
1332

Protocol to guide the
assessment of
external expert
opinions for
Morphological
Pathology (Histology
and Cytopathology).

May 2014

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MSAC and PASC

The Medical Services Advisory Committee (MSAC) is an independent expert committee appointed by the Australian Government Health Minister to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health on the evidence relating to the safety, effectiveness, and cost-effectiveness of new and existing medical technologies and procedures and under what circumstances public funding should be supported.

The Protocol Advisory Sub-Committee (PASC) is a standing sub-committee of MSAC. Its primary objective is the determination of protocols to guide clinical and economic assessments of medical interventions proposed for public funding.

Purpose of this document

This document is a protocol that will be used to guide the assessment of a proposed Medicare Benefits Schedule (MBS) item that allows second, expert opinions on a pathology specimen, where the initial pathology opinion is uncertain, or where further information is required. The draft protocol was finalised after inviting relevant stakeholders to provide input. The final protocol will provide the basis for the assessment of the intervention.

This protocol has been developed using the widely accepted "PICO" approach. The PICO approach involves a clear articulation of the following aspects of the research question that the assessment is intended to answer:

Patients – specification of the characteristics of those patients in whom the intervention is to be considered for use;

Intervention – specification of the proposed intervention;

Comparator – specification of the service most likely to be replaced by the proposed intervention; and

Outcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention.

Purpose of application

An application was received from The Royal College of Pathologists of Australasia (hereafter referred to as “the Applicant”) by the Department of Health in September 2012, requesting MBS reimbursement of second opinions for morphological pathology (histology, cytopathology, haematology, microbiology and genetic pathology). New MBS items are proposed that represent a second opinion on pathology services, for which an initial service is already available on the MBS. PASC agreed to restrict this Protocol and subsequent assessment to histology and cytopathology, and not include haematology (with the exception of bone marrow), microbiology or genetics items. The included service groups are therefore P5 (Tissue pathology, items 72813-72857), P6 (Cytology, items 73043-73067), and bone marrow items within P1 (Haematology, items 65084-65087). The proposed new MBS items would be used: (i) in instances where the initial pathologist requests that an external expert pathologist view the case due to the complexity of the disease or uncertainty around the initial interpretation or diagnosis; or (ii) in instances where a clinician in charge of patient management wants the initial opinion verified or refined by an expert pathologist for the purpose of diagnosis or patient management.

A contractor with the Department of Health has drafted this Protocol to guide the assessment of the safety, effectiveness and cost-effectiveness of second, expert opinions for morphological pathology in order to inform MSAC’s decision-making regarding public funding of this service.

Background

Current arrangements for public reimbursement

Currently, the public reimbursement of pathology opinions only applies to the initial pathology report. In circumstances where a second pathology opinion is considered necessary for patient management, it may be requested and provided through approved laboratories but this extra service is not eligible for MBS reimbursement. Therefore, the second pathologist opinion is currently provided either: (i) without payment; (ii) at the expense of the initial pathology laboratory, if this was the source of the referral; (iii) at the expense of the requesting hospital/unit (which may be publicly funded through other health budgets); or (vi) at the expense of the patient.

Estimated use of the proposed service

The estimated number of cases which would require a second, expert opinion is uncertain as there is little applicable evidence to support estimates. An estimate of 1-2%, originally suggested by the Applicant, was based on a second opinion workload of ~1.6% at St

Vincent's Hospital, NSW. However, as St Vincent's Hospital is a major, metropolitan referral centre, it is likely that this estimate is greater than would apply Australia-wide. Consequently, the Applicant has advised that a more realistic rate of second, expert opinion would be substantially less than 1%.

Expert advice suggests that large laboratories would only refer approximately 0.1-0.2% of cases for expert review and that small or single pathologist laboratories would refer less than 1%. Based on those estimates, it has been suggested that the overall proportion of histopathology specimens referred for a second, expert opinion would be unlikely to exceed 0.2-0.3% of cases.¹

According to a survey conducted by the College of American Pathologists of 180 institutions (including a small number of laboratories from Australia), the aggregate rate for referral to an extra-departmental expert for second opinion was 0.5% (median 0.7%, 10th percentile 0.2%, 90th percentile 2.0%) (Azam et al. 2002). This rate does not include cases resulting from a patient's referral to a different institution or cases in which no diagnostic impression was rendered in the primary laboratory.

Annual utilisation of the proposed expert opinion service can be estimated using a referral rate of 0.5% (range 0.1% to 1%), as discussed above, applied to MBS service data for the relevant pathology items that may require second, expert opinion. Current utilisation data for all "core" morphology items in Group P1 (bone marrow items only) and in Groups P5 and P6 are presented in Table 1. A list of the item numbers and descriptors is provided in Attachment 1.

¹ Feedback on Consultation Protocol (Assoc Prof Sanjiv Jain).

Table 1 All relevant "core" morphology MBS items in Groups P1, P5 and P6 processed from July 2012 to June 2013

Item Number	Service Fee	Number of Services	Total Value of Benefits
Group P1 – Bone marrow	-	-	-
65084	\$165.85	15,382	\$2,045,089
65087	\$83.10	2,643	\$178,091
Total <i>Bone marrow core items</i>	-	18,025	\$2,223,180
Group P5 – Tissue pathology	-	-	-
72813	\$71.50	10,983	\$624,596
72816	\$86.35	1,266,752	\$93,025,062
72817	\$96.80	313,420	\$25,852,127
72818	\$107.05	17,076	\$1,534,872
72823	\$97.15	633,867	\$49,916,025
72824	\$141.35	356,323	\$39,344,931
72825	\$180.25	56,333	\$7,860,761
72826	\$194.60	18,392	\$2,759,312
72827	\$208.95	5,618	\$909,330
72828	\$223.30	2,018	\$343,898
72830	\$274.15	80,498	\$17,700,203
72836	\$417.20	22,469	\$7,098,771
72838	\$466.85	12,872	\$4,536,317
Total <i>All P5 core items</i>	-	2,796,621	\$251,506,205
Group P6 - Cytology	-	-	-
73043	\$22.85	2,370	\$47,072
73045	\$48.60	99,501	\$4,016,545
73047	\$94.70	44,010	\$3,585,417
73049	\$68.15	58,404	\$3,489,727
73051	\$170.35	10,063	\$1,498,331
73053 ^a	\$19.45	1,548,645	\$25,898,224
73055 ^a	\$19.45	213,220	\$3,571,966
73057 ^a	\$19.45	30,916	\$519,617
73062	\$89.00	7,524	\$588,528
73063	\$99.35	16,189	\$1,384,349
73066	\$221.45	2,380	\$466,221
73067	\$129.15	2,488	\$277,118
Total <i>All P6 core items</i>	-	2,035,710	\$45,343,116
Total <i>excluding gynaecological tests^a</i>	-	242,929	\$15,353,309

Data Source: Medicare Australia Statistics website.

Note: Items 72855-72857 are for intraoperative consultation and examination of biopsy material by frozen section or tissue imprint or smear. Therefore, they are not relevant to the proposed expert opinion service and will not be included in the assessment.

^a Items 73053, 73055, 73057 are gynaecological tests.

Using the MBS data for bone marrow items (Group P1: 65084-65087) for the financial year 2012-2013, the estimated number of annual referrals for second, expert opinion is 90 (assuming a 0.5% rate) or approximately 18-180, assuming that 0.1-1% of initial cases could be referred.

The estimated annual utilisation of the proposed service for core tissue pathology items (Group P5: 72813-72838) is approximately 14,000 (using a referral rate of 0.5%) or approximately 2,800-28,000, assuming that 0.1-1% of initial cases could be referred. According to expert advice, cases that require a second opinion are usually at the complex end of the histology schedule – whereas the majority of histology that is done in Australia concerns simple skin and gastrointestinal tract (GIT) biopsies.²

Assuming that the same referral rates would apply across the three groups (P1, P5 and P6), the estimated number of annual cytology (Group P6: 73043-73057, 73062-73063 and 73066-73067) referrals for second, expert opinion is approximately 10,000 and could range from around 2,000-20,000. For cytology items, the estimated rate of second, expert opinions is expected to be toward the lower end of the range because in many instances the cytology is undertaken as a screening or preliminary test. It would be rare that a second, expert opinion would be required, except where it is difficult to re-biopsy sites (such as the pancreas).³ Difficult cases would usually be reported as suspicious or indeterminate and a formal histological biopsy suggested.

Second, expert opinions for gynaecological cytopathology

In the Draft Protocol and public consultation process, the possibility of excluding gynaecological cytology cases (items 73053-73057) from the proposed second, expert opinion item(s) was discussed. The rationale behind excluding those services was that the majority of current services relate to screening rather than diagnosis and that it is relatively cheap (\$19.45) to repeat the initial smear. It was subsequently argued that excluding gynaecological cytology items, particularly MBS item 73053, could be problematic given that the inconvenience and discomfort of obtaining a smear could be a deterrent against repeating the test and that a lack of funding for a second, expert opinion would disproportionately affect women, clinicians and laboratory staff in rural and remote areas.⁴

Consideration therefore needs to be given as to whether the inclusion of gynaecological cytology cases in the second, expert opinion service is appropriate. Currently, as shown in Table 1, approximately 75% of all initial cytopathology claims relate to MBS item 73053 for

³ Expert pathologist opinion (Prof A Morey, HESP), email 5/7/2013.

⁴ Feedback on Consultation Protocol (Dr F Douglas).

routine Pap smear screening (i.e. cytology of a smear from the cervix in women with no symptoms, signs or recent history suggestive of cervical neoplasia). In Australia, biennial Pap smears have been promoted through the National Cervical Screening Program since the early 1990s for women between the ages of 18 (or two years after first sexual intercourse, whichever is later) and 69 years. Despite the high usage of MBS item 73053, it may be that a second opinion for this and other gynaecological cytology items would rarely be required.

Furthermore, the current widespread use of item 73053 is likely to change substantially from 2016, when changes to the National Cervical Screening Program, recently recommended by MSAC, are anticipated to come into effect. The renewed screening pathway is based on five-yearly screening with human papillomavirus (HPV) testing in place of cytology as the primary screening tool. The estimated use of cytology is expected to decrease from 2.4 million per year in 2016 to 0.34 million per year, and conventional cytology will be replaced with liquid-based cytology.⁵

Other aspects of utilisation of second, expert opinions

There is anecdotal evidence that second, expert opinions are not sought as frequently as they should be (particularly from isolated regional or remote pathologists) if there is a charge levied on the service (or to the patient) by the referring laboratory or if it is seen as an impost on colleagues.⁶ This implies that, with MBS funding, a higher rate of requests for second opinions would be expected. It is also noted that in some institutions, second opinions on pathology are mandatory prior to commencing treatment in referral centres (Kronz, Joseph D., Westra & Epstein 1999; Manion, Cohen & Weydert 2008) and there is a view that this is 'best practice' in some settings (Davidov et al. 2010; Jara-Lazaro, Thike & Tan 2010; Kronz, J. D. & Westra 2005; Kronz, Joseph D., Westra & Epstein 1999; Manion, Cohen & Weydert 2008; Matasar et al. 2012).

However, PASC has advised that second, expert opinions requested by a treating clinician (such as in a referral centre) should only be considered for public funding when there is uncertainty in the diagnosis or insufficient information to effectively manage the patient. The intention of the proposed MBS item is not to provide funding for mandatory review of all cases referred to treatment centres.

⁵ MSAC 61st Meeting (3-4 April 2014) Outcomes for Application No. 1276 – Renewal of the National Cervical Screening Program [available at <http://www.msac.gov.au/>]

⁶ Expert pathologist opinion (Prof A Morey, HESP), email 5/7/2013.

Similarly, experts advise that within any given laboratory there are many referrals for second opinion between pathologists during the course of a day's work.⁷ It is not the intent of the application to provide funding for this intra-institutional activity.

Regulatory status

Second opinions for morphological pathology are often provided by pathologists and laboratories operating under the same regulatory requirements as those for initial pathology opinions; that is, Approved Pathology Practitioners (APP) operating in National Association of Testing Authorities (NATA) and RCPA accredited laboratories (Approved Pathology Laboratory; APL). To avoid any concern that inappropriate internal pathologist referrals might be made to generate revenue, the Applicant has suggested that a second pathology opinion, sought due to pathologist uncertainty, cannot be provided from within the same pathology laboratory and that requests for second opinions would need to be made from non-pathologists i.e. the treating clinician.

The Applicant has proposed that a second, expert opinion, requested due to pathologist uncertainty, would need to be sought from a second Approved Pathology Laboratory (APL) but not necessarily another Approved Pathology Authority (APA). Currently Medicare restricts an additional payment where a specimen is referred between 2 laboratories that are part of the same APA. For the purpose of this Protocol and the subsequent assessment, this restriction is referred to as 'external expert opinion' and refers to the relationship between the initial pathologist and the second, expert pathologist. However, consideration should be given as to whether there could also be inappropriate referrals between a clinician and an expert pathologist who are co-located at a tertiary treatment centre.

Intervention

Description

The proposal relates to MBS funding of pathologists providing second, expert opinions as part of morphological diagnoses in the sub specialties of tissue pathology, cytology and haematology (bone marrow only). An initial opinion in these sub specialties is currently funded through several MBS items.⁸ However, as stated previously, the MBS does not currently fund a second pathology opinion on the same sample.

Morphological diagnosis and staging is integral to the management of many diseases, particularly cancers. A definitive diagnosis can be difficult in rare or complex diseases and so

⁷ Expert pathologist opinion (Prof A Morey, HESP), email 5/7/2013.

⁸ Tissue Pathology (items 72813-72857); Cytopathology (items 73043-73067); Haematology – bone marrow (items 65084-65087).

a second opinion from another pathologist with a particular expertise in the condition, or type of disease (e.g. breast pathologist, dermatopathologist, urogenital pathologist, hepatopathologist), is sometimes required. The Applicant estimated that over 80% of requests for second, expert opinion would relate to diagnoses of malignancy.

When rare or complex diseases are identified, patients are often referred to specialist centres for treatment, where the second, expert pathology opinion refines the diagnosis, potentially altering treatment decisions. This optimisation of diagnosis and treatment can directly improve outcomes for the patient; however, providing these second opinions on complex cases, or on unusual or rare diseases, can be time and resource consuming work.

Delivery of the intervention

PASC agreed on two scenarios where second, expert opinions, funded through the MBS, should be considered:

Scenario 1:

Where the pathologist communicates with the clinician in charge of patient management, and suggests referral to an external expert pathologist, due to a rare, unusual or complex case where a primary or definitive diagnosis cannot be confidently made by the reporting pathologist; and

Scenario 2:

Where the clinician in charge of patient management wants the initial pathology opinion verified or refined by a second, expert pathologist or by their usual pathologist.

In *Scenario 1*, the initial pathologist reporting the case would normally identify an expert to whom the case would be referred for the second opinion. In *Scenario 2*, the expert review would typically be undertaken at the request of a clinician (most often a specialist) at a treatment centre to which a patient has been referred for further management. The review would be provided by the pathologist who would normally provide the service to the treatment centre. The most common context for this to occur is in cancer management as oncology patients are often referred to tertiary centres for management. However, other serious and/or unusual disease processes of sufficient clinical importance may also require specialist clarification of the diagnosis. It is also possible that the initial treating clinician (e.g. a general practitioner) with concerns regarding the diagnosis could request the second, expert opinion before referring a patient to a tertiary treatment centre.

In both scenarios, the slides and case material are collated and provided to the expert pathologist, who then generates a second pathology report. The expert pathologist may also

need to undertake additional tests (e.g. immunohistochemistry, molecular testing) in order to confirm, revise or refine the original diagnosis (see the 'Co-administered and associated interventions' section, page 11).

It is considered highly unlikely that a third opinion would be requested.⁹ Similarly, although the need for a second opinion is only anticipated to occur rarely, it is not possible to define or limit how many times a second opinion on different pathology services might be required for an individual patient. This would depend entirely on how many initial pathology services are requested for them, and the complexity of their illness(es) and future illness(es). It is thought that it would be rare that someone would need to utilise a second, expert pathology opinion more than once for a particular disease episode. However, it is possible.

Prerequisites

The provision of a second, expert pathology opinion would be provided by Anatomical Pathologists who provide morphological interpretive assessment. These providers would be required to have Fellowship of the RCPA, or equivalent. Furthermore, the service would be required to be undertaken in NATA/RCPA accredited laboratories within Australia.

Co-administered and associated interventions

Although the expert pathologist would use the specimens/samples/slides that were used to inform the original diagnosis, the second opinion might require the conduct of additional ancillary tests (e.g. immunohistochemistry, molecular testing) to provide a definitive diagnosis.

The "non-core" items listed in Table 2 include ancillary tests from Groups 5 and 6 that may be undertaken by a pathologist, such as immunohistochemistry, electron microscopy, immunocytochemistry and enzyme histochemistry. These services are not conducted in isolation and are always associated with one of the "core" pathology items (i.e. tissue pathology items 72813-72838; cytology items 73043-73057, 73062-73063 and 73066-73067 or bone marrow items 65084-65087).

It is anticipated that these ancillary tests would be able to be claimed in the normal way, in conjunction with the second, expert opinions. The Applicant proposes that this should be the case regardless of whether or not the test had already been conducted to inform the original pathology opinion (i.e. expert pathologists should be able to recharge for associated items

⁹ Expert pathologist opinion (Prof A Morey, HESP), email 5/7/2013.

that are required to provide a definitive diagnosis). The Applicant has advised that current MBS “cones” provide a significant disincentive to unnecessary ordering of ancillary tests.

Table 2 All “non-core” ancillary MBS items in Groups P5 and P6 processed from July 2012 to June 2013

Item Number	Service Fee	Number of Services	Total Value of Benefits
Group P5 – Tissue pathology	-	-	-
72844	\$30.75	285	\$7,134
72846	\$59.60	86,378	\$4,240,011
72847	\$89.40	41,575	\$3,034,995
72848	\$74.50	6,465	\$395,978
72849	\$104.30	14,393	\$1,202,532
72850	\$119.20	6,961	\$661,737
72851	\$184.35	976	\$146,160
72852	\$245.80	78	\$15,219
Total <i>All ancillary items</i>	-	157,111	\$9,703,766
Group P6 - Cytology	-	-	-
73059	\$43.00	1,629	\$59,021
73060	\$57.35	2,006	\$94,584
73061	\$51.20	336	\$14,396
73064	\$71.70	1,092	\$64,137
73065	\$86.00	479	\$34,570
Total <i>All ancillary items</i>	-	5,542	\$266,709

Data Source: Medicare Australia Statistics website.

Note: Group P5 ancillary items (e.g. item 72846 for immunohistochemical stains) are also regularly claimed in conjunction with the core bone marrow items (65084-65087) in Group P1.

MBS data for 2012-13 shows that the relative proportion of MBS services for “core” items 72813-72838 to associated items (i.e. immunohistochemistry and electron microscopy items 72846-72952) was approximately 18:1 (see Table 1 and Table 2). However, it is likely that the relative usage of those items would be higher in cases sent for expert review, particularly in difficult specimens such as lymphomas. Across all specimens sent for second, expert opinion (e.g. head and neck, breast, medical renal biopsies, skin, thyroid, lymphoma, non-gynaecological cytology) it has been suggested that approximately one in every 14 or 15 cases would require ancillary tests such as immunohistochemistry.¹⁰

There are different views as to whether utilisation of the “specimen referred fee” (MBS Group 11, Item 73940) would be appropriate to cover the administrative and transfer costs associated with transporting the original specimens/slides to external expert pathologist. Furthermore, although the current wording of MBS item 73940 is restricted to being claimed

¹⁰ Expert pathologist opinion (Prof J Dahlstrom, HESP), email 5/7/2013.

by the second laboratory, there are costs involved with both laboratories. Laboratory 1 may incur costs of retrieving the slides from the archives, and would incur the cost of collating the case, sending the slides and refining the original diagnosis and for re-filing the case material upon return. Laboratory 2 would incur costs in receiving the case material and accessioning the case; and packaging and returning the case material to Laboratory 1 at the end of the episode.¹¹ PASC suggested that these costs require separate consideration, similar to MSAC Application 1331 (Retrieval of tissue for further diagnostic testing specifically genetic testing for diagnostic/prognostic purposes).

The application of a Patient Episode Initiation fee is considered inappropriate in the provision of an external expert pathology opinion.

Listing proposed and options for MSAC consideration

Proposed MBS listing

The proposed MBS item descriptors for second, expert pathology opinions are shown in Table 3 and Table 4. Should the proposed MBS items be approved, additional explanatory notes may be required, as shown in the tables below.

Fees of \$180 and \$370 were proposed by the Applicant for non-complex and complex second opinions, respectively. The proposed fees were based on the existing fees for initial pathology opinions. The “non-complex” fee of \$180 is approximately equal to the initial fee for examination of a complexity level 4 biopsy with at least 12 separately identified specimens. The Applicant suggested that the lower fee should be used for any second opinion involving up to 30 minutes of work and also indicated that it would be appropriate to use the non-complex item number for second opinions on bone marrow specimens. The “complex” fee of \$370 is approximately equal to the average of the initial fees for examination of complexity level 5 and 7 biopsy materials and would be claimed when the expert review required more than 30 minutes of pathologists' time.

The provision of a second, expert opinion would include the examination of processed biopsy material and, if necessary, additional specimen dissection, processing of additional tissue, plus staining and light microscopy, and the production of a full, second written report. As discussed above, in addition to claiming reimbursement for the second opinion, expert pathologists would have the ability to recharge for ancillary items (such as immunohistochemical staining) in conjunction with one of the proposed new items.

¹¹ The Applicant's response to draft PROTOCOL, 9th August 2013

Table 3 Proposed MBS item descriptor for a non-complex, second, expert opinion on a patient sample

Category 6 – Pathology
<p>MBS item number (<i>assigned by the Department if listed</i>)</p> <p>A no more than 30 min limit, expert opinion and detailed written report on a patient sample, requested by a treating clinician, where further information is needed for accurate diagnosis and appropriate patient management.</p> <p>Fee: \$180.00</p> <p>The service will be initiated upon the request of the referring clinician where there is uncertainty in the initial morphological diagnosis, or when the clinician involved in the care of the patient requests a second opinion. The item is applicable to cases where the expert pathologist is able to examine and/or re-process case material and produce a full written report in ≤ 30 minutes. The fee will not be payable if the service is provided within the same Approved Pathology Laboratory.</p>

Table 4 Proposed MBS item descriptor for a complex, second, expert opinion on a patient sample

Category 6 – Pathology
<p>MBS item number (<i>assigned by the Department if listed</i>)</p> <p>A greater than 30 minute, second, expert opinion and detailed written report on a patient sample, requested by a treating clinician, where further information is needed for accurate diagnosis and appropriate patient management.</p> <p>Fee: \$370.00</p> <p>The service will be initiated upon the request of the referring clinician where there is uncertainty in the initial morphological diagnosis, or when the clinician involved in the care of the patient requests a second opinion. The item is applicable to cases that are not obvious or straightforward, where the examination and/or re-processing of case material and the production of a full written report takes more than 30 minutes. The fee will not be payable if the service is provided within the same Approved Pathology Laboratory.</p>

Clinical place for proposed intervention

A second, expert pathology opinion would be used in any circumstance where the original pathology diagnosis is uncertain or of insufficient detail, or where a second, expert opinion is considered desirable for treatment decision-making. The Applicant, PASC and HESP have suggested that the second, expert opinion requests will cover a range of conditions, including cancer-related diagnoses, dermatopathology (such as inflammatory skin), difficult liver biopsies, and difficult transplant biopsies, such as surveillance biopsies on heart or liver transplants.

Other than describing the burden of cancer disease in Australia as a broad incidence (age-standardised to 485 cases per 100,000 people in 2007), no more specific information with respect to the clinical areas which would most utilise or benefit from the availability of pathology second opinions is detailed in the application. AIHW data reports the most commonly diagnosed cancers in Australia in 2012 to be: prostate (15%), bowel (13%),

breast (12%), melanoma (10%) and lung (9%) (AACR 2012). It is unknown whether tissue pathology diagnosis requests are proportioned similarly, although it might be expected that there would be large numbers of dermatopathology samples which are not diagnosed as melanoma, and as such this clinical area may account for a relatively greater proportion of initial requests than the proportion of final diagnoses.

A second, expert pathology opinion is also more likely to be required to diagnose or stage rare diseases. The application states that the majority of second opinions are likely to be histopathological in nature.

During the preparation of the Protocol, various literature on the clinical impact and importance of second pathology opinions were sighted; however, the analysis of these studies were specific to defined clinical areas. Much of the literature was within the field of oncology, but tumour specific, for example, prostate cancer (Barqawi et al. 2011; Brimo, Schultz & Epstein 2010; Epstein, Walsh & Sanfilippo 1996; Fajardo et al. 2011; Jara-Lazaro, Thike & Tan 2010), breast pathology (Jara-Lazaro & Tan 2008; Price et al. 2010; Salles Mde et al. 2008), dermatological disease (Farmer, Gonin & Hanna 1996; Gaudi et al. 2013; Grant-Kels 2005), and thyroid disease (Bajaj et al. 2012; Davidov et al. 2010; Jones & Jordan 2010).

The following clinical management algorithms depict the place of morphological pathology expert opinions in current clinical management (Figure 1) and in the event that these services receive MBS funding (Figure 2 and Figure 3). Under current funding arrangements, the initial pathologist and the treating clinician both have the opportunity to consider whether second, expert opinion is required. Irrespective of the source of the referral, the provision of a second, expert opinion is a non-MBS funded service, as discussed in the 'Current arrangements for public reimbursement', see page 4. It is assumed that if the initial pathologist had obtained an expert opinion, the treating clinician would not seek further expert pathologist advice on the same sample. Importantly, in the current scenario there is a chance that some cases that may have benefited from a second, expert opinion would not receive one due to a lack of funding.

In the first proposed scenario (*Scenario 1*), MBS funding is available for second, expert opinions in some circumstances. The provision of MBS funding is restricted to circumstances where the initial pathologist recommends to the treating clinician that a second, expert opinion is required due to uncertainty and/or complexity of the case. If the treating clinician agrees that the diagnosis requires verification or refinement, they may refer the case to an expert pathologist at a different APL to that of the initial reporting pathologist. In *Scenario 1*, the treating clinician is unable to use the proposed item unless the pathologist has

recommended that pathway; however, the clinician is still able to obtain a second opinion using the current funding arrangements (i.e. ex-gratis or non-MBS funded).

In the second proposed scenario (*Scenario 2*), the treating clinician is able to request an MBS funded second, expert opinion through the proposed item(s), irrespective of whether the initial pathologist cited uncertainty in their initial diagnosis or not. The expert pathologist would receive MBS funding for the second opinion even if the initial pathologist had already provided a diagnosis.

Figure 1 Clinical management algorithm depicting current scenario (no second opinion funded)

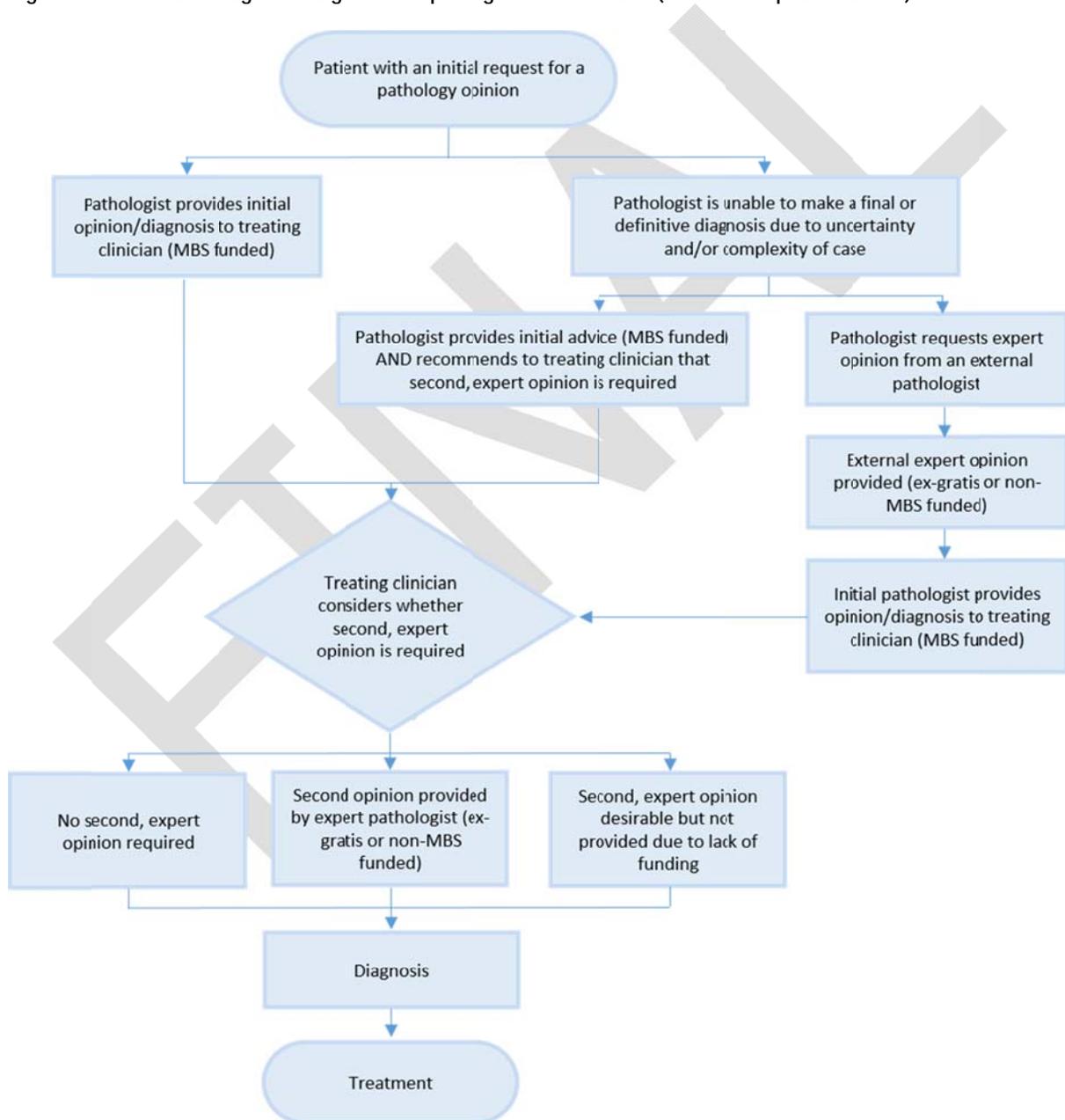


Figure 2 Clinical management algorithm including proposed MBS item for second pathology opinion (Scenario 1)

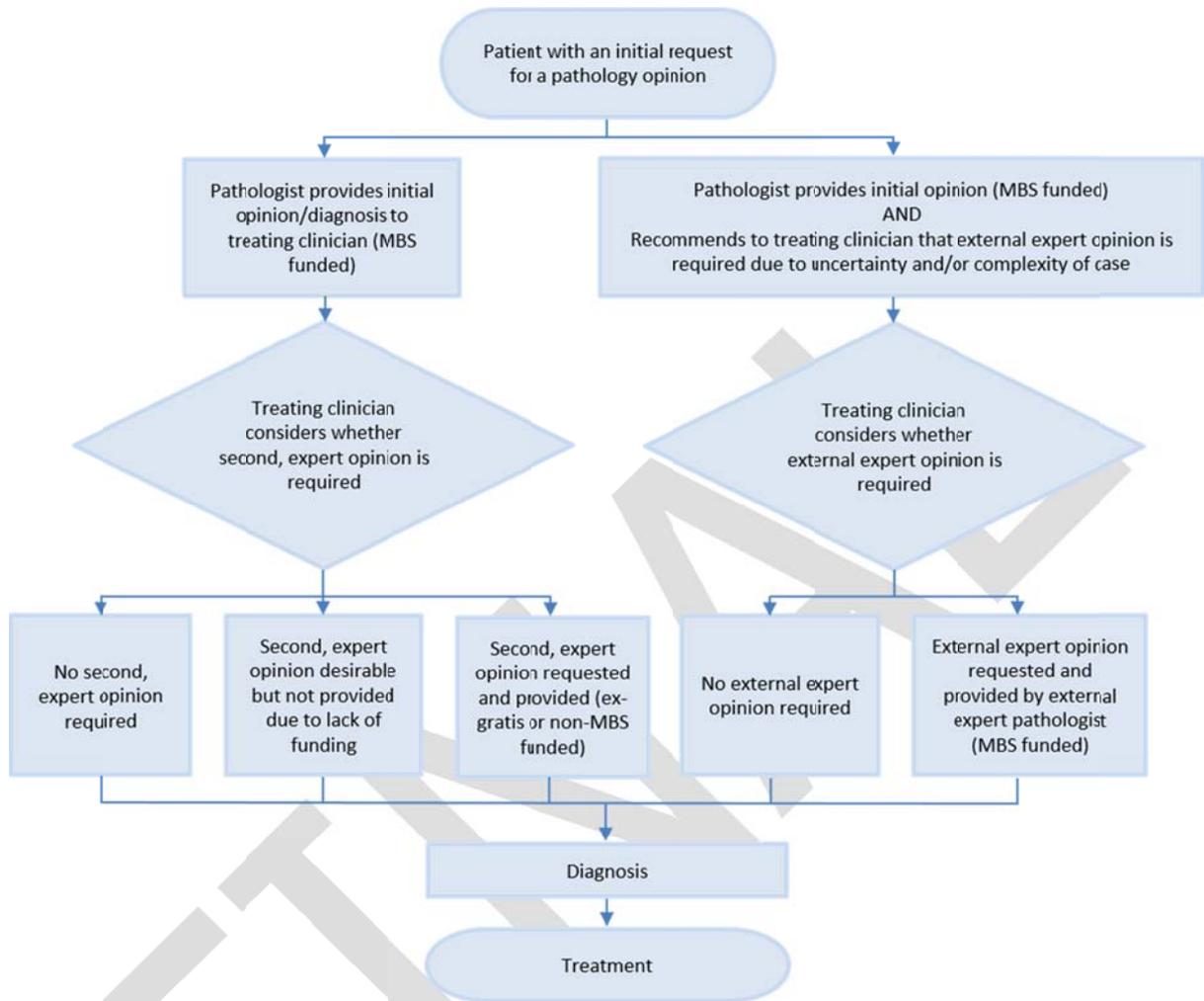
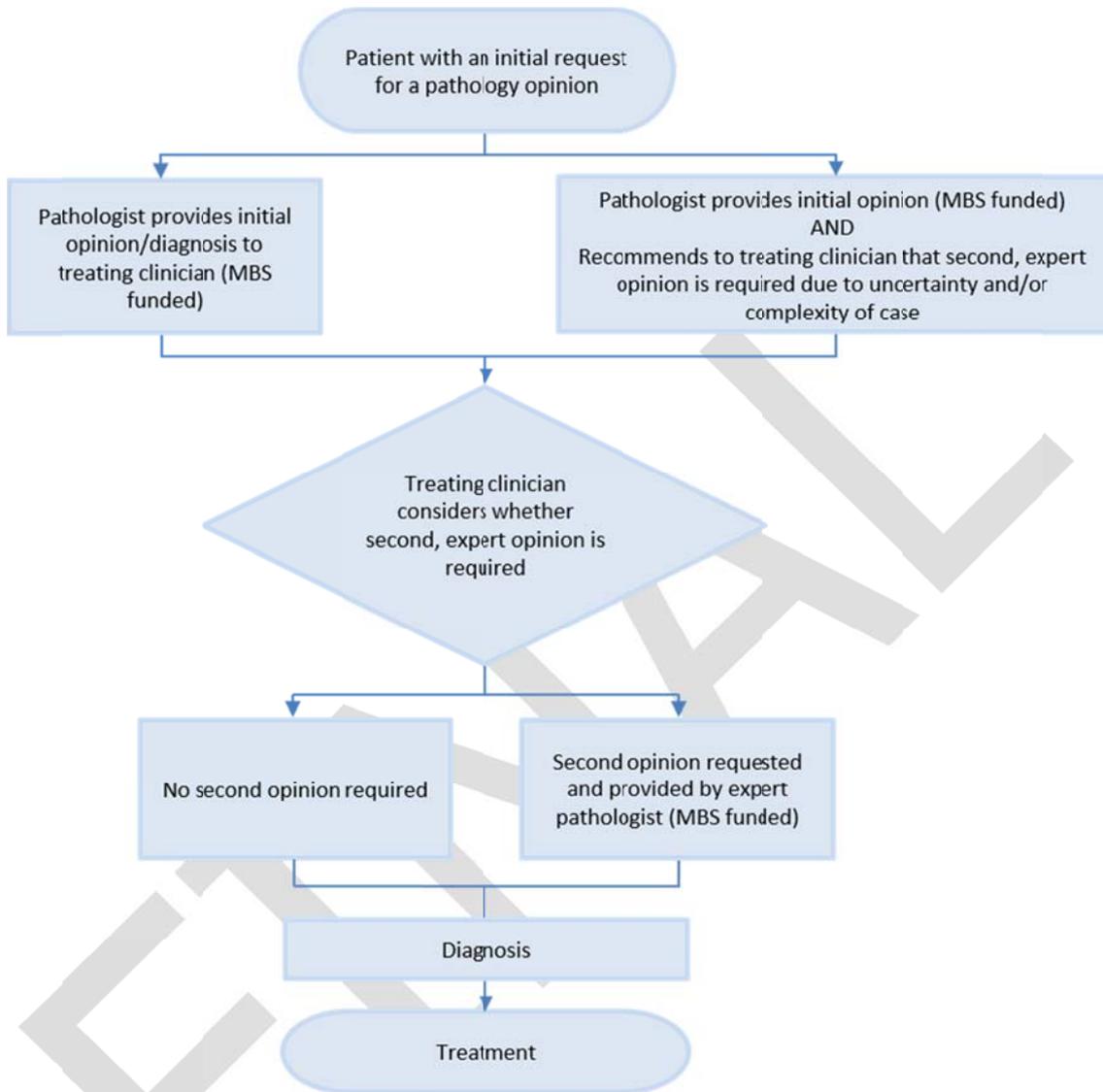


Figure 3 Clinical management algorithm including proposed MBS item for second pathology opinion (Scenario 2)



Comparator

Currently, there is no MBS-funding of second, expert opinions for pathology, yet there are circumstances where these are required or desirable. When either the original pathologist or the treating doctor requires a second expert pathology opinion for the purpose of patient management, a number of alternative pathways may be followed:

1. The original pathologist may request an expert opinion from an external pathologist who provides the opinion at no cost (but may be obliged to place low priority on the request), or the second pathology laboratory charges the initial

laboratory privately. It is very difficult in these circumstances to charge the patient, as they would not have consented to pay for a second opinion.

2. The treating clinician requests an expert opinion from an external pathology provider, and this is provided either at no cost (gratis) or at cost to the patient (privately) or the clinical unit.

The Applicant suggests that, in some cases, an expert opinion would be desirable (e.g. by the original pathologist who considers it a difficult case) but the costs associated with providing a second opinion and the lack of funding often means that an expert opinion is not sought. This can result in a sub-optimal diagnosis or report being provided to the treating clinician. This is identified as a potential problem particularly with remote isolated pathologists; thus, this issue is potentially contributing to inequities in the care of patients in remote areas. The Applicant further describes, in general terms, the associated risks of incomplete or incorrect diagnoses and subsequent inappropriate patient management, i.e. negative health outcomes, increased healthcare costs, and the potential for litigation.

The comparator, as defined by the Applicant, is the standard management which currently applies, which is described as a scenario where there is “an absence of funding for morphological second opinions. Such opinions are therefore not sought as often as they should be for optimal patient care”.

Outcomes for safety and effectiveness evaluation

The provision of a second opinion by an expert pathologist may lead to a change in diagnosis or staging, which may impact on a patient's subsequent management and treatment. The comparative clinical performance of MBS-funded second, expert opinions relative to standard management (i.e. no MBS-funded pathology second opinion service), can be assessed using the following health outcomes:

Effectiveness

Primary outcomes: morbidity, mortality, quality of life

Secondary outcomes: rates of clinically relevant revisions of initial pathology opinions, change in clinical management (e.g. biopsy rates, additional test ordering, change in treatment options).

Diagnostic accuracy: Sensitivity, specificity, positive predictive value, negative predictive value, concordance data.

Safety

Harms (physical and psychological) as a consequence of the delay in diagnosis, incorrect diagnosis/interpretation, incorrect treatment, and incorrect revision of diagnosis/interpretation.

Other relevant considerations

- Workforce issues, i.e. is there sufficient expert pathology workforce to accommodate the increase in pathology reporting?
- Equity in access to optimal care for remote patients

Summary of PICO to be used for assessment of evidence (systematic review)

Table 5 provides a summary of the PICO used to:

- (1) define the question for public funding;
- (2) select the evidence to assess the safety and effectiveness of second, expert pathology opinions in circumstances where:
 - the initial pathologist could not confidently provide a final or definitive diagnosis and recommends that external expert opinion is sought (*Scenario 1*),
 - an initial pathology opinion may have been provided, but where uncertainty or insufficient detail regarding the diagnosis remains (*Scenario 2*); and
- (3) provide the evidence-based inputs for determining the cost-impact of the proposed service.

Table 5 Summary of PICO to define research questions that assessment will investigate

Patients	Interventions	Comparators	Evidentiary standards	Outcomes to be assessed
<p>All patients having a morphology-based pathology test</p> <p>Subgroups: By suspected disease or indication</p>	<p><i>Scenario 1</i> External expert tissue pathology (including bone marrow) or cytology opinion sourced upon the suggestion of the initial reporting pathologist, due to uncertainty and/or complexity of the case.</p> <p><i>Scenario 2</i> Second, expert tissue pathology (including bone marrow) or cytology opinion sourced due to uncertainty and/or complexity of the case or a need to obtain, verify or refine a pathology diagnosis.</p>	<p>No publicly-funded second, expert opinion (i.e. ex-gratis second opinion or alternatively funded second opinion); or No second, expert opinion</p>	<p>Long term clinical diagnosis; or Follow-up pathology on subsequent sample; or Consensus pathology opinion</p>	<p><u>Safety</u> Harms (physical and psychological) due to delay in diagnosis, incorrect diagnosis/interpretation, incorrect treatment, incorrect revision of diagnosis/interpretation</p> <p><u>Diagnostic accuracy</u> Sensitivity, specificity, positive predictive value, negative predictive value, concordance data</p> <p><u>Change in management</u> Rate of clinically relevant revisions of initial pathology opinions Change in clinical management (e.g. biopsy rates, additional test ordering, change in treatment options)</p> <p><u>Effectiveness</u> Morbidity, mortality, quality of life</p> <p><u>Cost-effectiveness</u> Cost per clinically relevant change in diagnosis/interpretation</p>
<p><u>Research questions</u></p> <p><i>Scenario 1</i> What is the safety, effectiveness, and cost-effectiveness of clinicians sourcing an external expert, tissue pathology (including bone marrow) or cytology second opinion on a patient sample, upon the recommendation of the initial reporting pathologist, compared with no publicly funded external expert opinion?</p> <p><i>Scenario 2</i> What is the safety, effectiveness, and cost-effectiveness of clinicians sourcing a second, expert, tissue pathology (including bone marrow) or cytology opinion on a patient sample, where there is a need to obtain, verify or refine a diagnosis, compared with no publicly funded second opinion?</p>				

Specific clinical sub-groups might be considered, where the literature indicates that revisions in diagnoses, as a result of second, expert opinions, is clinically relevant, or has significant economic implications. This would allow MSAC to consider whether all pathology items

should be eligible for MBS-funded second opinions, or whether this should be restricted to particular pathology service types or patient groups.

Clinical claim

The application claims that 'the ability for clinicians to obtain a funded external expert opinion on diagnostically difficult or uncertain cases will positively impact on patient care via the more accurate classification of disease and thus more accurate planning and selection of therapy.' Therefore both a positive 'effectiveness' and 'safety' profile are assumed to be associated with the proposal. MBS costs are associated with providing the proposed service and so cost-effectiveness would normally need to be ascertained. Table 6 would therefore dictate that the appropriate economic evaluation would be a cost-effectiveness analysis or a cost-utility analysis.

Table 6 Classification of an intervention for determination of economic evaluation to be presented

		Comparative effectiveness versus comparator			
		Superior	Non-inferior	Inferior	
Comparative safety versus comparator	Superior	CEA/CUA	CEA/CUA	Net clinical benefit	CEA/CUA
				Neutral benefit	CEA/CUA*
				Net harms	None [^]
	Non-inferior	CEA/CUA	CEA/CUA*	None [^]	
				None [^]	
	Inferior	Net clinical benefit	CEA/CUA	None [^]	None [^]
Neutral benefit		CEA/CUA*			
Net harms		None [^]			

Abbreviations: CEA = cost-effectiveness analysis; CUA = cost-utility analysis

* May be reduced to cost-minimisation analysis. Cost-minimisation analysis should only be presented when the proposed service has been indisputably demonstrated to be no worse than its main comparator(s) in terms of both effectiveness and safety, so the difference between the service and the appropriate comparator can be reduced to a comparison of costs. In most cases, there will be some uncertainty around such a conclusion (i.e., the conclusion is often not indisputable). Therefore, when an assessment concludes that an intervention was no worse than a comparator, an assessment of the uncertainty around this conclusion should be provided by presentation of cost-effectiveness and/or cost-utility analyses.

[^] No economic evaluation needs to be presented; MSAC is unlikely to recommend government subsidy of this intervention

Outcomes and health care resources affected by introduction of proposed intervention

Outcomes for economic evaluation

Ideally, as a cost-utility analysis, economic outcomes would be transformed into QALYs to provide a conclusion in terms of costs per QALY gained.

However, while this may be possible for some patient sub-groups where data are available, a whole of pathology patient population analysis predicting QALY outcomes is unlikely to be feasible or credible with existing data sources.

It is therefore proposed that the main outcome of interest is cost per clinically-relevant change in diagnosis or interpretation.

PASC also decided that a small number of examples of cost-utility analysis, restricted to specific clinical areas where expert opinions are known to be sought, and where sufficient comparative evidence regarding health outcomes is available, and modelling is feasible, would be informative (for example, potential skin cancer, breast cancer, prostate cancer etc.).

Health care resources

A list of resources involved in requesting, preparing and reporting of second, expert opinions in pathology are listed in Table 7 below. The resources are expected to be the same, between the inpatient and outpatient setting, with the key difference being the amount reimbursed from Medicare (75% vs 85%). For the sake of reducing duplication, only the outpatient setting has been listed.

It should be noted that currently, patients are not charged for second, expert opinions within pathology. However, PASC raised the possibility that with the introduction of MBS item numbers related to this, patients may be asked to pay a co-payment, and possibly a gap between the fee and the amount pathologists charge for performing the service. In this manner, an MBS item for pathology second opinions may result in an additional cost to the patient. However, as pathology items have a greater than 90% bulk billing rate, out of pocket payments are the exception.

Table 7 List of resources for second, expert opinions in pathology, to be considered in the economic analysis (outpatient setting)

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets*	Other govt budget	Private health insurer	Patient	Total cost
Treating clinician consult to request a second opinion (MBS 23 or 105)	GP or specialist	Outpatient		1	\$36.30 \$36.55				- \$6.45 + gap	\$36.30 \$43.00 + gap
Retrieve slides from archive, collate slides	Pathologist 1	Outpatient	100%	1						

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets*	Other govt budget	Private health insurer	Patient	Total cost
Transport slides from one laboratory to another	Courier (?)	N/A	100%	2						
Specimen referred fee (MBS 73940)	Pathologist 2	Outpatient	100%	1	\$8.75				\$1.50	\$10.25
Bulk billing incentive (MBS 74996)	Pathologist 2	Outpatient	?	1	\$3.15				55c	\$3.70
Additional tests required (e.g. MBS 73059, 73060, 73061)	Pathologist 2	Outpatient	?	?	\$36.55				\$6.45	\$43.00
					\$48.75				\$8.60	\$57.35
					\$43.55				\$7.65	\$51.20
Read the slides and prepare report (proposed new MBS item)	Pathologist 2	Outpatient	100%	1	Proposed benefit				Proposed co-payment + gap	Proposed fee + gap
Refine diagnosis and prepare synthesised report	Pathologist 1	Outpatient	100%	1						

* Include costs relating to both the standard and extended safety net.

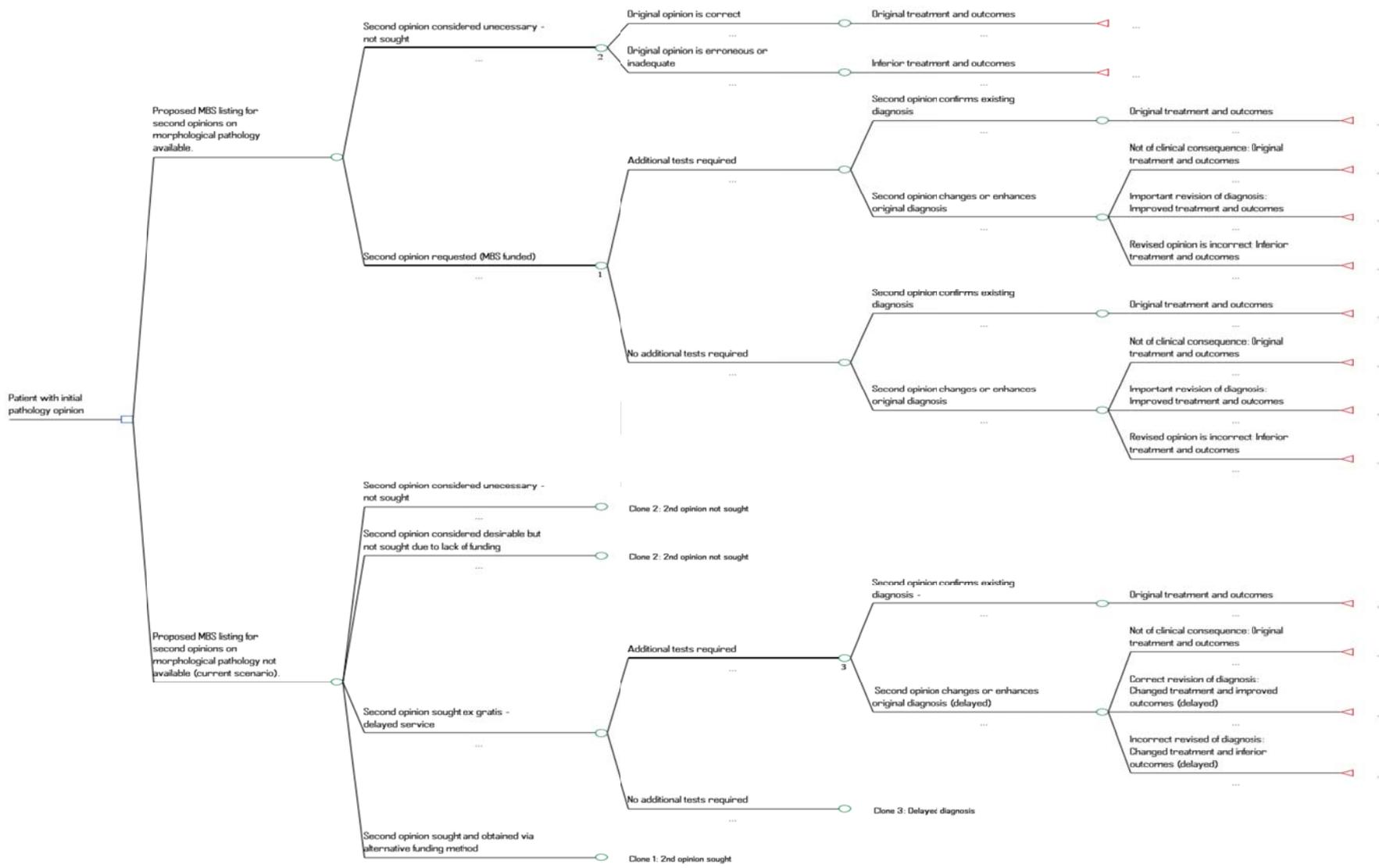
Proposed structure of economic evaluation (decision-analytic)

A decision analytic model has been developed to capture the potential clinical impacts of the proposed addition of second, expert pathology opinions on the MBS, see Figure 4. The diagram also indicates where workforce issues and concerns arise, for illustrative purposes; however, the relative value of these issues is not expected to be captured in the model.

This decision analytic is not specific to a disease or patient indication.

Multiple decision analytics would be required to model the cost-effectiveness of pathology second, expert opinions for possible patient groups that are likely to use that service.

Figure 4 Decision analytic structure for economic model to determine cost-effectiveness of MBS-funding for a second opinion on pathology items.



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Attachment 1.

GROUP P1 - HAEMATOLOGY	
65084	<p>Bone marrow trephine biopsy - histopathological examination of sections of bone marrow and examination of aspirated material (including clot sections where necessary), including (if performed): any test described in item 65060, 65066 or 65070</p> <p>Fee: \$165.85 Benefit: 75% = \$124.40 85% = \$141.00</p>
65087	<p>Bone marrow - examination of aspirated material (including clot sections where necessary), including (if performed): any test described in item 65060, 65066 or 65070</p> <p>Fee: \$83.10 Benefit: 75% = \$62.35 85% = \$70.65</p>
GROUP P5 – TISSUE PATHOLOGY	
72813	<p>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</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$71.50 Benefit: 75% = \$53.65 85% = \$60.80</p>
72816	<p>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</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$86.35 Benefit: 75% = \$64.80 85% = \$73.40</p>
72817	<p>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</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$96.80 Benefit: 75% = \$72.60 85% = \$82.30</p>
72818	<p>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</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$107.05 Benefit: 75% = \$80.30 85% = \$91.00</p>
72823	<p>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</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$97.15 Benefit: 75% = \$72.90 85% = \$82.60</p>
72824	<p>Examination of complexity level 4 biopsy material with 1 or more tissue blocks, including</p>

GROUP P5 – TISSUE PATHOLOGY	
	specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 2 to 4 separately identified specimens (Item is subject to rule 13) Fee: \$141.35 Benefit: 75% = \$106.05 85% = \$120.15
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 (Item is subject to rule 13) Fee: \$180.25 Benefit: 75% = \$135.20 85% = \$153.25
72826	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 - 8 to 11 separately identified specimens (Item is subject to rule 13) Fee: \$194.60 Benefit: 75% = \$145.95 85% = \$165.45
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 (Item is subject to Rule 13) Fee: \$208.95 Benefit: 75% = \$156.75 85% = \$177.65
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 (Item is subject to Rule 13) Fee: \$223.30 Benefit: 75% = \$167.50 85% = \$189.85
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 (Item is subject to rule 13) Fee: \$274.15 Benefit: 75% = \$205.65 85% = \$233.05
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 (Item is subject to rule 13) Fee: \$417.20 Benefit: 75% = \$312.90 85% = \$354.65
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. (Item is subject to rule 13) Fee: \$466.85 Benefit: 75% = \$350.15 85% = \$396.85
72844	

GROUP P5 – TISSUE PATHOLOGY	
	<p>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</p> <p>Fee: \$30.75 Benefit: 75% = \$23.10 85% = \$26.15</p>
72846	<p>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</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$59.60 Benefit: 75% = \$44.70 85% = \$50.70</p>
72847	<p>Immunohistochemical examination of biopsy material by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 4-6 antibodies</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$89.40 Benefit: 75% = \$67.05 85% = \$76.00</p>
72848	<p>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)</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$74.50 Benefit: 75% = \$55.90 85% = \$63.35</p>
72849	<p>Immunohistochemical examination of biopsy material by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen – 7-10 antibodies</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$104.30 Benefit: 75% = \$78.25 85% = \$88.70</p>
72850	<p>Immunohistochemical examination of biopsy material by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen – 11 or more antibodies</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$119.20 Benefit: 75% = \$89.40 85% = \$101.35</p>
72851	<p>Electron microscopic examination of biopsy material - 1 separately identified specimen</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$184.35 Benefit: 75% = \$138.30 85% = \$156.70</p>
72852	<p>Electron microscopic examination of biopsy material - 2 or more separately identified specimens</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$245.80 Benefit: 75% = \$184.35 85% = \$208.95</p>
72855	<p>Intraoperative consultation and examination of biopsy material by frozen section or tissue imprint or smear - 1 separately identified specimen</p>

GROUP P5 – TISSUE PATHOLOGY	
	(Item is subject to rule 13) Fee: \$184.35 Benefit: 75% = \$138.30 85% = \$156.70
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) Fee: \$245.80 Benefit: 75% = \$184.35 85% = \$208.95
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) Fee: \$286.75 Benefit: 75% = \$215.10 85% = \$243.75

GROUP P6 - CYTOLOGY	
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 Fee: \$22.85 Benefit: 75% = \$17.15 85% = \$19.45
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 tests Fee: \$48.60 Benefit: 75% = \$36.45 85% = \$41.35
73047	Cytology of a series of 3 sputum or urine specimens for malignant cells Fee: \$94.70 Benefit: 75% = \$71.05 85% = \$80.50
73049	Cytology of material obtained directly from a patient by fine needle aspiration of solid tissue or tissues - 1 identified site Fee: \$68.15 Benefit: 75% = \$51.15 85% = \$57.95
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 Fee: \$170.35 Benefit: 75% = \$127.80 85% = \$144.80
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

GROUP P6 - CYTOLOGY	
	<p>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; <i>(See para P16.11 of explanatory notes to this Category)</i></p> <p>Fee: \$19.45 Benefit: 75% = \$14.60 85% = \$16.55</p>
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 (a) for the management of previously detected abnormalities including precancerous or cancerous conditions; or (b) for the investigation of women with symptoms, signs or recent history suggestive of cervical neoplasia; <i>(See para P16.11 of explanatory notes to this Category)</i></p> <p>Fee: \$19.45 Benefit: 75% = \$14.60 85% = \$16.55</p>
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 <i>(See para P16.11 of explanatory notes to this Category)</i></p> <p>Fee: \$19.45 Benefit: 75% = \$14.60 85% = \$16.55</p>
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 (Item is subject to rule 13)</p> <p>Fee: \$43.00 Benefit: 75% = \$32.25 85% = \$36.55</p>
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 (Item is subject to rule 13)</p> <p>Fee: \$57.35 Benefit: 75% = \$43.05 85% = \$48.75</p>
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) (Item is subject to rule 13)</p> <p>Fee: \$51.20 Benefit: 75% = \$38.40 85% = \$43.55</p>
73062	<p>Cytology of material obtained directly from a patient by fine needle aspiration of solid tissue</p>

GROUP P6 - CYTOLOGY	
	<p>or tissues – 2 or more separately identified sites.</p> <p>Fee: \$89.00 Benefit: 75% = \$66.75 85% = \$75.65</p>
73063	<p>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</p> <p>Fee: \$99.35 Benefit: 75% = \$74.55 85% = \$84.45</p>
73064	<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 – 7 to 10 antibodies</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$71.70 Benefit: 75% = \$53.80 85% = \$60.95</p>
73065	<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 - 11 or more antibodies</p> <p>(Item is subject to rule 13)</p> <p>Fee: \$86.00 Benefit: 75% = \$66.75 85% = \$75.65</p>
73066	<p>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:</p> <p>(a) performs the aspiration; or</p> <p>(b) attends the aspiration and performs cytological examination during the attendance</p> <p>Fee: \$221.45 Benefit: 75% = \$166.10 85% = \$188.25</p>
73067	<p>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</p> <p>Fee: \$129.15 Benefit: 75% = \$96.90 85% = \$109.80</p>

Attachment 2.

P19.1 Rules for the Interpretation of the Pathology Services Table (*excerpts – relevant to this PROTOCOL only*)

Please note that in the Health Insurance (Pathology Services Table) Regulations 2010 (effective 1 November 2010) rules and sub-rules are referred to as clauses and sub-clauses. In addition in the Regulations a rule that refers to specific items within a pathology group, for example Group P1 Haematology, is listed directly above the Schedule of Services for that group.

1. (1) In this table

patient episode means:

(a) a pathology service or pathology services (other than a pathology service to which paragraph 1 (1) (b) refers) provided for a single patient whose need for the service or services was determined under section 16A of the Act:

(i) on the same day; or

(ii) if more than 1 test is performed on the 1 specimen within 14 days - on the same or different days;

whether the services:

(iii) are requested by 1 or more practitioners; or

(iv) are described in a single item or in more than 1 item; or

(v) are rendered by 1 approved pathology practitioner or more than 1 approved pathology practitioner; or

(vi) are rendered on the same or different days; or

(b) a pathology service to which rule 4 refers that is provided in the circumstances set out in that rule that relates to the service.

receiving APP means an approved pathology practitioner in an approved pathology authority who performs one or more pathology services in respect of a single patient episode following receipt of a request for those services from a referring APP.

recognised pathologist means a medical practitioner recognised as a specialist in pathology by a determination under section 3D, 3DB or 3E of the Act.

referring APP means an approved pathology practitioner in an approved pathology authority who:

- (i) has been requested to render 1 or more pathology services, all of which are requested in a single patient episode; and
- (ii) is unable, because of the lack of facilities in, or expertise or experience of the staff of, the laboratory of the authority, to render 1 or more of the pathology services; and
- (iii) requests an approved pathology practitioner (the **receiving APP**) in another approved pathology authority to render the pathology service or services that the referring APP is unable to render; and
- (iv) renders each pathology service (if any) included in that patient episode, other than the pathology service or services in respect of which the request mentioned in subparagraph (iii) is made.

serial examinations means a series of examinations requested on 1 occasion whether or not:

- (a) the materials are received on different days by the approved pathology practitioner; or
- (b) the examinations or cultures were requested on 1 or more request forms by the treating practitioner.

the Act means the *Health Insurance Act 1973*.

1. (2) In these rules, a reference to a request to an approved pathology practitioner includes a reference to a request for a pathologist-determinable service to which subsection 16A (6) of the Act applies.
1. (3) A reference in this table by number to an item that is not included in this table is a reference to the item that has that number in the general medical services table or the diagnostic imaging services table, as the case requires.
1. (4) A reference to a **Group** in the table includes every item in the Group and a reference to a **Subgroup** in the table includes every item in the Subgroup.

Precedence of items

2. (1) If a service is described:

- (a) in an item in general terms; and
- (b) in another item in specific terms;

only the item that describes the service in specific terms applies to the service.

2. (2) Subject to subrule (3), if:

- (a) subrule (1) does not apply; and
- (b) a service is described in 2 or more items;

only the item that provides the lower or lowest fee for the service applies to the service.

2. (3) If an item is expressed to include a pathology service that is described in another item, the other item does not apply to the service in addition to the first-mentioned item, whether or not the services described in the 2 items are requested separately.

Circumstances in which services rendered following 2 requests to be taken to have been rendered following 1 request

3. (1) In subrule 3(2), **service** includes assay, estimation and test.

3. (2) Two or more pathology services (other than services to which, under rule 4, this rule does not apply) rendered for a patient following 2 or more requests are taken to have been rendered following a single request if:

- (a) the services are listed in the same item; and
- (ab) that item is not item 74990 or 74991; and

(b) the patient's need for the services was determined under subsection 16A (1) of the Act on the same day even if the services are rendered by an approved pathology practitioner on more than one day.

Services to which rule 3 does not apply

4. (1) Rule 3 does not apply to a pathology service described in item 65060, 65070, 65120, 65123, 65126, 65129, 65150, 65153, 65156, 66500, 66503, 66506, 66509, 66512, 66584 or 66800, if:

- (a) the service is rendered in relation to one or more specimens taken on each of not more than 6 separate occasions in a period of 24 hours; and
- (b) the service is rendered to an inpatient in a hospital; and
- (c) each service must be rendered as soon as possible after collection and after authorization of the result of the previous specimen; and
- (d) the account for the service is endorsed 'Rule 3 Exemption'.

4. (2) Rule 3 does not apply to any of the following pathology services:

- (a) estimation of prothrombin time (INR) in respect of a patient undergoing anticoagulant therapy;
- (b) quantitative estimation of lithium in respect of a patient undergoing lithium therapy;
- (c) a service described in item 65070 in relation to a patient undergoing chemotherapy for neoplastic disease or immunosuppressant therapy;
- (d) a service described in item 65070 in relation to clozaril, ticlopidine hydrochloride, methotrexate, gold, sulphasalazine or penicillamine therapy of a patient;
- (e) a service described in item 66500 - 66512 in relation to methotrexate or leflunomide therapy of a patient;
- (f) quantitative estimation of urea, creatinine and electrolytes in relation to:
 - (i) cis-platinum or cyclosporin therapy of a patient; or
 - (ii) chronic renal failure of a patient being treated in a dialysis program conducted by a recognised hospital;
- (g) quantitative estimation of albumin and calcium in relation to therapy of a patient with vitamin D, its metabolites or analogues;
- (h) quantitative estimation of calcium, phosphate, magnesium, urea, creatinine and electrolytes in cancer patients receiving bisphosphonate infusions.

if:

- (i) under a request for a service, other than a request for a service described in paragraph (a), no more than 6 tests are requested; and
- (ii) the tests are performed within 6 months of the request; and
- (iii) the account for the service is endorsed "Rule 3 Exemption".

4. (3) Rule 3 does not apply to a pathology service described in items 65109 or 65110 if:

- (a) The service is rendered on not more than 5 separate occasions in the case of item 65109 and 2 separate occasions in the case of item 65110 in a period of 24 hours; and
- (b) The service is rendered in response to a written request separated in time from the previous request; and
- (c) The account for the service is endorsed "Rule 3 Exemption".

Certain items not to apply to a service referred by one pathology practitioner to another

6. (1) In this rule:

designated pathology service means a pathology service in respect of tests relating to a single patient episode that are tests of the kind described in item 65150, 65175, 66650, 66695, 66711, 66722, 66785, 66800, 66812, 66819, 66825, 69384, 69494, 71089, 71153 or 71165.

6. (2) This rule applies in respect of a designated pathology service where:

- (a) an approved pathology practitioner (***practitioner A***) in an approved pathology authority:
 - (i) has been requested to render the designated pathology service; and
 - (ii) is unable, because of the lack of facilities in, or expertise or experience of the staff of, the laboratory of the authority, to render 1 or more of the tests included in the service; and
 - (iii) requests an approved pathology practitioner (***practitioner B***) in another approved pathology authority to render the test or tests that practitioner A is unable to render; and
 - (iv) renders each test (if any) included in the service, other than the test or tests in respect of which the request mentioned in subparagraph (iii) is made; and
- (b) the tests mentioned in subparagraph (a) (iv) that practitioner A renders are not tests constituting a service described in item 65156, 65179, 66653, 66712, 66734, 66788,

66806, 66815, 66822, 66828, 69496, 71093, 71159 or 71168.

6. (3) If this rule applies in respect of a designated pathology service:

(a) item 65150, 65153, 65175, 65176, 65177, 65178, 66650, 66695, 66698, 66701, 66704, 66707, 66711, 66722, 66725, 66728, 66731, 66785, 66800, 66803, 66812, 66819, 66825, 69384, 69387, 69390, 69393, 69396, 69494, 69495, 71089, 71091, 71153, 71155, 71157, 71165, 71166 or 71167 (as the case requires) applies in respect of the test or tests rendered by practitioner A; and

(b) where practitioner B renders a service under a request referred to in subparagraph (2) (a) (iii) and:

(i) practitioner A has rendered one or more of the tests that the service comprises - subject to subrule (4), the amount specified in item 65158, 65181, 66652, 66697, 66715, 66724, 66790, 66805, 66817, 66821, 66827, 69401, 69498, 71092, 71156 or 71170 (as the case requires) shall be taken to be the fee for each test that the service comprises; or

(ii) practitioner A has not rendered any of the tests that the service comprises -

(A) the amount specified in item 65157, 65180, 66651, 66696, 66714, 66723, 66789, 66804, 66816, 66820, 66826, 69400, 69497, 71090, 71154 or 71169 (as the case requires) shall be taken to be the fee for the first test that the service comprises; and

(B) subject to subrule (4), the amount specified in item 65158, 65181, 66652, 66697, 66715, 66724, 66790, 66805, 66817, 66821, 66827, 69401, 69498, 71092, 71156 or 71170 (as the case requires) shall be taken to be the fee for each subsequent test that the service comprises.

6. (4) For paragraph (3) (b), the maximum number of tests to which item 65158, 65181, 66652, 66697, 66715, 66724, 66790, 66805, 66817, 66821, 66827, 69401, 69498, 71092, 71156 or 71170 applies is:

(a) for item 66652, 66715, 66790, 66817, 66821 or 66827:

2 - X; and

(b) for item 66805, 69498 or 71092:

3 - X; and

(c) for item 71156 or 71170:

4 - X; and

(d) for item 66724:

5 - X; and

where X is the number of tests rendered by practitioner A in relation to the designated pathology service in respect of which the request mentioned in that paragraph is made.

6. (5) Items in Group P10 (Patient episode initiation) do not apply to the second mentioned approved pathology practitioner in subrule (2).

Items not to be split

7. Except as stated in rule 6, the amount specified in an item is payable only to one approved pathology practitioner in respect of a single patient episode.

Tests on biopsy material - Group P5 (Tissue pathology) and Group P6 (Cytology)

13. (1) For items in Group P5 (Tissue pathology):

(a) **biopsy material** means all tissue received by the Approved Pathology Practitioner:

(i) from a medical procedure or group of medical procedures performed on a patient at the same time; or

(ii) after being expelled spontaneously from a patient.

(b) **cytology** means microscopic examination of 1 or more stained preparations of cells separated naturally or artificially from their normal environment by methods recognised as adequate to demonstrate their structure to a degree sufficient to enable an opinion to be formed about whether they are likely to be normal, abnormal but benign, or abnormal and malignant but, in accordance with customary laboratory practice, does not include examination of a blood film and a bone marrow aspirate; and

(c) **separately identified specimen** means an individual specimen collected, identified so that it is clearly distinguished from any other specimen, and sent for testing by or on behalf of the treating practitioner responsible for the procedure in which the specimen was taken.

13. (2) For Groups P5 and P6 of the pathology services table, services in Group P6 include any services described in Group P5 on the material submitted for a test in Group P6.
13. (3) For subrule (2), any sample submitted for cytology from which a cell block is prepared does not qualify for a Group P5 item.
- 13.(4) If more than 1 of the services mentioned in items 72813, 72816, 72817, 72818, 72823, 72824, 72825, 72826, 72827, 72828, 72830, 72836 and 72838 are performed in a single patient episode, only the fee for the item performed having the highest specified fee is applicable to the services.
- 13.(5) If more than 1 histopathological examinations are performed on separate specimens, of different complexity levels, from a single patient episode, a medicare benefit is payable only for the examination that has the highest schedule fee.
- 13.(6) In items 72813, 72816, 72817, 72818, 72823, 72824, 72825, 72826, 72827, 72828, 72830, 72836 and 72838 a reference to a **complexity level** is a reference to the level given to a specimen type mentioned in Part 4 of this Table.
- 13.(7) If more than 1 of the services mentioned in items 72846, 72847, 72848; 72849 and 72850 or 73059, 73060, 73061, 73064 and 73065 are performed in a single patient episode, a medicare benefit is payable only for the item performed that has the highest scheduled fee.
- 13.(8) If more than 1 of the services mentioned in items 73049, 73051, 73062, 73063, 73066 and 73067 are performed in a single patient episode, only the fee for the item performed having the higher or highest specified fee applies to the services.

Items in Groups P10 (Patient episode initiation) and P11 (Specimen referred) not to apply in certain circumstances

14. (1) For this rule and items in Groups P10 (Patient episode initiation) and P11 (Specimen referred):

approved collection centre has the same meaning as in Part IIA of the Act.

institution means a place at which residential accommodation or day care is, or both residential accommodation and day care are, made available to:

- (a) disadvantaged children; or
- (b) juvenile offenders; or
- (c) aged persons; or
- (d) chronically ill psychiatric patients; or
- (e) homeless persons; or

- (f) unemployed persons; or
- (g) persons suffering from alcoholism; or
- (h) persons addicted to drugs; or
- (i) physically or mentally handicapped persons;

but does not include:

- (j) a hospital; or
- (k) a residential aged care home; or
- (l) accommodation for aged persons that is attached to a residential aged care home or situated within a residential aged care home.

prescribed laboratory means a laboratory operated by:

- (a) the Australian Government; or
- (b) an authority of the Commonwealth; or
- (c) a State or internal Territory; or
- (d) an authority of a State or internal Territory; or
- (e) an Australian tertiary education institution.

specimen collection centre has the same meaning as in Part IIA of the Act.

treating practitioner has the same meaning as in paragraph 16A(1)(a) of the Act.

- 14. (2)** If a service described in an item in Group P10 is rendered by, or on behalf of, an approved pathology practitioner who is a recognised pathologist, the relevant one of those items does not apply to the service if:
 - (a) the service is rendered upon a request made in the course of a service provided to a public patient in a recognised hospital or when attending an outpatient service of a recognised hospital.
- 14. (3)** An item in Group P10 or P11 does not apply to a pathology service to which subsection 16A (7) of the Act applies.
- 14. (4)** An item in Group P10 or P11 does not apply to a pathology service unless at least 1 item in Groups P1 to P8 also applies to the service.
- 14. (5)** Subject to subrule (7), if one item in Group P10 applies to a patient episode, no other item in the Group applies to the patient episode.

14. (6) An item in Group P11 applies only to the approved pathology practitioner or approved pathology authority to whom the specimen mentioned in the item was referred.

14. (7) If, in respect of the same patient episode:

(a) services referred to in 1 or more items in Group P5 and 1 or more of Groups P1, P2, P3, P4, P6, P7 and P8 are rendered by an approved pathology practitioner in the laboratory of another approved pathology authority; or

(b) services referred to in 1 or more items in Group P6 and 1 or more of Groups P1, P2, P3, P4, P5, P7 and P8 are rendered by another approved pathology practitioner in the laboratory of another approved pathology authority;

the fee specified in the applicable item in Group P10 is payable to both approved pathology practitioners.

14. (8) If more than one specimen is collected from a person on the same day for the provision of pathology services:

(a) in accordance with more than 1 request; and

(b) in or by a single approved pathology authority;

the fee specified in the applicable item in Group P10 applies once only to the services unless an exemption listed in Rule 4 applies or an exemption has been granted under Rule 3 "S4B(3)".

14. (9) The amount specified in item 73940 is payable only once in respect of a single patient episode.

Application of an item in Group P11 (Specimen referred) to a service excludes certain other items

15. If item 73940 applies to a patient episode, none of the items in Group P10 applies to any pathology service rendered by the approved pathology authority or approved pathology practitioner who claimed item 73940 in respect of the patient episode.

Circumstances in which an item in Group P11 (Specimen referred) does not apply

16. (1) An item in Group P11 does not apply to a referral if:

(a) a service in respect of the same patient episode has been carried out by the referring approved pathology authority; and

(b) the approved pathology authority to which the referral is made is related to the referring approved pathology authority.

16. (2) An approved pathology authority is *related to* another approved pathology authority for

subrule (1) if:

- (a) both approved pathology authorities are employed (including employed under contract) by the same person, whether or not the person is also an approved pathology authority; or
- (b) either of the approved pathology authorities is employed (including employed under contract) by the other; or
- (c) both approved pathology authorities are corporations and are related corporations within the meaning of the Corporations Act; or
- (d) the approved pathology authorities are partners (whether or not either or both of the approved pathology authorities are individuals and whether or not other persons are in partnership with either or both of the approved pathology authorities); or
- (e) both approved pathology authorities are operated by the Commonwealth or an authority of the Commonwealth; or
- (f) both approved pathology authorities are operated by the same State or internal Territory or an authority of the same State or internal Territory.

16. (3) An item in Group P11 does not apply to a referral if the following common tests are referred either singly or in combination (except if the following items are referred in combination with other items not similarly specified): 65060, 65070, 65120, 66500, 66503, 66506, 66509, 66512, 66536, 66596, 69300, 69303, 69333 or 73527.

Abbreviations

17. (1) The abbreviations in Part 4 of this table may be used to identify particular pathology services or groups of pathology services.

17. (2) The names of services or drugs not listed in Part 4 of this table must be written in full.

Certain pathology services to be treated as 1 service

18. (1) In this rule:

general practitioner means a medical practitioner who:

- (a) is not a consultant physician in any specialty; and
- (b) is not a specialist in any specialty.

set of pathology services means a group of pathology services:

- (a) that consists of services that are described in at least 4 different items; and
- (b) all of which are requested in a single patient episode; and
- (c) each of which relates to a patient who is not an admitted patient of a hospital; and

(d) excludes services referred to in an item in Group P10, Group P11, Group P12 or

Group P13, items 66900, 69484, 73053 and 73055; and

(e) excludes services described in the following items:

65079, 65082, 65157, 65158, 65166, 65180, 65181, 66606, 66609, 66610, 66639, 66642, 66651, 66652, 66663, 66666, 66696, 66697, 66714, 66715, 66723, 66724, 66780, 66783, 66789, 66790, 66792, 66804, 66805, 66816, 66817, 66820, 66821, 66826, 66827, 66832, 69325, 69328, 69331, 69379, 69383, 69400, 69401, 69419, 69451, 69500, 69484, 69489, 69492, 69497, 69498, 71076, 71090, 71092, 71096, 71148, 71154, 71156, 71169, 71170, 73309, 73312, 73315, 73318, 73321 and 73324;

where those services are performed by an approved pathology practitioner in an accredited pathology laboratory of an approved pathology authority following referral by another approved pathology practitioner in an accredited pathology laboratory of an approved pathology authority which is not **related to** the first mentioned approved pathology authority.

(1A) An approved pathology authority is **related to** another approved pathology authority for the purposes of paragraph 18(1)(e) if that approved pathology authority would be related to the other approved pathology authority for the purposes of rule 16(2).

18. (2) If a general practitioner requests a set of pathology services, the pathology services in the set are to be treated as individual pathology services in accordance with this rule.

18. (3) If the fee specified in 1 item that describes any of the services in the set of pathology services is higher than the fees specified in the other items that describe the services in the set:

(a) the pathology service described in the first-mentioned item is to be treated as 1 pathology service; and

(b) either:

(i) the pathology service in the set that is described in the item that specifies the second-highest fee is to be treated as 1 pathology service; or

(ii) if 2 or more items that describe any of those services specify the second-highest fee, the pathology service described in the item that specifies the second-highest fee, and has the lowest item number, is to be treated as 1 pathology service; and

(c) the pathology services in the set, other than the services that are to be treated as 1 pathology service under paragraphs (a) and (b), are to be treated as 1 pathology service.

18. (4) If the fees specified in 2 or more items that describe any of the services in the set of pathology services are the same, and higher than the fees specified in the other items that describe the services in the set:

(a) the pathology service in the set that is described in the item that specifies the highest fee, and has the lowest item number, is to be treated as 1 pathology service; and

(b) the pathology service in the set that is described in the item that specifies the highest fee, and has the second-lowest item number, is to be treated as 1 pathology service; and

(c) the pathology services in the set, other than the services that are to be treated as 1 pathology service under paragraphs (a) and (b), are to be treated as 1 pathology

service.

18. (5) If pathology services are to be treated as 1 pathology service under paragraph (3) (c) or (4) (c), the fee for the 1 pathology service is the highest fee specified in any of the items that describe the pathology services that are to be treated as the 1 pathology service.

Limitation on certain items

25. (a) For any particular patient, items 66539, 66605, 66606, 66607, 66610, 69380, 69488, 69489, 71075, 71127, 71135 or 71137 is applicable not more than twice in a 12 month period.

(b) For any particular patient, item 66626 is applicable not more than 36 times in a 12 month period.

(c) For any particular patient, items 66655, 66659, 69482, 69491, 69499 or 69500 are applicable not more than once in a 12 month period.

(d) For any particular patient, item 66750 or 66751 is applicable not more than once in a pregnancy.

(e) For any particular patient, item 69336 is applicable not more than once in each period of 7 days.

(f) For any particular patient, items 66551, 66660, 69445, 69451, 69483, 71079 or 73523 are applicable not more than 4 times in a 12 month period.

(g) For any particular patient, items 66554, 66830 and 71077 are applicable not more than 6 times in a 12 month period.

(h) For any particular patient, item 66819, 66820, 66821, 66822, 66825, 66826, 66827 or 66828 is applicable not more than 3 times in a 6 month period.

(i) For any particular patient, items 69418 and 69419 are applicable not more than twice in a 24 month period.