



Australian Government
Medical Services Advisory Committee

Public Summary Document

Application 1332 – Second opinion for morphological pathology (Histology, cytopathology & haematology)

Applicant: **Royal College of Pathologists of Australasia**

Date of MSAC consideration: **MSAC 62nd Meeting, 26-28 November 2014**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, see at www.msac.gov.au

1. Purpose of application and links to other applications

In September 2012, the Department of Health and Ageing received an application from the Royal College of Pathologists of Australasia (RCPA) requesting Medicare Benefits Schedule (MBS) reimbursement of external expert opinions for morphological pathology (histology, cytopathology, haematology, microbiology and genetic pathology). The application was initially considered in August 2013 by the Protocol Advisory Sub-Committee (PASC) of the Medical Services Advisory Committee (MSAC), and was reconsidered by PASC in April 2014. The Final Protocol, dated May 2014, restricted the scope of the assessment to external expert opinions for bone marrow specimens (included in Group P1), all tissue pathology (which includes Group P5 items) and all cytopathology (which includes Group P6 items).

Morphological/Interpretive diagnosis in the sub specialties of Anatomical Pathology, Cytology, Haematology, Microbiology and Genetic pathology is integral to the diagnosis and management of many diseases, particularly cancers. For such complex diseases, making a definitive diagnosis can be difficult and a second opinion from a second pathologist with a particular expertise in the condition or type of cancer is sometimes required.

Any disease that requires a tissue sampling procedure to be performed which is found by the original reporting pathologist to be diagnostically challenging or where a second opinion is requested by the clinician in charge of patient management (treating doctor).

2. MSAC's advice to the Minister

After considering the available evidence in relation to safety, clinical effectiveness and cost-effectiveness, MSAC agreed to support public funding of two new time-tiered MBS items for

seeking a second external expert opinion for morphological pathology in bone marrow specimens, tissue pathology and cytopathology:

- non-complex second opinions (requiring less than 30 minutes to complete an assessment); and
- complex second opinions (requiring more than 30 minutes to complete an assessment)

where:

- the second pathologist is from a different Accredited Pathology Laboratory (APL) to that of the pathologist providing the initial report, and
- the non-pathologist specialist clinician or general practitioner involved in the care of the patient and the original pathologist must be in agreement before a second expert opinion is sought.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that this application was for MBS reimbursement of external expert opinions for morphological pathology (histology, cytopathology, haematology). Morphological diagnosis and staging is integral to the management of many diseases, especially cancers. Once a definitive diagnosis has been made, appropriate management of the disease process can proceed. Incorrect or incomplete diagnoses may lead to delayed or sub-optimal care, adversely affecting clinical outcomes and resulting in inefficient use of resources. For complex diseases, making a definitive diagnosis can be difficult and a second opinion from a second pathologist with a particular expertise in the condition or type of cancer is sometimes required.

Reasons why a pathologist may not be able to provide a primary or definitive diagnosis (or why a clinician may lack confidence in the initial pathologist's diagnosis) were identified:

- the rare or esoteric nature of the lesion;
- complexity of, or lack of familiarity with, a particular cancer classification scheme;
- the type, quantity or quality of the diagnostic biopsy specimen;
- the requirement for special ancillary stains or tests to aid interpretation.

A two-tier fee structure with different rebates for 'non-complex' and 'complex' expert opinions was proposed. Other than the time required the two item descriptors are very similar. MSAC noted that the intention should not be to provide funding for mandatory or routine review of all cases referred to treatment centres or intra-department/intra-institutional cases. MSAC noted that the items and the specific rules to support their listing should be referred to the Pathology Services Advisory Committee to finalise. MSAC also indicated that the expert opinion should not be undertaken 'blinded', as was proposed at ESC. MSAC considered that the second opinion needed to be informed by relevant clinical, imaging and previous pathological information.

MSAC noted that the comparator is the standard management where (1) no second opinion is obtained; (2) a second expert opinion is requested by the original pathologist and is provided at no cost, or billed by the second pathology laboratory to the initial laboratory; (3) a second opinion is requested by the treating clinician at no cost (gratis) or at cost to the patient or clinical unit.

MSAC agreed that comparative data for safety and clinical effectiveness of a second, expert opinion for pathology is limited. With respect to safety, only two identified studies (Hutton Klein et al, 2010; Tavora et al, 2009) provided any patient follow-up information upon which an assessment of the safety (i.e. accuracy) of the expert pathologist's diagnosis could be made. MSAC agreed with its ESC that the majority of studies in the assessment report assumed that expert opinion was correct, without sufficient follow up, therefore making the results uninterpretable or unreliable. MSAC also noted a lack of data addressing how a change in diagnosis might impact on clinically relevant endpoints such as morbidity, mortality or quality of life. MSAC agreed that no evidence was provided to support positive changes in patient care and patient outcomes. Similarly, MSAC also discussed that no studies quantified harms due to delay in diagnosis.

Due to the limited data, the economic evaluation estimated the incremental cost per significant (clinically relevant) change in diagnosis or interpretation rather than health outcome. MSAC agreed that if this service were MBS funded, there would be a higher volume of second opinion referrals than currently but noted that there was no evidence to suggest that this would lead to an increase in change of diagnosis. Using histopathology alone to inform the base case analysis, the incremental cost was calculated to be \$3,838 for one significant change in diagnosis. A sensitivity analysis including both histopathology and cytopathology calculated incremental costs up to \$5,279 for one significant change in diagnosis.

MSAC also discussed the effect that this proposal could have on changes in behaviour, and new, medical business models. In particular, MSAC questioned whether this could lead to a more inefficient medical business model. For example, whether the proposal would lead to clinicians uniformly requesting expert second opinions for every case. MSAC noted that reimbursing second opinions may risk leakage of this service to circumstances where it was not required. For instance, MSAC noted that the routine re-review of tumours in oncology was not intended to be covered by the current submission.

MSAC emphasised that clinicians should not solely be able to request second opinions, as most of their requests would not relate to diagnostic uncertainty. MSAC agreed that the clinician (or general practitioner) involved in the care of the patient and the original pathologist must be in agreement before a second expert opinion is sought. This is to ensure there is still a clinical need for the second expert opinion (for example the patient is alive and suitable for treatment) and the original pathologist has confirmed the diagnosis is indeed uncertain. These measures are required to reduce the risk that second opinions will be used in circumstances where they will have no impact on patient care.

MSAC also discussed whether an 'expert pathologist' should be defined and questioned whether restrictions should be applied according to credentials, training, subspecialty, experience, or malpractice. MSAC agreed, however, that within their networks, pathologists know who the experts are for the more difficult pathology cases.

Despite uncertainty around comparative data, MSAC noted that in some circumstances second opinions are an integral part of improving patient management by assisting in diagnosis and/or disease staging. It was acknowledged that currently second opinions by pathologists are done *pro bono* (as part of their 'professional responsibilities' and against an expanding workload), or that additional costs are borne by the patient or by the requesting lab/hospital. It was considered likely that funding second pathologist assessments would

improve the priority given to such requests and provide an avenue for reimbursement for complicated work that is time and resource consuming

4. Background

The intended purpose of a benefit payable for second opinion is to assist the initial pathologist and/or the clinician in charge of patient management to arrive at a definitive diagnosis in difficult cases with the help of an external expert pathologist. Morphological diagnosis and staging is integral to the management of many diseases. Once a definitive diagnosis has been made, appropriate management of the disease process can proceed.

There are a number of reasons why a pathologist may not be able to provide a primary or definitive diagnosis or why a clinician may lack confidence in the initial pathologist's diagnosis: the rare or esoteric nature of the lesion; complexity of, or lack of familiarity with, a particular cancer classification scheme; the type, quantity or quality of the diagnostic biopsy specimen; or the requirement for special ancillary stains or tests to aid interpretation.

Expert opinions for morphological pathology are undertaken using the specimens/samples/slides used to inform the initial opinion/diagnosis from the initial pathologist. However, where necessary, the expert pathologist may repeat or conduct 'ancillary' tests (such as immunohistochemistry, immunocytochemistry or molecular testing) to provide a more refined diagnosis. It is anticipated that any ancillary services undertaken in conjunction with a second, expert opinion could be reimbursed through the MBS in the normal way, as the fee for these additional services reflects the cost of performing and interpreting the tests. The need to repeat or conduct ancillary tests will vary according to the clinical condition under review.

The provision of external expert opinion is also associated with administrative and handling costs relating to transferring the original specimens/slides to and from an external expert pathologist. The 'specimen referred fee' (MBS Group 11, item 73940) may be appropriate to cover some of these costs, but can only be claimed by the second laboratory. PASC suggested that handling costs require separate consideration, similar to MSAC Application 1331¹.

It would be expected that a second, expert opinion on any specific pathology service episode would only be requested once. However, it is possible that a third opinion may be sought if the expert pathologist was unable to provide a definitive diagnosis, or if the clinician had concerns regarding the diagnosis provided by the expert pathologist.

5. Prerequisites to implementation of any funding advice

The provision of an external expert second pathology opinion would be provided by Anatomical, Haematology and General Pathologists, who provide morphological interpretive assessment.

Expert opinions for morphological pathology would be 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

¹ MSAC Application 1331: Retrieval of tissue for further diagnostic testing specifically genetic testing for diagnostic/prognostic purposes.

of Testing Authorities (NATA)/RCPA accredited laboratories (Approved Pathology Laboratory; APL) within Australia.

6. Proposal for public funding

The applicant seeks MBS funding for expert opinions for morphological pathology, to facilitate access to expert pathologists for review of rare, unusual or complex cases, thereby decreasing the frequency of incorrect or incomplete diagnoses. The applicant claims that expert pathologists often have to prioritise routine work over unfunded expert opinions and therefore the introduction of an MBS item (or items) could result in more timely and optimal treatment of patients.

Proposed MBS item descriptor for 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 minute 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>

Abbreviations: MBS, Medicare Benefits Schedule

Proposed MBS item descriptor for 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>

Abbreviations: MBS, Medicare Benefits Schedule

The proposed item descriptors reflect the amount of time taken to process and examine the specimen and prepare a full written report (either ≤ 30 minutes or > 30 minutes). It would be up to the expert pathologist to determine the workload involved in providing the second opinion and bill the service accordingly (similar to the situation where a clinician is allowed to determine whether they bill for a short or long consultation).

It is possible that some patients may receive a second, expert pathology opinion as an inpatient; however, the majority of services are expected to be provided in an outpatient setting. Explanatory notes are needed to limit second, expert opinion to tissue pathology, cytology and bone marrow items.

The proposed Schedule fee for the ‘non-complex’ expert opinion item is approximately equal to the fee for initial examination of a complexity level 4 biopsy with at least 12 separately identified specimens; the proposed fee for ‘complex’ expert opinion is approximately equal to the average of the initial fees for examination of complexity level 5 and 7 biopsy materials. The Assessment Report provides a full list of the existing services and fees for morphological pathology and a list of the complexity levels assigned to tissue types from different anatomic sites.

7. Summary of Public Consultation Feedback/Consumer Issues

A number of consumer organisations support the value of the second opinion test if there is evidence of further morphological diagnosis and staging. It was noted that this could lead to better patient outcomes, although there appears to be no real data to support this.

It was noted that there may be access and equity issues for those consumers (such as rural or remote consumers) with limited access to pathology services. Conversely, it was noted that with more tests conducted in the larger laboratories, the larger data pool may better enable the identification of disease type and stage.

Under the current system, it is unclear who pays for the second opinion, with some consumers paying for the second opinion test, leading to out of pocket costs. It was noted that there may be additional hospital costs (to take a further biopsy, for example).

Lastly, it was noted that the proposal may lead to added stress on the patient and family having additional tests.

8. Proposed intervention’s place in clinical management

The proposed intervention will be in addition to current practice. A two-tier fee structure is proposed with different rebates for ‘non-complex’ and ‘complex’ expert opinions.

The current clinical management algorithm for patients having a morphology-based pathology test is shown below in Figure 1. The proposed clinical management algorithms, with the addition of MBS funding for pathologist- and clinician-initiated second, expert opinion are shown in Figure 2 (*Scenario 1*) and Figure 3 (*Scenario 2*), respectively. All of the algorithms refer to cases in which the primary pathologist cannot provide a definitive diagnosis and an expert opinion is considered desirable.

Under the current treatment algorithm, second, expert opinion is either provided: (i) without payment (*ex gratis*); (ii) at the expense of the patient; (iii) at the expense of the requesting hospital/unit (which may be publicly funded through other health budgets); or (iv) at the expense of the initial pathology laboratory, if this was the source of the referral.

Alternatively, the expert opinion, although desirable, may not be requested due to lack of funding.

In the proposed treatment algorithms the patient pathway is similar to the current situation. However, expert pathologists are able to claim a fee for their opinion using one of the new MBS items. Theoretically, in the proposed scenario all cases in which the initial pathologist

was unable to confidently provide a definitive diagnosis would have the opportunity to be reviewed by an expert pathologist, provided that: (i) the initial pathologist and treating clinician agree that uncertainty remains in the diagnosis (*Scenario 1*); or (ii) the treating clinician requires verification or further information to effectively manage the patient (*Scenario 2*).

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

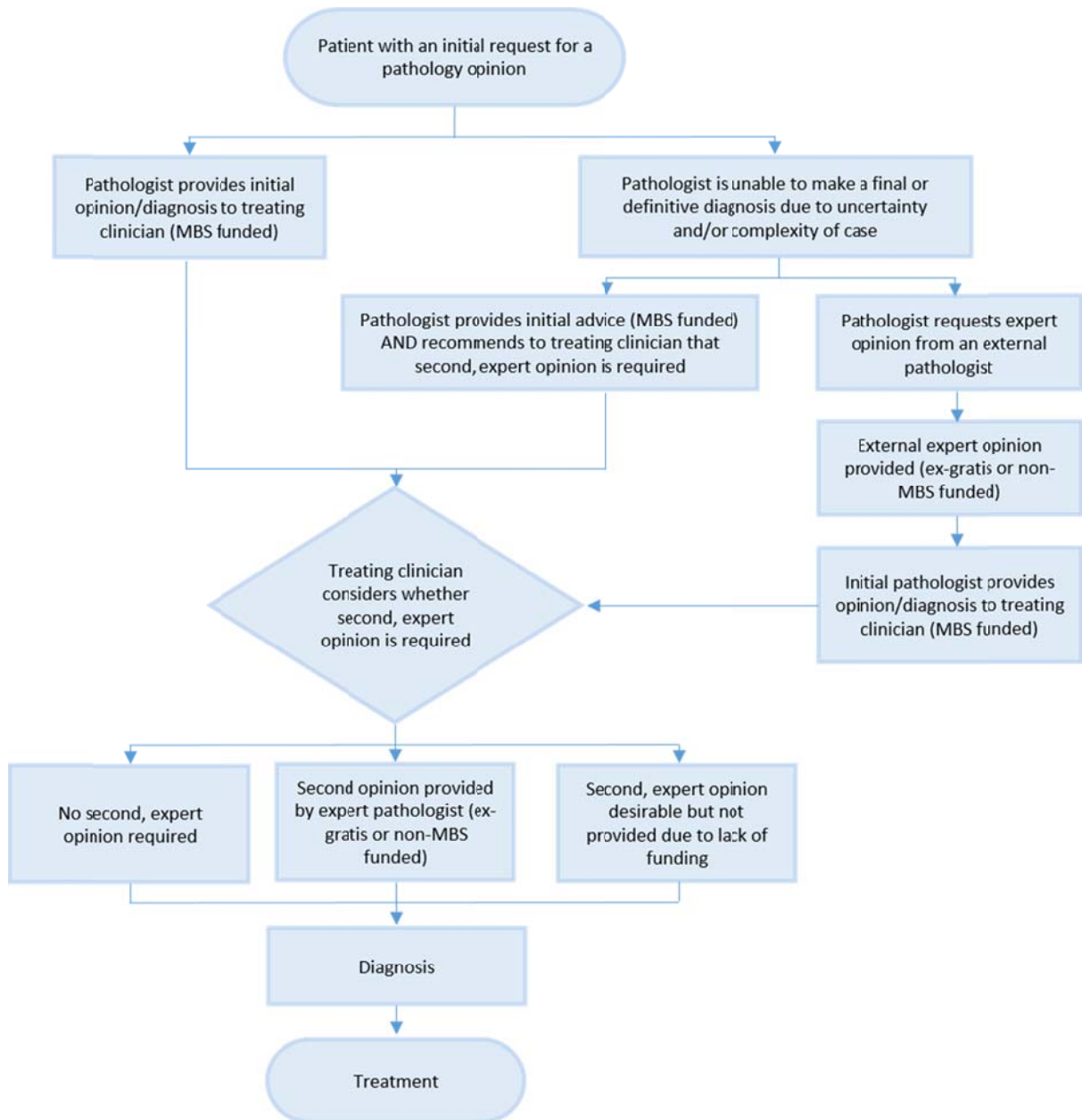


Figure 2 Clinical management algorithm including proposed MBS item for second pathology opinion (*Scenario 1*)

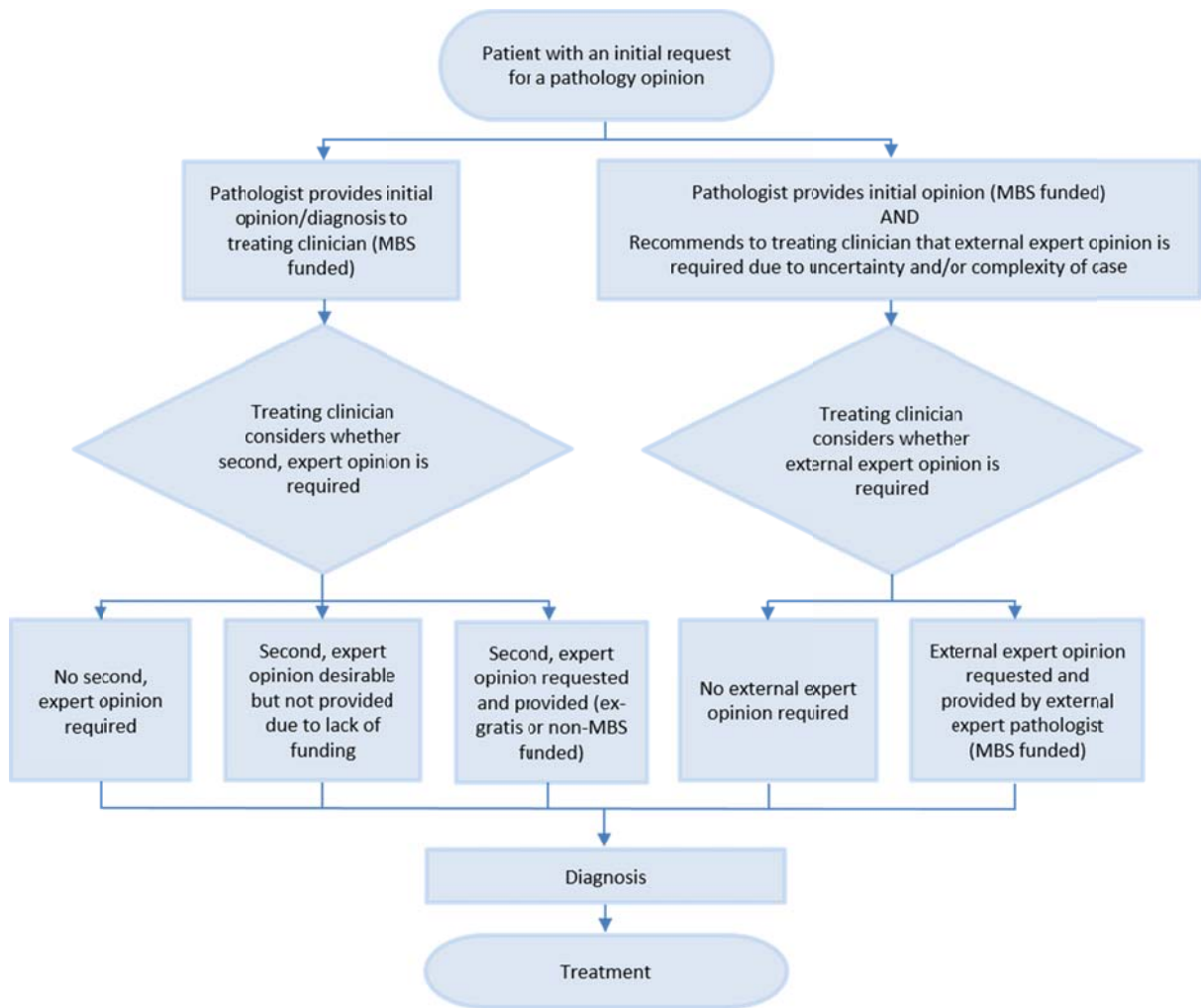
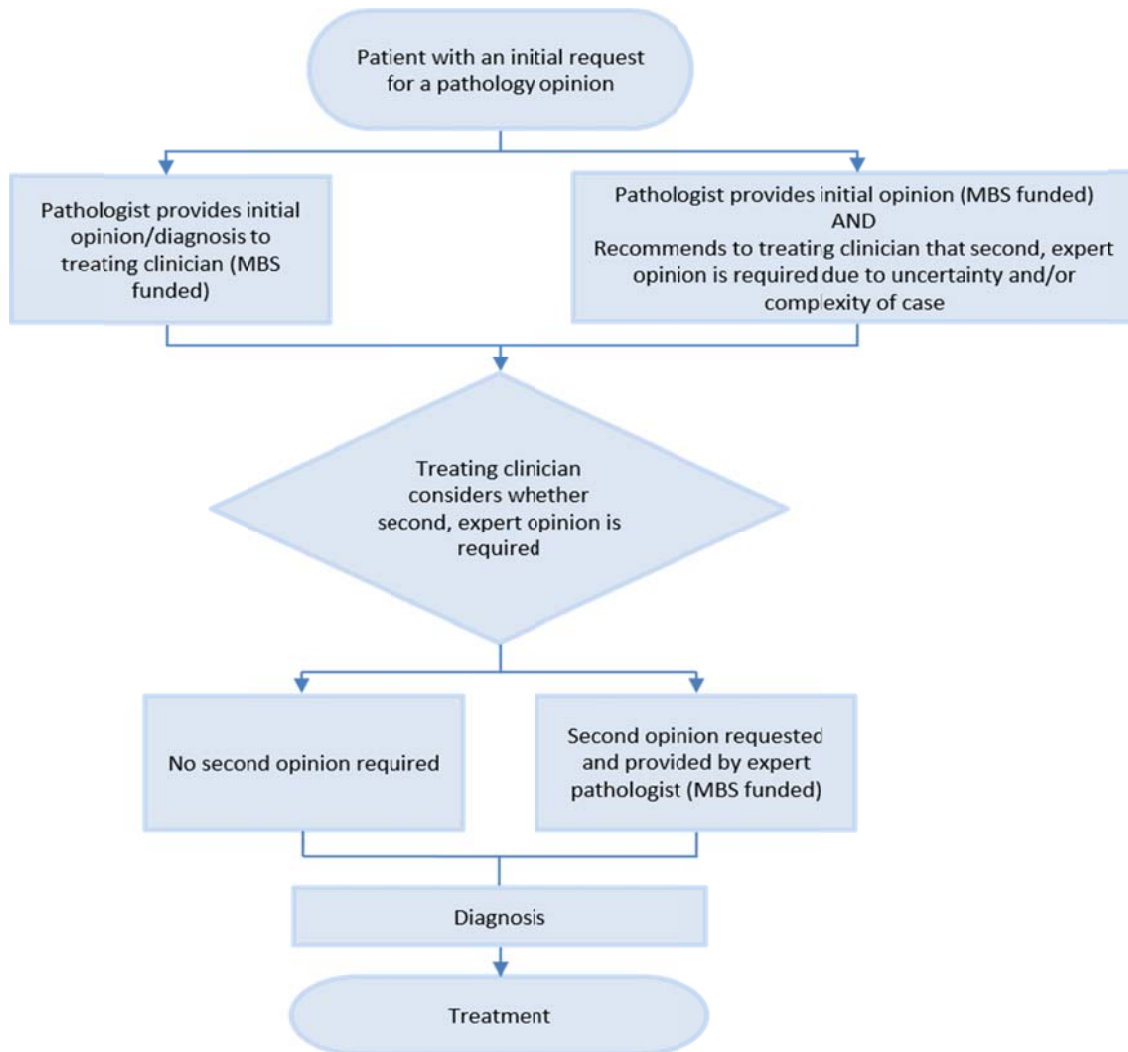


Figure 3 Clinical management algorithm including proposed MBS item for second pathology opinion (*Scenario 2*)



9. Comparator

The comparator is the standard management which currently applies. Under current arrangements, the MBS does not provide reimbursement for second, expert opinions for pathology. However, there are circumstances where the primary pathologist or the treating clinician may require an expert opinion to optimise patient management. In those instances, 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; or
- 2) The treating clinician requests an expert opinion from a pathology provider, and this is provided either at no cost (gratis) or at cost to the patient (privately) or the clinical unit.

The Applicant claimed that, in some cases, an expert opinion would be desirable but the costs associated with providing a second opinion and the lack of funding means that an expert opinion is not sought.

10. Comparative safety

Only two of the included studies provided any patient follow-up information upon which an assessment of the safety (i.e. accuracy) of the expert pathologist's diagnosis could be made. However, in both cases, follow-up was inadequate and the results were therefore uninterpretable or unreliable. While several of the included studies provided information regarding turnaround time, none of the studies attempted to quantify harms due to a delay in diagnosis.

11. Comparative effectiveness

None of the included studies reported relevant effectiveness outcomes such as mortality, morbidity or quality of life.

12. Economic evaluation

The economic model was based upon the Decision Analytic structure presented in the Final Protocol, with structural changes due to limitations in the evidence base. Health outcomes are derived from the rate of major discrepancies between the initial (provisional) diagnosis and the expert pathologist diagnosis, from studies that included all surgical pathology from any organ system. Such cases are representative of those that could potentially result in a change in clinical management due to second, expert opinion. These cases are often those in which diagnosis is modified from benign to malignant or vice versa and can, therefore, be thought of as 'significant'.

The most notable simplification of the structure was that there is no explicit consideration of either improved or inferior treatment outcomes. Instead, on the basis of available data, the economic evaluation estimates the incremental cost per significant (clinically relevant) change in diagnosis or interpretation. The focus is therefore on the attainment of a definitive diagnosis and, as a consequence, the economic evaluation does not extrapolate to final health outcomes. While it may be argued that comprehensive modelling beyond this point would be warranted, there are several reasons why this is unlikely to be informative:

- The general nature of the requested listings render it very difficult to accurately assess the cost-effectiveness beyond the point of definitive diagnosis. It is not feasible to comprehensively consider the differential impacts of significant changes in diagnosis on all conditions to which the listing would apply; the range of conditions means that the range of different treatments, natural histories and subsequent mortality/morbidity implications is enormous.
- The paucity of data imposes very real limitations on the ability to extrapolate beyond diagnosis. Long term data describing the transition from final diagnosis to mortality (and intermediate morbidity) do not exist for the research questions at hand.

Rather than attempting complex downstream modelling of a wide range of illnesses, the evaluation focusses on providing decision-makers with the most informative assessment of

cost-effectiveness. Specifically, the evaluation provides an assessment of how much it will cost, on average, to provide information to trigger a change in diagnosis where required if second, expert opinions are funded by the MBS.

Cases in which no diagnosis is offered by the initial pathologist are excluded from the model as no data is available to inform how such patients may be managed, or how clinical management may change in the event of a second, expert opinion.

The economic evaluation considers tissue pathology and cytopathology independently, appropriately applying data relevant to each analysis. Due to data limitations, cytopathology is considered in a sensitivity analysis while tissue pathology forms the base case analysis. In addition to claiming reimbursement for the second opinion, expert pathologists would have the ability to recharge for ancillary items in conjunction with one of the proposed new items. These costs are also factored into the evaluation.

The incremental cost-effectiveness is shown in the table below. The economic evaluation demonstrates that if second, expert opinions were to be funded by the MBS as per the requested listing, it would cost an additional \$3,838 to generate one significant change in diagnosis in the case of tissue pathology.

Incremental cost per significant (clinically relevant) change in diagnosis or interpretation

	Proposed funding arrangements	Current funding arrangements	Incremental
Average cost per patient	\$4.19	\$0.15	\$4.04
Average rate of significant change in diagnosis per patient	0.0018	0.0007	0.0011
Incremental cost per significant (clinically relevant) change in diagnosis or interpretation	-	-	\$3,838.26

Note: Figures may not sum due to rounding

Importantly, in the absence of information otherwise, this analysis assumes that there is a zero cost associated with second, expert opinions under the current funding arrangements. As such, it represents a worst-case scenario in that sense.

A series of sensitivity analyses were conducted to highlight potential areas of uncertainty with regards to the base case. Key sensitivity analyses are shown in the table below.

Incremental cost per significant (clinically relevant) change in diagnosis or interpretation: Sensitivity analyses

Description	Incremental cost	Incremental outcome	Incremental cost per significant change in diagnosis
<i>Base case</i>	<i>\$4.04</i>	<i>0.0011</i>	<i>\$3838.26</i>
Cytopathology	\$2.58	0.0011	\$2460.01
<i>Scenario 1</i> alone	\$4.21	0.0011	\$4000.26
<i>Scenario 2</i> alone	\$3.53	0.0011	\$3353.95
'Complex' second, expert opinions alone	\$5.55	0.0011	\$5278.96
'Non-complex' second, expert opinions alone	\$2.66	0.0011	\$2531.19
Soft tissue/sarcoma	\$4.04	0.0013	\$3193.34
Dermatology	\$4.04	0.0018	\$2208.92

Description	Incremental cost	Incremental outcome	Incremental cost per significant change in diagnosis
Average cost of second, expert opinion in the comparator arm set to unit cost of 'non-complex' second, expert opinion	\$1.49	0.0011	\$1420.59

13. Financial/budgetary impacts

The number of second, expert opinion services that would be expected to occur under the current and proposed funding arrangements was calculated by applying estimates from the Expert Opinion Survey to the predicted number of 'core' pathology items (based on historical data from Medicare Australia).

For simplicity, the financial estimates assume that 100% of cases are outpatients, bulk-billed using the 85% benefit. Any use of the proposed service for private inpatients would reduce the financial impact to the MBS.

The estimated number of MBS services for the proposed items is shown in the table below.

Estimated number of MBS services for second, expert opinions, over the first five years of the proposed MBS listing – Proposed funding arrangements

	Year 1 (2015-16)	Year 2 (2016-17)	Year 3 (2017-18)	Year 4 (2018-19)	Year 5 (2019-20)
Scenario 1	-	-	-	-	-
Tissue pathology ^a	32,994	34,190	35,385	36,580	37,776
Complex	17,734	18,377	19,019	19,662	20,305
Non-complex	15,260	15,813	16,366	16,918	17,471
Non-gynaecological cytology	1820	1872	1925	1978	2031
Complex	338	348	358	367	377
Non-complex	1482	1525	1568	1611	1654
All cytology	14,475	14,633	14,791	14,949	15,107
Complex	2,688	2,718	2,747	2,776	2,806
Non-complex	11,787	11,915	12,044	12,173	12,302
<i>Sub-total (excluding gynaecological cytology)</i>	<i>34,814</i>	<i>36,062</i>	<i>37,310</i>	<i>38,558</i>	<i>39,807</i>
<i>Sub-total (including all cytology)</i>	<i>47,469</i>	<i>48,822</i>	<i>50,176</i>	<i>51,530</i>	<i>52,883</i>
Scenario 2	-	-	-	-	-
Tissue pathology ^a	11,368	11,780	12,191	12,603	13,015
Complex	3,410	3,534	3,657	3,781	3,905
Non-complex	7,957	8,246	8,534	8,822	9,111
Non-gynaecological cytology	1,239	1,275	1,310	1,346	1,382
Complex	227	234	240	247	253
Non-complex	1,012	1,041	1,070	1,100	1,129
All cytology	9,853	9,960	10,068	10,176	10,283
Complex	1,806	1,826	1,846	1,866	1,885
Non-complex	8,046	8,134	8,222	8,310	8,398
<i>Sub-total (excluding gynaecological cytology)</i>	<i>12,606</i>	<i>13,054</i>	<i>13,502</i>	<i>13,950</i>	<i>14,398</i>
<i>Sub-total (including all cytology)</i>	<i>21,220</i>	<i>21,740</i>	<i>22,259</i>	<i>22,779</i>	<i>23,298</i>
TOTAL (S1 and S2 – excluding gynaecological cytology)	47,420	49,116	50,812	52,508	54,204
TOTAL (S1 and S2 – all cytology)	68,689	70,562	72,436	74,309	76,182

Source: Section E.2

Abbreviations: S1, Scenario 1; S2, Scenario 2.

^a Includes bone marrow items

The table below presents a summary of the total cost to the MBS of the proposed listing, including associated costs related to ancillary tests, specimen referral and bulk billing.

Estimated total cost to the MBS of second, expert opinion and associated services, over the first five years of the proposed MBS listing

	Year 1 (2015-16)	Year 2 (2016-17)	Year 3 (2017-18)	Year 4 (2018-19)	Year 5 (2019-20)
Scenario 1	-	-	-	-	-
Tissue pathology ^a	\$9,213,248	\$9,547,064	\$9,880,889	\$10,214,714	\$10,548,537
Second, expert opinion	\$7,912,188	\$8,198,864	\$8,485,547	\$8,772,231	\$9,058,912
Ancillary tests	\$908,430	\$941,345	\$974,260	\$1,007,175	\$1,040,090
Specimen referred fee ^b	\$288,698	\$299,158	\$309,619	\$320,079	\$330,540
Bulk billing incentive ^c	\$103,931	\$107,697	\$111,463	\$115,229	\$118,994
Non-gynaecological cytology	\$368,113	\$378,792	\$389,471	\$400,150	\$410,830
Second, expert opinion	\$332,981	\$342,641	\$352,300	\$361,960	\$371,621
Ancillary tests	\$13,479	\$13,870	\$14,261	\$14,652	\$15,043
Specimen referred fee ^b	\$15,922	\$16,384	\$16,846	\$17,308	\$17,769
Bulk billing incentive ^c	\$5,732	\$5,898	\$6,064	\$6,231	\$6,397
All cytology	\$2,928,249	\$2,960,250	\$2,992,248	\$3,024,246	\$3,056,246
Second, expert opinion	\$2,648,780	\$2,677,727	\$2,706,671	\$2,735,615	\$2,764,561
Ancillary tests	\$107,219	\$108,391	\$109,563	\$110,734	\$111,906
Specimen referred fee ^b	\$126,654	\$128,038	\$129,422	\$130,806	\$132,190
Bulk billing incentive ^c	\$45,596	\$46,094	\$46,592	\$47,090	\$47,589
<i>Sub-total (excluding gynaecological cytology)</i>	<i>\$9,581,360</i>	<i>\$9,925,856</i>	<i>\$10,270,360</i>	<i>\$10,614,865</i>	<i>\$10,959,366</i>
<i>Sub-total (including all cytology)</i>	<i>\$12,141,497</i>	<i>\$12,507,314</i>	<i>\$12,873,137</i>	<i>\$13,238,960</i>	<i>\$13,604,783</i>
Scenario 2	-	-	-	-	-
Tissue pathology ^a	\$2,673,673	\$2,770,546	\$2,867,422	\$2,964,298	\$3,061,172
Second, expert opinion	\$2,290,025	\$2,372,998	\$2,455,973	\$2,538,948	\$2,621,922
Ancillary tests	\$248,372	\$257,371	\$266,371	\$275,370	\$284,369
Specimen referred fee ^b	\$99,467	\$103,071	\$106,675	\$110,279	\$113,883
Bulk billing incentive ^c	\$35,808	\$37,106	\$38,403	\$39,701	\$40,998
Non-gynaecological cytology	\$250,059	\$257,313	\$264,567	\$271,822	\$279,076
Second, expert opinion	\$226,174	\$232,736	\$239,297	\$245,859	\$252,420

	Year 1 (2015-16)	Year 2 (2016-17)	Year 3 (2017-18)	Year 4 (2018-19)	Year 5 (2019-20)
Ancillary tests	\$9,145	\$9,411	\$9,676	\$9,941	\$10,207
Specimen referred fee ^b	\$10,838	\$11,152	\$11,466	\$11,781	\$12,095
Bulk billing incentive ^c	\$3,902	\$4,015	\$4,128	\$4,241	\$4,354
All cytology	\$1,989,157	\$2,010,895	\$2,032,631	\$2,054,368	\$2,076,106
Second, expert opinion	\$1,799,163	\$1,818,824	\$1,838,484	\$1,858,144	\$1,877,806
Ancillary tests	\$72,749	\$73,544	\$74,339	\$75,134	\$75,929
Specimen referred fee ^b	\$86,210	\$87,152	\$88,094	\$89,036	\$89,978
Bulk billing incentive ^c	\$31,036	\$31,375	\$31,714	\$32,053	\$32,392
<i>Sub-total (excluding gynaecological cytology)</i>	<i>\$2,923,732</i>	<i>\$3,027,860</i>	<i>\$3,131,989</i>	<i>\$3,236,119</i>	<i>\$3,340,249</i>
<i>Sub-total (including all cytology)</i>	<i>\$4,662,830</i>	<i>\$4,781,442</i>	<i>\$4,900,053</i>	<i>\$5,018,665</i>	<i>\$5,137,278</i>
TOTAL (S1 and S2 – excluding gynaecological cytology)	\$12,505,092	\$12,953,716	\$13,402,349	\$13,850,984	\$14,299,615
TOTAL (S1 and S2 – all cytology)	\$16,804,327	\$17,288,756	\$17,773,190	\$18,257,625	\$18,742,061

Abbreviations: S1, *Scenario 1*; S2, *Scenario 2*.

^a Includes bone marrow items

The estimated costs also represent the total incremental cost of the proposed and associated services to the MBS, given that under current funding arrangements the relevant services are provided either without MBS reimbursement or not at all (i.e. specimen referred fee and bulk billing incentive).

For the same reasons cited for the economic evaluation, the financial analysis does not attempt to capture the use and cost of resources that are downstream of the provision of second, expert opinion. The proposed MBS listing may result in a subsequent increase or decrease in the use of other services (e.g. biopsy, imaging, treatment, monitoring). The results of key sensitivity analyses are shown in the table below.

Estimated total incremental costs of the proposed and associated services over the first five years of the proposed MBS listing: Results of key sensitivity analyses

Assumption	Year 1 (2015-16)	Year 2 (2016-17)	Year 3 (2017-18)	Year 4 (2018-19)	Year 5 (2019-20)
Base case – excluding gynaecological cytology	\$12,505,092	\$12,953,716	\$13,402,349	\$13,850,984	\$14,299,615
Expert opinion survey results summarised using the	\$8,976,757	\$9,300,238	\$9,623,726	\$9,947,215	\$10,270,701

Assumption	Year 1 (2015-16)	Year 2 (2016-17)	Year 3 (2017-18)	Year 4 (2018-19)	Year 5 (2019-20)
median.					
Expert Opinion Survey responses from a HESP member.	\$2,545,984	\$2,637,846	\$2,729,710	\$2,821,575	\$2,913,439
Higher second, expert opinion rate than the base case.	\$17,886,453	\$18,526,898	\$19,167,356	\$19,807,817	\$20,448,273
Assume a one-tier fee structure – Schedule fee \$200	\$9,805,126	\$10,156,207	\$10,507,295	\$10,858,386	\$11,209,473
Assume that all <i>Scenario 1</i> tissue pathology cases are 'complex' – involving more than 30 minutes of expert pathologist's time.	\$15,334,763	\$15,885,912	\$16,437,073	\$16,988,236	\$17,539,394
Assume that second, expert opinion is not requested for complexity 2 or 3 items (MBS items 72813-72818).	\$5,984,984	\$6,267,373	\$6,549,767	\$6,832,168	\$7,114,561
Base case – including gynaecological cytology	\$16,804,327	\$17,288,756	\$17,773,190	\$18,257,625	\$18,742,061
Assume that proposed changes to the NCSP come into effect in 2016, with an immediate 86% decrease in use of MBS items 73053 and 73055.	\$14,983,693	\$13,614,312	\$14,065,575	\$14,516,839	\$14,968,101

14. Key issues from ESC for MSAC

ESC agreed that the proposed eligible population refers to the type of tests being proposed to be funded for second, expert opinions. That is, cytopathology, tissue pathology and bone marrow testing.

ESC considered that the funding of second opinion for the purposes of quality control should not be eligible for reimbursement.

ESC noted that the majority of studies presented in the assessment report assumed that expert opinion was correct, without sufficient follow up. Due to this, ESC noted that the safety of second, expert, opinions was not able to be clearly defined.

ESC considered that patient safety may be improved by the proposed service if patients are more accurately diagnosed and therefore not be subject to treatments they do not need.

ESC was concerned that evidence regarding the degree of change of diagnosis was missing in the assessment report and that no studies quantified harms due to a delay in diagnosis.

ESC was concerned about a lack of evidence relating to the rate of diagnosis change versus the volume of referrals. If this service were MBS funded, ESC considered there would be a higher volume of second opinion referrals than currently but agreed that there was no evidence to suggest this would lead to an increase in change of diagnosis.

ESC noted that the assessment report did not provide evidence-based data to support positive changes in patient care and patient outcomes.

ESC noted that expert opinions are becoming a large component of specialist pathologists' workload. ESC questioned the degree to which lack of government funding was a barrier to providing second opinions.

ESC noted that the economic model is based on the Decision Analytic structure in the final protocol, with structural changes due to limitations in the evidence base. ESC further noted that the rate of major discrepancies between the initial (provisional) diagnosis and the expert pathologist diagnosis are derived from studies that included all surgical pathology from any organ system. ESC also noted that cost-utility analysis was not undertaken due to limitations in existing data sources.

ESC noted that the Assessment Group did a pre modelling study in lieu of reliable published data. ESC noted that an expert opinion survey was designed to obtain quantitative estimates from large public and private pathology laboratories about the number and nature of tissue pathology and non-gynaecological cytology cases that are currently referred for second, expert opinion in Australia, and any potential changes that would result from MBS funding of second, expert opinions.

ESC noted that most of the economic evaluation was derived from expert opinion rather than evidence.

ESC noted that the evidence presented did not show evidence of effectiveness outcomes such as changes to morbidity, mortality or quality of life, and therefore did not support the claim that second opinions would lead to cost efficiencies in patient management or changes to patient outcomes due to changes in diagnosis or interpretation by the second expert opinion.

Due to the lack of data and evidence, ESC concluded that the application cannot be treated purely as a scientific claim, because important workforce considerations were inherent in the application.

ESC was concerned about the potential to incentivise unintended behaviour if requests for a second opinion could be sent to the same Approved Pathology Laboratory as the original service.

ESC noted that the Assessment Group provided a linear regression of historical MBS data from 2008-09 to 2012-13 to project the future utilisation of MBS items for initial pathology opinions over the next five years. ESC noted that this data was based on the expert opinion survey.

ESC also noted that the application presumes that the MBS item for a second opinion would be bulk billed, that all second opinions would give rise to a claim for a specimen referred fee (MBS item 73940) which would also be bulk billed, and that all second opinions would also give rise to a claim for the 'bulk billing incentive' item (MBS item 74996).

ESC noted the assumption that the MBS fees will remain constant over the 5-year period of the financial projections. As a result, all increases in MBS outlays over the projection period result from an assumed increase (more than two-fold) in the numbers of cases referred for second opinions. ESC further noted that noncomplex cases seeking a second opinion will increase.

ESC noted that 'expert pathologists' were not well defined and questioned whether restrictions should be applied according to credentials, training, subspecialty, experience, or malpractice history.

ESC noted that currently, second opinion pathologists are working pro bono (as part of their 'professional responsibilities') and the introduction of MBS items could provide an avenue for reimbursement for complicated work that is time and resource consuming.

ESC noted that the application proposes the creation of two new MBS items; one for non-complex second opinions (requiring less than 30 minutes to complete an assessment) and the other for complex second opinions (requiring more than 30 minutes to complete an assessment). Other than the time required the two item descriptors are very similar.

ESC noted that there are two scenarios in which this service can be requested. ESC discussed that the intention should not be to provide funding for mandatory or routine review of all cases referred to treatment centres or intra-department/intra-institutional cases.

ESC discussed removing "and/or reprocessing" from both the item descriptors, as they are ambiguous. ESC noted that if left as is, it has the potential to push simple cases with additional immunohistochemistry into the complex category.

ESC noted that the item descriptor could require that the initial assessment is 'blinded' to ensure independent review, however, a copy of the original report should be provided for review at an appropriate time and the expert pathologist should attempt to reach a consensus diagnosis where possible.

15. Other significant factors

Nil.

16. Applicant's comments on MSAC's Public Summary Document

The Royal College of Pathologists of Australasia (the RCPA) is pleased that MSAC supports the public funding of morphological second opinions on cases where there is some uncertainty over the initial diagnosis. The RCPA acknowledges that it is difficult to analyse the overall financial benefits from such intervention under the current modelling system, and notes that the analysis provided only models the scenario of a change in diagnosis from benign to malignant (or vice versa) rather than the more likely situation where a diagnosis is refined and/or more accurately classified (allowing for more precise treatment planning). The RCPA has some concerns about the practical logistics involved in the process of requesting a second opinion, if both the clinician involved in the care of the patient and the original pathologist must always be in agreement before a second expert opinion is sought. In certain situations this may prove unworkable, and careful consideration of the wording of an item is required in order to avoid unintended consequences.

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website at: www.msac.gov.au.