longer be performed. This means that patients will either have to undergo a separate second operative procedure (with the inherent risks of a second anaesthetic) at a later date rather than have a definitive single procedure, or travel large distances to a tertiary referral centre for their treatment.

Data modelling

The dominant Medicare claim in Tissue Pathology (accounting for 44.3%) is a single level 3 biopsy (mostly simple skins), with single level 4 biopsies accounting for another 22.5% (see *Table 3* above). Numbers (and rebates) for higher-complexity specimens are almost negligible by comparison.

Data on coned vs unconed data are obviously not available from the Department of Health, and laboratory information systems issues at many sites make it difficult to extract such data. Unconed /coned data obtained with considerable effort from four laboratories has enabled the effect of current coning and tiering to be modelled. The parameters of this data were described above (*Table 4*).

Data obtained from four different laboratories demonstrated that between 29% and 53% of income was being lost in each laboratory due to coning/tiering rules, compared with the potential income had each specimen been received separately (*Table 8*).

* 11% of practicing pathologists (13% in NSW) are aged > 65 (August 16 Workforce Data, RCPA)

Table 8. Current impact of coning/tiering rules on Histology billing

	Number of specimens	Number of accessions	Coned revenue	Nominal unconed revenue	Impact of coning (% loss of potential revenue)
Lab A	8 518	17 230	1 185 247	2 098 236	43.51%
Lab B		673	48 684	103 032	52.70%
Lab C	234	475	32 923	52 937	37.80%
Lab D	11 118	16 971	1 161 139	1 640 016	29.20%

Similar effects were seen with data from Laboratory A on immunohistochemistry stains (see Section 4.4) and frozen-section items (see Section 4.6), which are also tiered.

It is currently estimated that coning across all areas of pathology affects around 15% of specimens. We believe our data (particularly from laboratory D) are a representative snapshot of Australian histology testing and indicate that coning rules are having at least twice the effect in Tissue Pathology (~30%) as across pathology more generally.

This is obviously highly inequitable and makes it almost impossible for an Anatomical Pathology laboratory to break even financially (usually they are cross-subsidised as 'loss-leaders'). This also makes it extremely difficult for single discipline Anatomical Pathology laboratories to exist as isolated entities.

Other Medical specialities have alternate coning models, for example:

△ **The Surgical model** (T.8.2 Multiple operation rule) allows:

- 100% of the most expensive item performed during a single anaesthetic episode by the same surgeon
- 50% of the next most expensive and then
- 25% of each item thereafter.

This pre-supposes a degree of economy in having the patient already anaesthetised and on the table (an economy of scale not actually present in histopathology), but provides an interesting comparison.

△ **The Radiology MRI model** (the most restrictive of the many complicated rules relating to billing multiple radiology procedures), allows:

- 100% of the most expensive item, and
- 50% of each item thereafter.

[Other radiology rules are more generous, reducing second and subsequent procedures by only \$5.00].

Utilising the data from Laboratory D (which was ranked in decreasing specimen complexity within each accession) we were able to explore the possibility of applying such alternate strategies, compared with the current coning and no coning at all (*Table 9*).

Table 9. Modelling of ‘Surgical’ and ‘Radiology MRI’ coning strategies

Coning Method	Rebate (\$)	Increase%
Current nominal coned billing	1 161 139	0
Surgical Model 100/50/25, etc. based on current complexity	1 308 922	12.70%
Radiol MRI Model 100/50, etc. based on current complexity	1 367 619	17.80%
100% unconed based on current complexity	1 640 016	41.20%

Application of the ‘Surgical’ model (100% of the most expensive item, 50% of the next most expensive then 25% thereafter) resulted in a 12.7% increase in nominal revenue, while the ‘Radiology MRI’ model (100% of the most expensive item then 50% thereafter) resulted in a 17.8% increase in nominal revenue.

This relatively modest increase came about because most cases assessed by Laboratory D had only 1 (70.3%) or 2 (18.36%) specimens. Less than 5% of cases had more than 3 specimens. The cases with very high numbers of specimens were generally prostate core biopsy cases.

The application of an alternative coning model along these lines has various advantages:

- △ It would avoid the necessity to introduce additional tiers for levels 2, 5, 6 and 7 and the unpicking of Rule 13, while recognising (at least in part) the impost of multiple high-complexity items within an accession.
- △ It would be amenable to future negotiated changes in rebate (by percentage) without complicated adjustment of coning/tiering rules.

4.3 Coning in Cytology core items

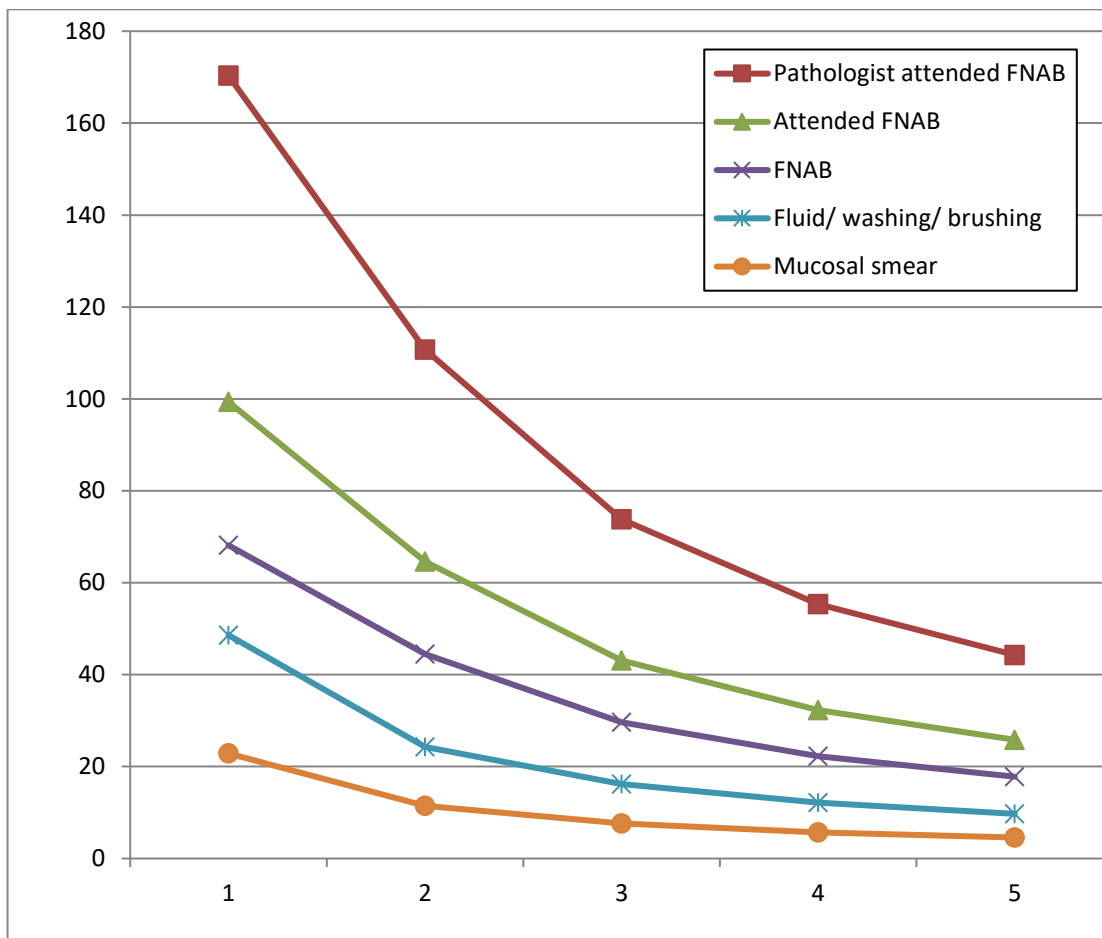
Recommendations

- △ Remove the multiplier cytology core items and all within-level coning/tiering, having a single item for each Cytology specimen type:
 - minor rewording of Cytology items: 73043, 73045, 73049, 73051, 73063 (remove stipulation of number of sites)
 - removal of Cytology items: 73062, 73066, 73067.
- △ Remove the item 73047 for a series of three (urine or sputum) and allow each specimen to be dealt with independently (as item 73045).
- △ If simple removal of coning is deemed financially unacceptable, consider the adoption of an alternative 'Surgical' model of reimbursement of cytology core items, providing 100% rebate for the most expensive item, 50% rebate for the next most expensive item, and 25% rebate for each subsequent item thereafter.
- △ Recommendations relating to Cytology Immunocytochemistry items are provided below in Section 4.4.

Rationale

- △ The Cytology rebates are widely recognised as even more inequitable for the work involved than histology. There is no additional funding for the preparation of a cell block, unless it is used for immunocytochemistry stains. The lack of additional funding for multiple mucosal smears, fluids and washing/brushing samples (except the coned series of 3 urine/sputa) and the limitation on FNAB reimbursements to 1 or 2+ sites (despite the difficulty and time involved in assessing these samples) is particularly inequitable.
- △ As in histology, there are no economies of scale involved in the laboratory preparation and microscopic examination of multiple cytology specimens. Cytology laboratories are under extreme pressure at present due to changes in the National Cervical Screening program, workforce changes and understaffing.
- △ The effective rebate for cytology specimens of different complexity type with increasing numbers of specimens is shown in *Figure 8* below. If cytology staff attend an FNAB to make a specimen-adequacy assessment (item 73063) the effective rebate is \$99.35; if two sites are biopsied (as is common in breast cancer assessment) the effective rebate per biopsy is \$64.58; if three sites are aspirated the effective rebate per biopsy is only \$43.05). The clinician performing the FNABs is not constrained by similar coning rules.
- △ Currently in cytology a series of three urine or sputum specimens sent from the same patient over a period of several days (or even weeks) is regarded as a 'single item' (73047), which is rebated at \$94.70 (less than the rebate for two independent specimens of equivalent complexity). This is unprecedented across the MBS. It causes significant logistic complexity (the case cannot be billed until the third specimen is received, the first two are regarded as 'no-bill') despite each specimen having to be handled, processed, assessed and reported independently.
- △ Cytology services are under considerable stress at present and if work is not appropriately remunerated, closures will inevitably occur, leading to loss of access to these services.
- △ The lack of availability of on-site cytological assessment is disproportionately likely to affect patients in non-metropolitan locations.
- △ The replacement of cytology services by (more expensive) histology services is not cost effective for the MBS.

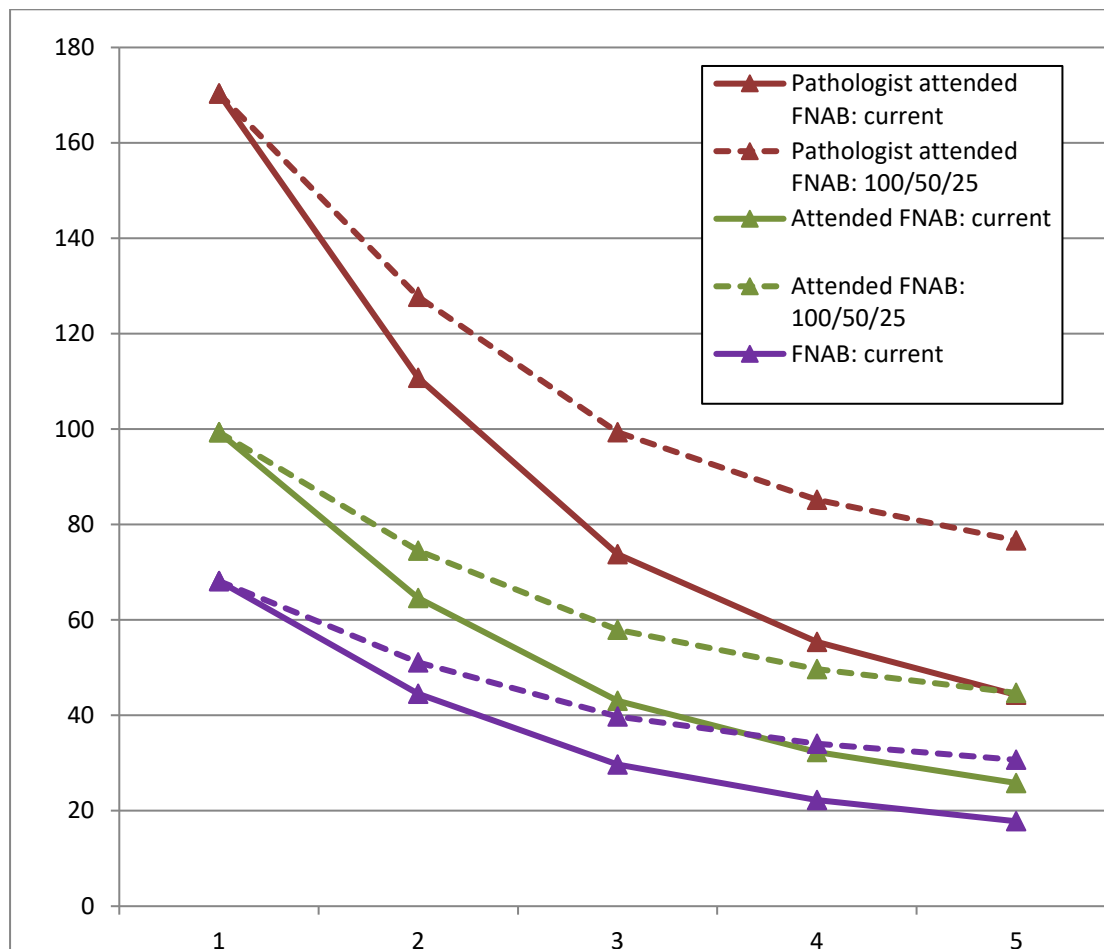
Figure 8. Current effective rebates for Cytology specimens of different complexity with increasing numbers of specimens.



Data modelling

As for histology, an alternative and more simple model for cytology would be to simply adopt the ‘Surgical’ rule for core cytology items (i.e. 100% rebate for the most expensive item, 50% rebate for the next most expensive, and 25% of the rebate for every item thereafter). While high-level multiples of cytology specimens are extremely rare, this would address the (not infrequent) situation of multiple FNABs far more equitably than present. Modelling of the effective rebates using the Surgical rule (vs the status quo) for the three FNAB items is shown in *Figure 9*.

Figure 9. Comparison of potential rebates with Surgical 100%/50%/25% model vs status quo with increasing numbers of FNAB specimens of different complexity.



4.4 Alignment of Immunohistochemical (IHC) and Immunocytochemical (ICC) item rebates and consideration of coning/Rule 13

Recommendations

- △ Remove the multiplicity of different tiered standard immunohistochemistry items and replace with a single standard IHC item:
 - reword item 72846
 - remove items: 72847, 72849, 72850, 72852, 72856 & 72857
- △ Maintain the higher-complexity IHC item 72848 but remove the stipulation of 1–3 antibodies.
- △ Consider re-wording of 72848 along the lines:

“Immunohistochemical examination of biopsy material by immunoperoxidase or other labelled antibody technique where the assay requires enumeration or scoring and functions as a predictive or prognostic biomarker, with one of the following antibodies - oestrogen, progesterone, c-erb-b2 (Her2).” Consider future expansion to include Ki67, ALK and PD-L1.
- △ Introduce a third level IHC item for the chromogenic labelling of nucleic acid targets detected by in situ hybridization where required for tumour diagnosis/classification (eg, EBV, HPV, kappa/lambda light chains) .
- △ Remove Rule 13 in relation to immunohistochemistry.
- △ If simple removal of the coning is considered financially unacceptable, consider funding via a ‘Surgical’ multiplier model allowing 100% of the most expensive item, 50% of the next, then 25% of the cost of subsequent assays.
- △ Align the remuneration for the cytology immunocytochemistry with histology immunohistochemistry (since they are same test) by deleting the immunocytochemistry items from the Cytology schedule but permitting use of the remaining immunohistochemistry items for cytology specimens:
 - removal of Cytology items: 73060, 73064, 73065, 73066 & 73067
 - rewording of 72846 and 72848 to allow use on specimens obtained by procedures described in items 73043 (currently not allowed), 73045, 73049, 73051, and 73063 (N.B. currently also allowed for items 73047, 73062, 73066 and 73067, but it is proposed to delete these items).
- △ Update the Pathologist-Determinable legislation to remove redundant items.

Rationale

- △ Immunohistochemistry (IHC) stains are used to detect specific antigenic targets (usually proteins) in cells or tissues via the use of monoclonal antibodies and chromogenic or fluorescent labels. They are crucially necessary for many diagnoses, particularly the appropriate classification of tumours.
- △ The current Histology (Tissue Pathology) schedule is complicated by numerous different items for different multiples of the same immunohistochemistry assay, as well as reduplication of similar items in the Cytology schedule under the name ‘immunocytochemistry’ (ICC). These assays are the same procedure, the immunocytochemistry generally performed on paraffin-embedded cell blocks on the same staining platforms with the same reagents, and requiring the same work for laboratory scientist and pathologist interpretation.
- △ Separate Immunohistochemistry and Immunocytochemistry items also exist for the assessment of oestrogen receptor, progesterone receptor and HER2, because these more complex assays require counting/scoring by the pathologist. Participation in specific quality assurance programs is also required for assessing these antibodies.
- △ Misalignment developed in the rebate for Immunohistochemistry and Immunocytochemistry items through administrative oversight (despite the fact that they are the same test). This was drawn to the attention of the Department of Health and the Pathology Services Advisory Committee in 2013, and PSAC determined that the rebates should be aligned, however this did not occur. The item definitions and usage are shown in *Tables 10 and 11*. The usage of immunostains in cytology is obviously quite low.

Table 10. Item comparison table for item 72846, 72847, 72849, 72850 (Histology) vs 73059, 73060, 73064, 73065 (Cytology)

Item number	Descriptor	Schedule fee	Volume of services (2015/16)	Services average annual growth (2010/11-2015/16)	Benefits (2015/16)
72846	<u>Immunohistochemical</u> examination of biopsy material by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 1 to 3 antibodies (Item is subject to rule 13) except those listed in 72848	\$59.60	112 573	18.8%	\$5 511 521
72847	[ditto] 4-6 antibodies (Item is subject to rule 13)	\$89.40	49 986	11.1%	\$3 623 218
72849	[ditto] 7-10 antibodies (item is subject to rule 13)	\$104.30	18 658	14.8%	\$1 559 152
72850	[ditto] 11 or more antibodies (item is subject to rule 13)	\$119.20	10 280	26.9%	\$971 380
73059	<u>Immunocytochemical</u> examination of material obtained by procedures described in items 73045, 73047, 73049, 73051, 73062, 73063, 73066 and 73067 for the characterisation of a malignancy by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 1 to 3 antibodies except those listed in 73061(item is subject to rule 13)	\$43.00	1 749	12.8%	\$62 372
73060	[ditto] - 4 to 6 antibodies(item is subject to rule 13)	\$57.35	2 175	9.6%	\$101 355
73064	[ditto] – 7 to 10 antibodies (item is subject to rule 13)	\$71.70	1 278	16.9%	\$74 692
73065	[ditto] - 11 or more antibodies (item is subject to rule 13)	\$86.00	616	24.4%	\$43 069

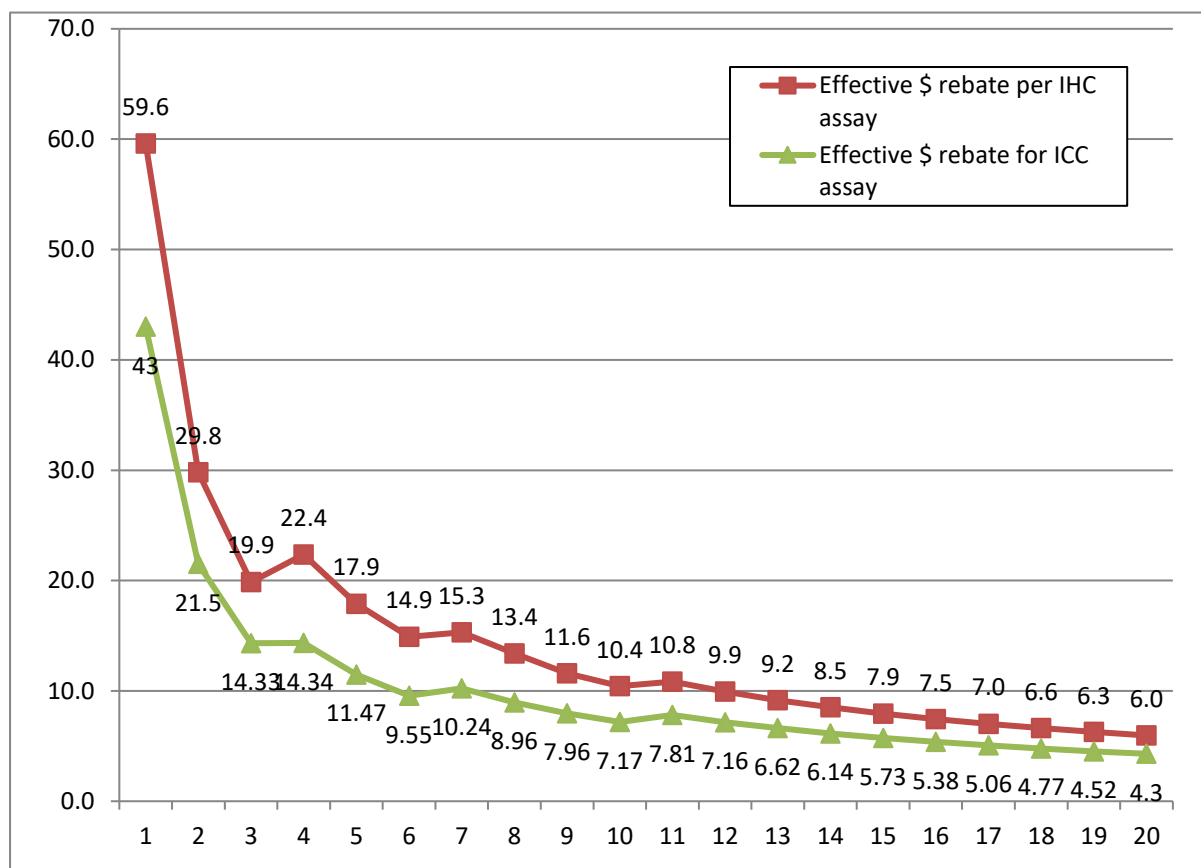
Table 11. Item comparison table for item 72848 (Histology) vs 73061 (Cytology)

Item number	Descriptor	Schedule fee	Volume of services (2015/16)	Services average annual growth (2010/11-2015/16)	Benefits (2015/16)
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72848	Immunohistochemical examination of biopsy material by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 1 to 3 of the following antibodies - oestrogen, progesterone and c-erb-b2 (Her2) (Item is subject to rule 13)"	74.50	5 908	-1.7%	\$360 162
73061	Immunocytochemical examination of material obtained by procedures described in items 73045, 73047, 73049, 73051, 73062, 73063, 73066 and 73067 for the characterisation of a malignancy by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 1 to 3 of the following antibodies - oestrogen, progesterone and c-erb-b2 (her2)(item is subject to rule 13)	51.20	93	-1.4%	\$3 972

- △ The misalignment between the rebates is demonstrated graphically in *Figure 10*, along with the perverse effect of tiering, which determines that the effective rebate per assay is actually greater if four IHC assays are done instead of three, if seven assays are done instead of six, or if 11 are done instead of 10. For ICC there is similarly a higher effective rebate per test if 7 assays are done instead of 6, or 11 assays are done instead of 10.

Figure 10. Effective rebate per Immunohistochemistry/Immunocytochemistry assay when additional assays are performed.



- △ As in other areas of Histopathology and Cytology, there are negligible economies of scale related to the performance of multiple immunohistochemistry assays on a specimen, with fixed reagent costs and similar labour.
- △ The cost of each particular assay might vary with the particular antibody clone, staining platform and necessity for signal amplification, but it would be generally true of all Australian laboratories that performance of more than two IHC assays incurs a financial loss, with very heavy financial penalties involved in performing the multiple assays.
- △ The current tiering rules are inequitable and unfair to laboratories undertaking complex diagnostic work (in particular, lymphoma characterisation), which involves a substantial financial loss due to the numbers of immunostains required.
- △ Pressure to limit the number of immunostains is impacting on the ability of smaller laboratories to adequately investigate complex malignancies, leading to additional costs and delays associated with referrals and second opinions.
- △ Currently, separate items are in place for the performance of breast receptor immunostains (72848: histology, and 73061: cytology). These items were introduced in recognition of the additional difficulty or time involved in assessing these markers (numeric scoring or grading is required). However, the rebate is the same whether one or three stains are performed, and the item is subject to Rule 13, meaning that if this item used, it ‘trumps’ any other IHC item of lesser value.
- △ This could mean that in a breast cancer case (where oestrogen receptor (ER), progesterone receptor (PR) and HER2 testing is normally done: item 72848), staining on the same case for e-cadherin (to confirm whether the tumour is lobular or ductal cancer), Ki67 (to assess proliferation) and a cytokeratin stain (to assess the sentinel node for micrometastases) all go unfunded (since they add up to item 72846, of lesser value). However, if four (not three) other stains were performed (item 72847), this is rebated higher than 72848, therefore the

ER/PR/HER2 stains would go unfunded. This was certainly not the intention when the item was introduced, and needs to be resolved.

- △ The necessity for ongoing additional item for higher complexity IHC stains (ER/PR/HER2) was considered. In view of the necessity for additional effort in the analysis of these stains, and the requirement for involvement in QAP programs, it was thought be the Committee that retention of the higher-complexity item was justified, allowing the possibility that additional targets may be added to the higher complexity group in future.
- △ Certain other IHC currently in use as predictive biomarkers (or soon to be required) could also be considered to be ‘complex’ IHC stains, requiring enumeration or scoring and requiring additional specific training and/or involvement in quality assurance programs. These include Ki67, ALK and PD-L1.
- △ Furthermore, the Committee considered that an additional 3rd tier higher complexity item should be introduced for the performance of chromogenic in situ hybridization (ISH) for detection of nucleic acid targets in tissue sections, exclusive of the current ISH biomarker assays for HER2 oncogene on the Genetics schedule (73332 & 73342). The detection of Epstein Barr virus (EBV) mRNA by ISH is necessary for the accurate classification of many lymphomas, and the detection of integrated oncogenic human papillomavirus (HPV) has recently been recognised as of critical prognostic importance in head and neck squamous cell carcinomas. Currently these automated assays are generally billed as IHC tests (as they involve immunohistochemical detection of the labelled target), but they are more costly and time consuming to perform than routine immunohistochemistry, and this should be recognised by an appropriately higher rebate.
- △ Lastly, it is noted that currently immunocytochemistry is not permitted in association with cytology tem 73043 (mucosal smear). The logic of this is not clear and there are circumstances in which this may be unfair to the patient.

Data modelling

Immunocytochemical analysis on cytology specimens is a relatively low-volume test (< 6000 usages in 2014–15). The effect on expected rebates of cytology and histology immunohisto/cytochemistry items being aligned without other adjustment (based on MBS data 2014–15) is shown in *Table 12*.

Table 12. Financial effects of aligning cytology and histology IHC rebates

Number of items	Histo. item	Histo. rebate (\$)	Cytology item	Cytology rebate (\$)	Cytology usage MBS 14-15	Current total MBS Cyto IHC rebate	Nominal Cyto MBS rebate if aligned
1 to 3	72846	59.6	73059	43	1749	75 207.00	104 240.40
4 to 6	72847	89.4	73060	57.35	2175	124 736.30	194 445.00
7 to 10	72849	104.3	73064	71.7	1278	91 632.60	133 295.40
11+	72850	119.2	73065	86	616	52 976	73 427.20
1 to 3br BR	72848	74.5	73061	51.2	93	4761.60	6 928.50
Totals					5911	349 313.50	512 336.50

Data from Laboratory A (8 months period, 2011) compares the coned rebates for Histological and Cytological immunostains versus the nominal unconed rebate if all tests were received singly

(Table 13). Substantial numbers (7.5%) of cases involving immunohistochemistry required more than 11 immunostains. If each assay were received as a single test, the overall rebate would have been almost fivefold higher.

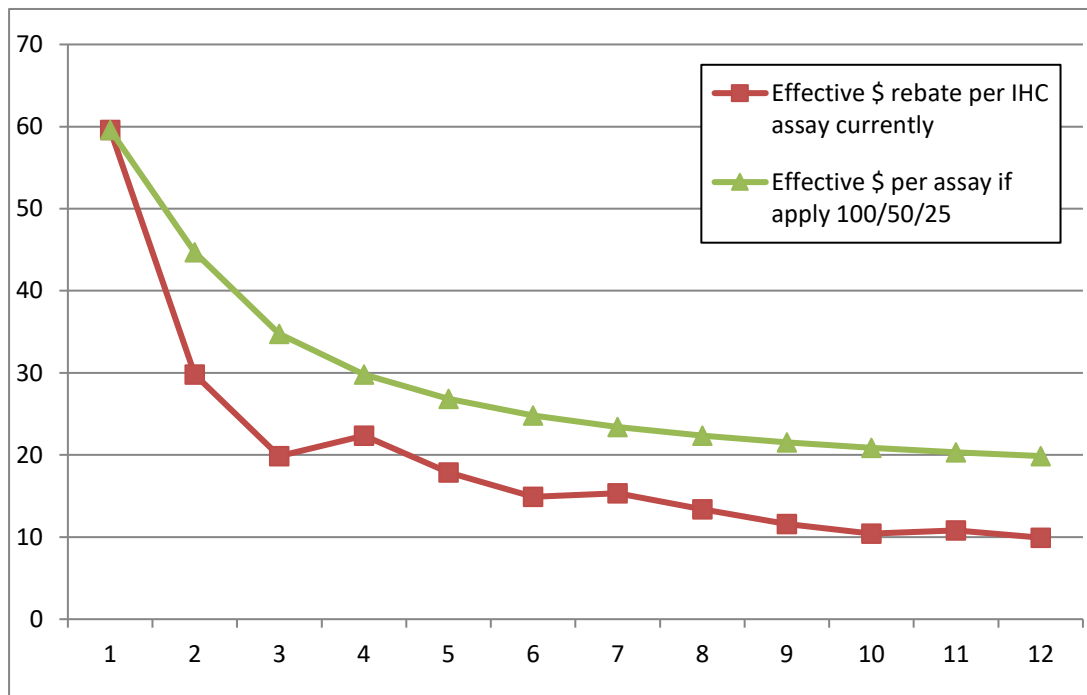
Table 6. Laboratory A data on coned and nominal unconed IHC rebates, 8 months 2011

CONED		No. of items	Rebate (\$)	Total
IPX 1-3	72846	807	59.60	48 097.20
IPX 4-6	72847	658	89.40	58 825.20
IPX-BR	72848	51	74.50	3 799.50
IPX 7-10	72849	246	104.30	25 657.80
IPX 11+	72850	151	119.20	17 999.20
C-IHC 1-3	73059	37	43.00	1 591.00
C-IHC 4-6	73060	34	57.35	1 949.90
C-IHC-BR	73061	5	51.20	256.00
C-IHC 7-10	73064	18	71.70	1 290.60
C-IHC 11+	73065	10	86.00	860.00
Totals		2017		160 326.40
UNCONED		No. of tests	Rebate	Nominal total
IPX	72846	11,255	59.6	670 798.00
IPX-BR	72848	1,137	74.5	84 706.50
C-IHC	73059	834	43	35 862.00
C-IHC-BR	73061	67	51.2	3 430.40
Totals		13 293		794 796.90

Consideration was given to alternate reimbursement strategies for immunohistochemistry. One possibility would be a flat fee per assay of each complexity (for however many were required), set at a level sufficient to cover costs but not induce an incentive to perform unnecessary tests.

An alternate strategy would be to introduce a 'Surgical' model (100%/50%/25%, etc.) similar to that considered for core Histology and Cytology reimbursement above. Comparison of the effects of the 'Surgical' model compared with the status quo for IHC is shown in *Figure 11* below.

Figure 1. Comparison of current effective rebate per IHC assay compared to 'Surgical' rebate model of 100%/50%/25% thereafter



The incremental percentage rebate for multiple specimens using the 100/50/25 rule is easily summarised in *Table 14*. This could be used for calculating IHC rebates or other situations with multiples of the same item using the 'Surgical' model.

Table 14. Percentage multiplier of unit rebate with increasing numbers of the same assay

# assays	1	2	3	4	5	6	7	8	9	10
% rebate	100	150	175	200	225	250	275	300	325	350
# assays	11	12	13	14	15	16	17	18	19	20
% rebate	375	400	425	450	475	500	525	550	575	600

The presence of two (or three) different IHC items of different complexity would be analogous to the situation with different complexity histology and cytology items, and still be amenable to application of the 'Surgical' model.

4.5 Electron microscope items

Recommendations

- △ Increase the rebate for electron microscopy item 72851 from \$184.35 to \$565 in line with the Ernst & Young report median value for this item.
- △ Remove item 72852 in line with recommendations to remove coning across the Histology schedule (preferred option) or increase rebate to \$753.33.
- △ If item 72852 is removed, the 97 instances where two or more tests were required could be rebated by the 100/50/25 rule, producing similar outcome.

Rationale

- △ Electron microscopic (EM) examination is a very-low-volume item but critically necessary in the analysis of a small number of specimen types, in particular renal biopsies when it is required to examine the fine detail of glomerular membranes and deposits. In many other circumstances it has been supplanted by immunohistochemistry. Specialist skill is required to process and analyse these specimens, and the equipment required is very expensive, therefore the test is now only performed in a limited number of referral laboratories.
- △ EM examination has been markedly under-remunerated for a very long time, despite vigorous efforts to have the issue reviewed. These items have not been updated since 2003, and the remaining EM laboratories are operating at a substantial loss. Once again, coning fails to recognise there are no economies of scale in processing multiple items. The total usage of these items accounts for less than 0.05% of Histology items claimed annually (see *Table 15*).

Table 7. Item introduction table for items 72851 and 72852

Item number	Descriptor	Schedule fee	Volume of services (2014/15)	Services average annual growth (2010/11-2014/15)	Benefits (2014/15)
72851	Electron microscopic examination of biopsy material - 1 separately identified specimen (Item is subject to rule 13)	\$184.35	1,289	4.5%	\$194 027
72852	Electron microscopic examination of biopsy material - 2 or more separately identified specimens (Item is subject to rule 13)	\$245.80	97	-1.4%	\$18 408

- △ Ernst & Young were contracted by the Department to review the issue in 2015; they produced a report and identified median costs for these two items in 2013 (\$536 for renal, \$565 for non-renal) but failed to provide definite recommendations. Recommended rebate prices were provided by the RCPA following surveys of the laboratories that perform this work, and are in line with the median costs stipulated in the Ernst & Young report.
- △ If this work is not appropriately funded and continues to be cross-subsidised, the availability of the service will diminish and the turn-around times will increase to the point where the test becomes irrelevant. This will impact on accuracy of renal biopsy diagnosis and thus potentially on efficacy of treatment.
- △ If the numbers of laboratories able to offer this service diminishes, the numbers of skilled staff and training opportunities for scientists and pathologists to become competent in preparation and reporting of EM specimens will also diminish.

- △ If the rebate is not aligned with the work involved, laboratories will be forced to charge patients (and/or other referring laboratories) substantial out-of-pocket supplements.
- △ Service volumes are low and are unlikely to be affected by the proposed changes, although ongoing viability of the service will hopefully be protected.

Data modelling

If the Ernest and Young median value of \$565 is adopted for item 72851, and item 72852 (two or more examinations) is \$753.33 (i.e. proportional to the current relationship between the rebates), the expected effect on total rebates is shown in *Table 16* below.

Table 16. Predicted effect on EM rebate if Ernest & Young median values adopted (MBS data 2014–15)

Item	Scheduled fee (\$)	Usage 2014–15	Total rebate (\$)	Proposed rebate (\$)	Proposed total rebate (\$)
72851	184.35	1289	237 627.15	565.00	728 285.00
72852	245.80	97	23 842.60	753.10	73 073.01
Totals			261 469.75		801 358.01

4.6 Frozen-section items

Recommendations

- △ Remove the current tiered frozen section items and replace with a single item.
- △ If simple removal of the coning is considered financially unacceptable, consider funding via an alternative more equitable model such as the ‘Surgical’ 100/50/25 model.

Rationale

- △ Frozen sections for intraoperative diagnosis are extremely time-consuming and labour-intensive examinations, which often require a pathologist and technician attending off-site. They are critically important for efficient operative planning and in many instances save the patient a second anaesthetic and surgical procedure. Currently there are three tiered items for 1, 2-4 or 5+ specimens, with no additional rebate for more than five frozen sections (*Table 17*).

Table 8. Item introduction table for items 72855, 72856, 72857

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change % (CAGR)	Benefits (2014–15)
72855	Intraoperative consultation and examination of biopsy material by frozen section or tissue imprint or smear - 1 separately identified specimen (Item is subject to rule 13)	184.35	7 587	2.2%	\$1 056 148
72856	Intraoperative consultation and examination of biopsy material by frozen section or tissue imprint or smear - 2 to 4 separately identified specimens (Item is subject to rule 13)	245.80	2 504	-0.5%	\$465 101
72857	Intraoperative consultation and examination of biopsy material by frozen section or tissue imprint or smear - 5 or more separately identified specimens (Item is subject to rule 13)	286.75	513	11.1%	\$112 867

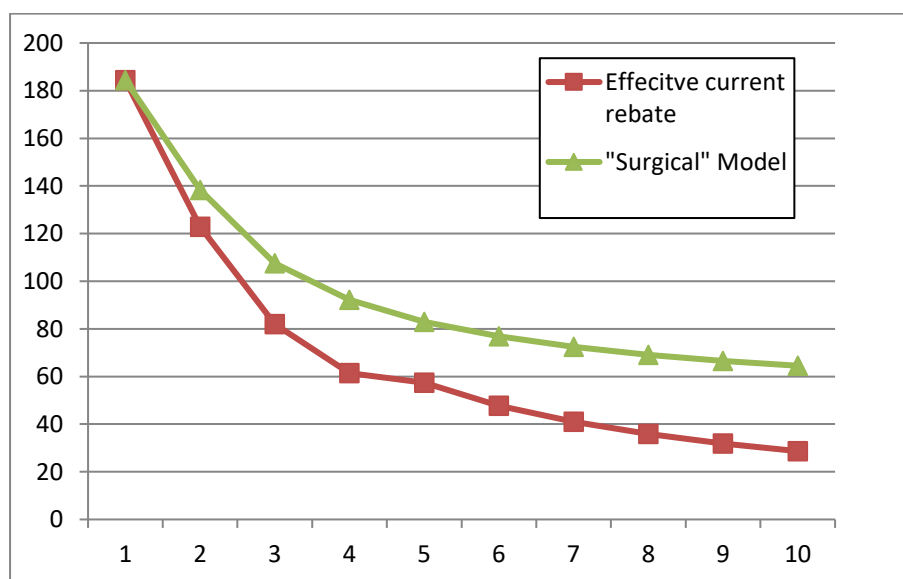
- △ When frozen sections are required for margin assessment of complicated tumours it is not infrequent that many more than five frozen sections are required. This may require a pathologist to spend many hours away from the laboratory, unable to undertake any other diagnostic work.
- △ This is demonstrated in data from Laboratory A (*Table 18*) showing coned versus unconed data on frozen sections over an 8-month period (2011). Although 944 actual frozen sections were performed, only 167 of these were single tests, and only 293 items were rebated. Many of the procedures therefore involved well over five frozen sections. If each procedure had been received as a single test, the overall rebate would have been 275% higher.

Table 18. Frozen Sections Laboratory A, coned and unconded data

CONED		No.Items	Rebate (\$)	Total (\$)
FS 1	72855	167	184.35	30 786.45
FS 2-4	72856	93	245.8	22 859.40
FS 5+	72857	33	286.75	9 462.75
		293		63 108.60
UNCONED		No.Items	Rebate	Nominal Total
FS	72855	944	184.35	174 026.40

- △ The current coning rules mean that the effective rebate for multiple specimens is not commensurate with the effort required. The effective rebate with increasing numbers of specimens is shown in *Figure 12*, along with potential rebate if the ‘Surgical’ 100/50/25 model was employed.

Figure 12. Current effective rebate per Frozen Section with increasing numbers of specimens compared with the ‘Surgical’ model.



- △ If this work is not appropriately funded and continues to be cross-subsidised, the availability of frozen section services, particularly in regional centres, will continue to diminish, as pathology practices cannot justify the extended pathologist availability required for them.
- △ Releasing pathologists for extended periods to attend frozen sections impacts on the workload of other pathologists in the laboratory and/or on the turn-around times of other work.
- △ Some private laboratories have already indicated their unwillingness to offer frozen section services, or have found it necessary to impose substantial out-of-pocket charges, particularly for out-of-hours attendances.
- △ A shortage of histopathologists and technicians (particularly in regional centres) has meant that in some centres intraoperative histopathological examination of tissue specimens (frozen sections) can no longer be performed. This means that patients will either have to undergo a separate second operative procedure (with the inherent risks of a second anaesthetic) at a later date rather than have a definitive single procedure, or travel large distances to a tertiary referral centre for their treatment.

4.7 Second Opinion Items

Recommendations

- △ Split items 72858 and 72859 into: pathologist-requested second opinions and non-pathologist clinician-requested second opinions (necessitating the creation of two additional items).
- △ Change the wording of the item descriptors. The proposed revised item descriptor for existing items 72858 and 72859 is as follows:
 - 72858: A second opinion, provided in a written report, where the opinion and report together require no more than 30 minutes to complete, on a patient specimen, requested by a treating practitioner, where further information is needed for accurate diagnosis *and/or* appropriate patient management.
 - 72859: A second opinion, provided in a written report, where the opinion and report together require more than 30 minutes to complete, on a patient specimen, requested by a treating practitioner, where further information is needed for accurate diagnosis *and/or* appropriate patient management.
- △ Change the wording of the explanatory notes to the following: 28.1 b) ‘... only if the treating practitioner and the approved pathology practitioner who provided the original opinion on the patient specimen agree that a second opinion is reasonably necessary for diagnostic *and/or patient management purposes*.
- △ Add the following new items specifically for pathologist-requested second opinions, with proposed descriptors as follows:
 - 728XX: A second opinion, provided in a written report, when the opinion and report together require more than 30 minutes to complete, on a patient specimen, initiated by the reporting pathologist and co-requested by a treating practitioner, when further information is needed for accurate diagnosis *and/or* appropriate patient management.
 - 728XX: A second opinion, provided in a written report, when the opinion and report together require more than 30 minutes to complete, on a patient specimen, initiated by the reporting pathologist and co-requested by a treating practitioner, when further information is needed for accurate diagnosis *and/or* appropriate patient management.
- △ Update the Explanatory notes to include these two additional items (as well as deleting reference to any histology or cytology items made redundant through this review).

Rationale

- △ Second opinion items were added to the MBS in November 2015 to fund morphological second opinions, following a successful MSAC application by the RCPA. The items were intended to be used in two different scenarios: a pathologist requests a second opinion in a difficult case, or a non-pathologist clinician requests a second opinion on the initial pathology to assist in patient management. In both scenarios, MSAC required that both requesting clinician and the initial reporting pathologist agreed that a second opinion was reasonably required for diagnostic purposes (*see Table 19 below*).
- △ At present it is not possible to tell how many second opinions are pathologist-requested versus clinician-requested.
- △ There has been considerable confusion in the pathology sector as to the appropriate utilisation of these items, the requirement for co-requesting, and the medicolegal implications of requests to agree that a second opinion is necessary. This has led to much lower than expected utilisation of these items since their addition to the MBS and marked discrepancy between different states.

Table 19. Item introduction table for items 72858 and 72859

Item number	Descriptor	Schedule fee	Volume of services (2014/15)	Services average annual growth (2010/11-2014/15)	Benefits (2015/16)
72858	A second opinion, provided in a written report, where the opinion and report together require no more than 30 minutes to complete, on a patient specimen, requested by a treating practitioner, where further information is needed for accurate diagnosis and appropriate patient management.	\$180.00	—	—	—
72859	A second opinion, provided in a written report, where the opinion and report together require more than 30 minutes to complete, on a patient specimen, requested by a treating practitioner, where further information is needed for accurate diagnosis and appropriate patient management.	\$370.00	—	—	—

- △ The Working Group notes that the RCPA has recently released updated Guidelines regarding the provision of second opinions. The Working Group also notes the departmental advice that a non-pathologist provider number is required for second opinion requests to be rebated (i.e. the provider number of clinician who initially referred the specimen for histology, another clinician involved in the treatment of the patient, or the non-pathologist clinician requesting the 2nd opinion is required for billing purposes).
- △ The Working Group remains of the opinion that the inability of a pathologist to request a rebated second opinion in a diagnostically difficult case is an anachronism in view of the funded availability of any number of clinical second opinions, but notes that a referring surgeon or clinician is most unlikely to refuse to agree with the request to obtain such an opinion.
- △ Splitting the items will facilitate better data collection/tracking of the utilisation of the items, and may also help identify potential resourcing issues (i.e. isolated pathologist requiring alternative support structure).
- △ Clarification of the co-requesting requirement will assist in allaying fears of medicolegal vulnerability and is aligned with MSAC's intention to avoid overuse of the item while making it available where there is genuine clinical concern about the diagnosis and its management implications.
- △ It is expected that usage of the items will gradually increase compared with the (current) unexpectedly low volumes. Ongoing review is appropriate in line with MBS audit schedule for new items.

4.8 Pathologist-determinable Items

Recommendations

- △ Revise relevant MBS item descriptors and explanatory notes to make it clear which items are pathologist-determinable, and the conditions under which such testing can occur.
- △ The Working Group recommends that the Department of Health/MSAC review the issue of pathologist-determinable tests specifically in the context of companion biomarkers, and consider whether legislative amendment may be appropriate to allow pathologists to on-refer such tests when they cannot perform them in their own laboratory, without the necessity to seek an additional request form from a non-pathologist clinician.
- △ If changes proposed elsewhere in this review relating to the simplification of the Tissue Pathology and Cytology Schedule are made, the Pathologist Determinable legislation will have to be updated.

Rationale

- △ There is currently considerable confusion over what ‘pathologist determinable’ actually means in the context of biomarker testing. Delays in testing are occurring because of the necessity to seek an additional request form from a non-pathologist clinician for tests to be rebated. This may impact on patient treatment planning and/or eligibility for trials.
- △ The absence of clear information within the MBS itself regarding which tests are pathologist determinable, and what restrictions are in place regarding the utilisation of this facility adds to the confusion.
- △ The Working Group has received advice from the Department that confirms that on-referral of a pathology test (including ‘pathologist determinable’ companion biomarkers such as HER2 in situ hybridization and epidermal growth factor receptor [EGFR] mutation analysis) to a second laboratory for testing and reporting requires a request from a non-pathologist clinician for the second laboratory to bill for the test. Pathologist-determinable testing only works within a pathologist’s own laboratory in association with an initial core item histology or cytology request.
- △ To allow pathologists to order even a limited subset of pathology items from another pathology provider would require a change in legislation (not just the MBS).
- △ The Working Group believes that MSAC’s intention in deeming certain companion biomarker assays “pathologist determinable” (i.e. to facilitate and streamline patient testing to optimise treatment) is being thwarted by current legislative restrictions around pathologist determinable tests.

5. References

This contains references to sources and materials referenced in this report.

- i) Elshaug A, et al (2012). Over 150 potentially low-value health care practices: an Australian study. *Medical Journal of Australia*; Vol.197 (10): 556-560
- ii) Buzacott K (2017) Dollars and sense: the true cost of histopathology. *Pathology* 2017: 49 (Suppl 1): S67
- iii) Royal College of Pathologists Australasia, Cancer Protocols. Surry Hills, NSW, 2016
- iv) Ellis DW, Srigley J: Does standardised structured reporting contribute to quality in diagnostic pathology? The importance of evidence-based datasets. *Virchows Arch* 2016; 468: 51-9.

6. Glossary

Term	Description
ACSQHC	The Australian Commission on Safety and Quality in Health Care
AHMAC	Australian Health Ministers' Advisory Council
Department, The	Australian Government Department of Health
DHS	Australian Government Department of Human Services
GP	General practitioner
High-value care	Services of proven efficacy reflecting current best medical practice, or for which the potential benefit to consumers exceeds the risk and costs.
Inappropriate use / misuse	The use of MBS services for purposes other than those intended. This includes a range of behaviours ranging from failing to adhere to particular item descriptors or rules, through to deliberate fraud.
Low-value care	The use of an intervention that evidence suggests confers no or very little benefit on patients, or that the risk of harm exceeds the likely benefit, or, more broadly, that the added costs of the intervention do not provide proportional added benefits.
MBS item	An administrative object listed in the MBS and used for the purposes of claiming and paying Medicare benefits, comprising an item number, service descriptor and supporting information, Schedule fee and Medicare benefits.
MBS service	The actual medical consultation, procedure, test to which the relevant MBS item refers.
MMM	Monash Modifier Model—a classification system that categorises metropolitan, regional, rural and remote areas according to both geographical remoteness and population size. The system was developed to recognise the challenges in attracting health workers to more remote and smaller communities.
MSAC	Medical Services Advisory Committee
NICE	National Institute for Health and Care Excellence
Obsolete services	Services that should no longer be performed as they do not represent current clinical best practice and have been superseded by superior tests or procedures.
PBS	Pharmaceutical Benefits Scheme
PHCAG	Primary Health Care Advisory Group
RCPA	Royal College of Pathologists of Australasia

Appendix A — Assigned MBS items: recommendations list

Table 20. Tissue Pathology items recommendations

Item	Current descriptor	Recommendation	Page reference
72813	Examination of complexity level 2 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 1 or more separately identified specimens	Change	29
72816	Examination of complexity level 3 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 1 separately identified specimen	Change	29
72817	Examination of complexity level 3 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 2 to 4 separately identified specimens	Change/ Consolidate	29
72818	Examination of complexity level 3 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 5 or more separately identified specimens	Change/ Consolidate	29
72823	Examination of complexity level 4 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 1 separately identified specimen	Change	29
72824	Examination of complexity level 4 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 2 to 4 separately identified specimens	Change/ Consolidate	29
72825	Examination of complexity level 4 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 5 to 7 separately identified specimens	Change/ Consolidate	29
72826	Examination of complexity level 4 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light	Change/ Consolidate	29

Item	Current descriptor	Recommendation	Page reference
	microscopy and professional opinion or opinions - 8 to 11 separately identified specimens		
72827	Examination of complexity level 4 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 12 to 17 separately identified specimens	Change/ Consolidate	29
72828	Examination of complexity level 4 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 18 or more separately identified specimens	Change/ Consolidate	29
72830	Examination of complexity level 5 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 1 or more separately identified specimens	Change	29
72836	Examination of complexity level 6 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 1 or more separately identified specimens	Change	29
72838	Examination of complexity level 7 biopsy material with multiple tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 1 or more separately identified specimens.	Change	29
72844	Enzyme histochemistry of skeletal muscle for investigation of primary degenerative or metabolic muscle diseases or of muscle abnormalities secondary to disease of the central or peripheral nervous system - 1 or more tests	No change	
72846	Immunohistochemical examination of biopsy material by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 1 to 3 antibodies except those listed in 72848	Change/ Consolidate	37
72847	Immunohistochemical examination of biopsy material by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 4-6 antibodies	Change/ Consolidate	37
72848	Immunohistochemical examination of biopsy material by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 1 to 3 of the following	Change	37

Item	Current descriptor	Recommendation	Page reference
	antibodies - oestrogen, progesterone and c-erb-B2 (HER2)		
72849	Immunohistochemical examination of biopsy material by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 7-10 antibodies	Change/ Consolidate	37
72850	Immunohistochemical examination of biopsy material by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 11 or more antibodies	Change/ Consolidate	37
72851	Electron microscopic examination of biopsy material - 1 separately identified specimen	Change	44
72852	Electron microscopic examination of biopsy material - 2 or more separately identified specimens	Change/ Consolidate	44
72855	Intraoperative consultation and examination of biopsy material by frozen section or tissue imprint or smear - 1 separately identified specimen	Change	46
72856	Intraoperative consultation and examination of biopsy material by frozen section or tissue imprint or smear - 2 to 4 separately identified specimens	Change/ Consolidate	46
72857	Intraoperative consultation and examination of biopsy material by frozen section or tissue imprint or smear - 5 or more separately identified specimens	Change/ Consolidate	46
72858	A second opinion, provided in a written report, where the opinion and report together require no more than 30 minutes to complete, on a patient specimen, requested by a treating practitioner, where further information is needed for accurate diagnosis and appropriate patient management.	Change	48
72859	A second opinion, provided in a written report, where the opinion and report together require more than 30 minutes to complete, on a patient specimen, requested by a treating practitioner, where further information is needed for accurate diagnosis and appropriate patient management.	Change	48

Table 21. Cytopathology items recommendations

Item	Current descriptor	Recommendation	Page reference
73043	Cytology (including serial examinations) of nipple discharge or smears from skin, lip, mouth, nose or anus for detection of precancerous or cancerous changes 1 or more tests	Change	34
73045	Cytology (including serial examinations) for malignancy (other than an examination mentioned in item 73053); and including any Group P5 service, if performed on: (a) specimens resulting from washings or brushings from sites not specified in item 73043; or (b) a single specimen of sputum or urine; or (c) 1 or more specimens of other body fluids; 1 or more test	Change	34
73047	Cytology of a series of 3 sputum or urine specimens for malignant cells	Change	34
73049	Cytology of material obtained directly from a patient by fine needle aspiration of solid tissue or tissues - 1 identified site	Change	34
73051	Cytology of material obtained directly from a patient at one identified site by fine needle aspiration of solid tissue or tissues if a recognized pathologist: (a) performs the aspiration; or (b) attends the aspiration and performs cytological examination during the attendance	Change	34
73053	Cytology of a smear from cervix where the smear is prepared by direct application of the specimen to a slide, excluding the use of liquid based slide preparation techniques, and the stained smear is microscopically examined by or on behalf of a pathologist - each examination (a) for the detection of precancerous or cancerous changes in women with no symptoms, signs or recent history suggestive of cervical neoplasia, or (b) if a further specimen is taken due to an unsatisfactory smear taken for the purposes of paragraph (a); or (c) if there is inadequate information provided to use item 73055;	No recommendation (New items for National Cervical Screening Program)	

Item	Current descriptor	Recommendation	Page reference
73055	<p>Cytology of a smear from cervix, not associated with item 73053, where the smear is prepared by direct application of the specimen to a slide, excluding the use of liquid based slide preparation techniques, and the stained smear is microscopically examined by or on behalf of a pathologist - each test</p> <p>(a) for the management of previously detected abnormalities including precancerous or cancerous conditions; or</p> <p>(b) for the investigation of women with symptoms, signs or recent history suggestive of cervical neoplasia;</p>	No recommendation (New items for National Cervical Screening Program)	
73057	<p>Cytology of smears from vagina, not associated with item 73053 or 73055 and not to monitor hormone replacement therapy, where the smear is prepared by direct application of the specimen to a slide, excluding the use of liquid based slide preparation techniques, and the stained smear is microscopically examined by or on behalf of a pathologist - each test</p>	No recommendation (New items for National Cervical Screening Program)	
73059	<p>Immunocytochemical examination of material obtained by procedures described in items 73045, 73047, 73049, 73051, 73062, 73063, 73066 and 73067 for the characterisation of a malignancy by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 1 to 3 antibodies except those listed in 73061</p>	Change	37
73060	<p>Immunocytochemical examination of material obtained by procedures described in items 73045, 73047, 73049, 73051, 73062, 73063, 73066 and 73067 for the characterisation of a malignancy by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 4 to 6 antibodies</p>	Change/Consolidate	37
73061	<p>Immunocytochemical examination of material obtained by procedures described in items 73045, 73047, 73049, 73051, 73062, 73063, 73066 and 73067 for the characterisation of a malignancy by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 1 to 3 of the following antibodies - oestrogen, progesterone and c-erb-B2 (HER2)</p>	Change	37

Item	Current descriptor	Recommendation	Page reference
73062	Cytology of material obtained directly from a patient by fine needle aspiration of solid tissue or tissues - 2 or more separately identified sites.	Change/Consolidate	34
73063	Cytology of material obtained directly from a patient at one identified site by fine needle aspiration of solid tissue or tissues if an employee of an approved pathology authority attends the aspiration for confirmation of sample adequacy.	Change	34
73064	Immunocytochemical examination of material obtained by procedures described in items 73045, 73047, 73049, 73051, 73062, 73063, 73066 and 73067 for the characterisation of a malignancy by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 7 to 10 antibodies	Change/Consolidate	37
73065	Immunocytochemical examination of material obtained by procedures described in items 73045, 73047, 73049, 73051, 73062, 73063, 73066 and 73067 for the characterisation of a malignancy by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 11 or more antibodies	Change/Consolidate	37
73066	Cytology of material obtained directly from a patient at 2 or more separately identified sites by fine needle aspiration of solid tissue or tissues if a recognized pathologist: (a) performs the aspiration; or (b) attends the aspiration and performs cytological examination during the attendance.	Change/Consolidate	34
73067	Cytology of material obtained directly from a patient at 2 or more separately identified sites by fine needle aspiration of solid tissue or tissues if an employee of an approved pathology authority attends the aspiration for confirmation of sample adequacy	Change/Consolidate	34

Table 22. Items considered in discussion with Genetics Working Group

Item	Current descriptor
73332	An in situ hybridization (ISH) test of tumour tissue from a patient with breast cancer requested by, or on the advice of, a specialist or consultant physician who manages the treatment of the patient to determine if the requirements relating to human epidermal growth factor receptor 2 (HER2) gene amplification for access to trastuzumab under the Pharmaceutical Benefits Scheme (PBS) or the Herceptin Program are fulfilled.
73336	A test of tumour tissue from a patient with unresectable stage III or stage IV metastatic cutaneous melanoma, requested by, or on behalf of, a specialist or consultant physician, to determine if the requirements relating to BRAF V600 mutation status for access to dabrafenib or vemurafenib under the Pharmaceutical Benefits Scheme are fulfilled.
73337	A test of tumour tissue from a patient diagnosed with non-small cell lung cancer, shown to have non-squamous histology or histology not otherwise specified, requested by, or on behalf of, a specialist or consultant physician, to determine if the requirements relating to epidermal growth factor receptor (EGFR) gene status for access to erlotinib or gefitinib under the Pharmaceutical Benefits Scheme (PBS) are fulfilled.
73338	A test of tumour tissue from a patient with metastatic colorectal cancer (stage IV), requested by a specialist or consultant physician, to determine if the requirements relating to rat sarcoma oncogene (RAS) gene mutation status for access to cetuximab or panitumumab under the Pharmaceutical Benefits Scheme (PBS) are fulfilled, if: (a) the test is conducted for all clinically relevant mutations on KRAS exons 2, 3 and 4 and NRAS exons 2, 3, and 4; or (b) a RAS mutation is found.
73341	Fluorescence in situ hybridisation (FISH) test of tumour tissue from a patient with locally advanced or metastatic non-small cell lung cancer, which is of non-squamous histology or histology not otherwise specified, with documented evidence of anaplastic lymphoma kinase (ALK) immunoreactivity by immunohistochemical (IHC) examination giving a staining intensity score > 0, and with documented absence of activating mutations of the epidermal growth factor receptor (EGFR) gene, requested by a specialist or consultant physician to determine if requirements relating to ALK gene rearrangement status for access to crizotinib or ceritinib under the Pharmaceutical Benefits Scheme (PBS) are fulfilled
73342	An in situ hybridisation (ISH) test of tumour tissue from a patient with metastatic adenocarcinoma of the stomach or gastro-oesophageal junction, with documented evidence of human epidermal growth factor receptor 2 (HER2) overexpression by immunohistochemical (IHC) examination giving a staining intensity score of 2+ or 3+ on the same tumour tissue sample, requested by, or on the advice of, a specialist or consultant physician who manages the treatment of the patient to determine if the requirements relating to HER2 gene amplification for access to trastuzumab under the Pharmaceutical Benefits Scheme are fulfilled.

Appendix B- New or split items

Table 23. New or split items recommendations

Item	Descriptor	Recommendation	Page reference
728xx	A second opinion, provided in a written report, where the opinion and report together require more than 30 minutes to complete, on a patient specimen, initiated <u>by the reporting pathologist</u> and co-requested by a treating practitioner, where further information is needed for accurate diagnosis and/or appropriate patient management.	Split item 72858 into: pathologist-requested second opinions and non-pathologist clinician requested second opinions.	48
728xx	A second opinion, provided in a written report, where the opinion and report together require more than 30 minutes to complete, on a patient specimen, initiated <u>by the reporting pathologist</u> and co-requested by a treating practitioner, where further information is needed for accurate diagnosis and/or appropriate patient management.	Split item 72859 into: pathologist-requested second opinions and non-pathologist clinician requested second opinions.	48
728xx	Chromogenic in situ hybridization performed on biopsy material involving immunohistochemical localization of nucleic acid target	Create 3 rd tier IHC item for use of chromogenic in situ hybridization assays on tissue sections	37

Appendix C Summary for consumers

Pathology Clinical Committee (Anatomical Pathology/Cytology Working Group) recommendations

Recommendation 1: Changes to the complexity table

Histopathology (or histology) is the examination of tissue samples. It is also known as Tissue Pathology or Anatomical Pathology. Unlike other areas of pathology, there is minimal automation of the process.

Before microscopic examination, scientists prepare the specimen. The preparation of tissue specimens can be very labour intensive and the scientists must be highly skilled.

Examination is then performed by a specialist doctor, known as an anatomical pathologist. The examination requires a careful examination under a microscope and preparation of a written diagnostic report.

Large tissue specimens can be whole organs or parts of an organ from the body that are removed during surgery. Smaller pieces of tissue removed from skin or organs are called biopsies.

The Complexity Table is part of the MBS and contains an alphabetical list of different specimen types classified according to the amount of the time it takes to prepare and examine samples from these different organs.

The proposed changes to the Complexity Table are to ensure that the classification of samples from different organs is accurate and reflects the effort required to examine them. The proposed changes would potentially result in a 5% increase in payment for the work done by an average laboratory.

This will help maintain the viability of laboratories, which are currently underfunded for the work they do. This is important to ensure that access and equity issues for both the patient and the service are addressed.

Recommendation 2: Changes to coning in Anatomical Pathology items

Currently the funding received by Anatomical Pathology laboratories for the work they do examining tissue specimens is limited by complicated tiering and coning rules. This effectively means that 30% to 50% of the work performed is not funded.

This underfunding is impacting on the viability of laboratories. It also affects staffing, which has potential impacts on the time taken to get results to patients, which may delay diagnosis and have an adverse effect on patient outcomes. It may even affect the accuracy of those results, as overworked staff are more likely to make errors.

The Committee is recommending simplification of the items and coning rules and a fairer way of calculating the payment for examining tissue specimens.

Recommendation 3: Changes to coning in Cytology items

Cytology is the examination of cells that have been removed from the body and placed onto glass slides for examination. The best known example is the cervical Pap smear, but similar testing can be performed on cells from many sites. Cytology is usually divided into gynaecological (e.g. Pap smears) and non-gynaecological testing.

Currently there are different MBS items for non-gynaecological cytology related to the degree of effort required in preparing and examining the sample, but as in Histology, coning rules mean the funding does not accurately reflect the amount of work done. This underfunding is impacting on the viability of cytology laboratories, which are already under considerable stress due to changes in the National Cervical Screening Program and loss of Pap smear work.

The Committee is recommending simplification of the items and coning rules and a fairer way of calculating the payment for examining cytology specimens.

Recommendation 4: Alignment of Immunohistochemistry and Immunocytochemistry items and consideration of coning

Immunohistochemistry is the use of monoclonal antibody stains to identify certain proteins or other targets in cells and tissues. This is most frequently used to identify what type of tumour is present in a biopsy. If performed on cytology samples it is also known as immunocytochemistry, but it is actually exactly the same test.

Multiple different items for this test are present in the MBS for both Histology and Cytology, relating to the number of different antibody stains done. Over time, the rebates for immunohistochemistry and immunocytochemistry have 'got out of sync'. They should be funded exactly the same way.

The Committee also considers that the current complicated tiering/coning rules are illogical and should be replaced by two basic items (simple and complex immunohistochemistry) funded at an appropriate level.

The Committee has also recommended the introduction of a third item to adequately rebate the use of in situ hybridization assays, which involve detection of a DNA/RNA target in cells using a procedure which incorporates an immunohistochemistry step, but is much more costly to perform.

Recommendation 5: Electron microscope items 72851, 72852

Electron microscopic examination of a specimen involves looking at extremely high magnification (up to 2 million times) at a specially prepared sample using specialised and expensive equipment which uses beams of electrons instead of light rays. It is most commonly done on kidney biopsies to help determine why the kidney is failing.

Not all laboratories can do this test and it is done in specialised laboratories with experienced staff. It has been consistently underfunded for decades, despite efforts to have it reviewed.

The Committee recommends the rebate be increased to maintain the availability of this low-volume but very important test.

Recommendation 6: Frozen-section items 72855, 72856, 72857

A tissue biopsy taken from a patient in the operating theatre can be frozen and cut very thinly onto a slide to enable the pathologist to make a preliminary diagnosis while the patient is still asleep. This can help the surgeon plan how to proceed with the operation.

Currently there are coning rules that limit the funding available for this very labour-intensive test. The Committee recommends removing these rules and calculating the payment for frozen sections in a fairer way.

Recommendation 7: Second-opinion items 72858, 72859

New items recently added to the MBS allow a pathologist or other doctor to request a second opinion from another pathologist in a difficult case. Confusion exists about how this is to be ordered.

The Committee recommends splitting the items so it can be seen who is requesting the second opinion (pathologist or other doctor) and clarifying the wording to ensure the items are used appropriately.

Recommendation 8: Pathologist-determinable items

Certain tests on the MBS are 'pathologist determinable', meaning that a pathologist can add them on to a request without a written request from the clinician who sent the biopsy. Immunohistochemistry is one such test, which is frequently required to classify a particular tumour.

Other genetic tests that allow access to certain targeted cancer therapies are also 'pathologist determinable' (HER2 testing in breast cancer and epidermal growth factor receptor [EGFR] testing in lung cancer), but if a pathologist needs to send the specimen to a second pathology laboratory to do the testing, it is no longer 'pathologist determinable' and a delay may occur while a second request form is obtained from the clinician.

The Committee recommends that the Department of Health review this issue to provide greater clarity.