



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1431.1 – HbA1c point of care test for the management of diabetes mellitus

Applicant: Pathology Technology Australia Limited

Dates of MSAC Executive consideration: 9 December 2019 and
6 March 2020

Date of MSAC consideration: MSAC 75th Meeting, 28-29 March 2019

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

1. Purpose of application

An application for the resubmission of glycated haemoglobin (HbA1c) Point of Care (PoC) testing for the management of patients with diabetes mellitus was received from HTAnalysts for IVD Australia by the Department of Health. Sponsorship of the application was subsequently taken over by Pathology Technology Australia Limited.

2. MSAC's advice to the Minister

March 2020 MSAC Executive consideration

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, the MSAC executive supported the MBS listing of HbA1c PoC testing for the management and monitoring of established diabetes mellitus, including in pregnancy.

The MSAC executive recalled MSAC had previously concluded that, based on currently available evidence, PoC testing for managing and monitoring established diabetes was associated with no differences in health outcomes compared with laboratory based testing. In other words, both test methodologies can be successfully used to manage and monitor patients with diabetes, and neither method has been demonstrated to deliver better patient health outcomes. The MSAC executive recalled the applicant has previously accepted this conclusion.

The MSAC executive advised that the cost-effective price for HbA1c PoC would be between \$7.84 and \$11.80 per test. At a price in this range, the average annual cost of the two approaches, PoC with one laboratory test per year versus laboratory testing for all tests, would be similar. The MSAC executive further advised that, even at a price in this range, there is potential for the inclusion of HbA1c PoC testing on the MBS to result in a higher overall cost to Government than with current laboratory based testing. This is because the

overall number of HbA1c tests conducted in any year may increase above current levels, without evidence that the increased testing improves health outcomes.

The MSAC executive considered there is currently no justification, on cost-effectiveness grounds, for paying the applicant's requested price of \$19.50 per test. The MSAC executive considered that if the applicant wished to pursue a price that is any higher than the range recommended above, it would need to provide evidence that PoC HbA1c testing results in better health outcomes than laboratory based HbA1c testing, and this evidence would need to be supported with an appropriate economic analysis.

The MSAC executive noted the Department's advice that work on ensuring the appropriate quality assurance standards and processes for accreditation of practices is well advanced.

December 2019 MSAC Executive

The MSAC executive deferred making a recommendation for reasons set out in Section 3 of this Public Summary Document.

March 2019 MSAC consideration

MSAC indicated it was supportive of MBS listing of HbA1c PoC testing for the management and monitoring of established diabetes mellitus, including in pregnancy.

Before making a final recommendation, MSAC advised that, to ensure good testing practice and cost-neutrality, the appropriate quality assurance standards and accreditation of practices needs to be determined, along with costs. MSAC noted that it is desirable that there be a single set of standards and that the National Pathology Accreditation Advisory Council (NPAAC) is currently undertaking a review of its *Guidelines for point of care testing*.

The cost-minimisation calculation also needs to be re-examined to take into account concerns about the coning assumptions, the updated costs of accreditation and quality assurance, and to reflect the costs of different test devices. Further consolidation of the application's utilisation estimates is also required.

MSAC requested that this information be provided to the MSAC Executive for review, with reconsideration by MSAC out-of-session if considered necessary by the MSAC Executive.

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

March 2020 MSAC Executive

At its March 2020 meeting, the MSAC executive noted the applicant had proposed a revised test cost of \$19.50. The applicant claimed this price was supported by assumptions that:

- An average number of 2 HbA1c tests/year for each stable diabetic patient (in case of PoCT one test will be done at GP and one in a laboratory)
- 34% of all laboratory HbA1c tests will be coned out.

The applicant cited the Laurence 2009 study as evidence for the 34% coning assumption.

The MSAC executive noted the cost-minimisation analysis results from its December 2019 advice and the applicant's new proposal as report in Table 1 (addendum).

Table 1 (addendum): Comparison of MSAC Executive and applicant's cost-minimisation analysis.

Inputs					
Laboratory Test	\$19.61	Assumes MBS fee of \$16.80 and PEI/BBI# of \$2.81			
PoCT Test	\$19.50	Proposed by applicant 11 February 2020			
MSAC Executive Cost-Minimisation Analysis December 2019			Applicant Cost-Minimisation Analysis February 2020		
	POC	Lab		POC	Lab
No Poc Tests	1.5		No Poc Tests	1	
No Lab Tests	1	2.5	No Lab Tests	1	2
Prop Lab coned	60%	60%	Prop Lab coned	34%	34%
Total cost tests at proposed price	\$37.09	\$19.61	Total cost tests at proposed price	\$32.44	32.36
PoCT Price to achieve cost-minimisation	\$7.84		PoCT Price to achieve cost-minimisation	\$19.41	

#Average Patient Episode Initiation (PEI) and Bulk Billing Incentive (BBI) is based on out of hospital services.

The MSAC Executive did not accept the applicant's revised assumptions. The executive noted the DVA data show patients receive an average of 2.4 HbA1c tests each year, which supports the use of 2.5 tests in the current consideration.

The MSAC Executive noted the coning estimate cited in Laurence 2009 was based on reports from the pathology sector (Laurence page 265) – no data was provided in support of this claim.

The MSAC Executive noted the Department has further analysed both Veteran's Affairs data and Specialist requesting (un-coned) MBS data for MBS item 66551 (HbA1c monitoring). Based on 2018-19 data 60% - 65% of HbA1c laboratory tests would be coned.

However, the MSAC Executive considered it possible that a higher proportion of laboratory tests would be coned in the PoC group compared to the laboratory only group, on the basis that it is likely that when a GP orders a laboratory based HBA1c test on one occasion per year (as required by the proposed MBS listing) the GP will also order a range of other tests, increasing the likelihood that the HBA1c test will be coned out. The MSAC executive thus considered it would be reasonable to assume between 60 – 90% of laboratory HBA1c tests in the PoC group will be coned out. The ranges of PoC HBA1c prices that arise from this analysis are provided in Table 2 (addendum).

Table 2 (addendum) Price range at which HbA1c PoC likely to be cost-effective

Inputs					
Laboratory Test	\$19.61	Assumes MBS fee of \$16.80 and PEI/BBI# of \$2.81			
PoC Test	\$19.50	Proposed by applicant 11 February 2020			
MSAC Executive Cost-Minimisation Analysis March 2002					
	POC	POC	Lab		
No Poc Tests	1.5	1.5			
No Lab Tests	1	1	2.5		
Prop Lab coned	60%	90%	60%		
Total cost tests at applicant's proposed price	\$37.09	\$37.09	\$19.61		
PoC test Price to achieve cost-minimisation	\$7.84	\$11.80			

#Average Patient Episode Initiation (PEI) and Bulk Billing Incentive (BBI) is based on out of hospital services.

The MSAC Executive noted the applicant continues to claims the Laurence 2009 study showed hospitalisations in the POC test group (intervention group) were significantly lower, at just 33% of the control (laboratory group) (applicant submission 11 Feb 2020, page 1).

The MSAC Executive noted the Laurence study did not examine the rate of hospitalisations due to diabetes in the intervention and control groups. However, it did examine the rate of serious adverse events (including hospitalisations) in both the PoCT group and the control group. Laurence reported that a higher percentage of patients with diabetes in the control group, 10.7% were hospitalised than patients in the intervention group, 7.49% (Laurence, 2009, Table 106). However, as Laurence did not report the cause of hospitalisation, the MSAC Executive considered it is not possible to make any inference whether PoC HbA1c testing leads to reduced hospitalisations compared to laboratory based HbA1c testing in patients with diabetes, on the basis of the Laurence study.

The MSAC executive noted the applicant’s most recent comments on the likely uptake of PoC HbA1c testing, in particular that it is a difficult estimation to make. However, the MSAC executive noted the applicant has previously claimed only 1% to 5% of all HbA1c tests will be conducted via PoC testing, and that each practice that adopts PoC HbA1c testing will use it 6 times per week or 350 times per year for a total of 103,306 tests per year. Based on these figures it would appear the applicant expects only around 295 medical practices will take up PoC testing. The executive recalled MSAC had considered these estimates implausibly low.

The MSAC executive noted the Department had estimated with proposed cost of PoC HbA1c testing at both the applicant’s price of \$19.50 per price and at \$11.77 (the upper end of the range of prices at which the executive considered the test would be acceptably cost-effective) as presented in Table 3 (addendum). The MSAC executive noted that at the applicant’s requested price of \$19.50 per PoC test, a **redacted**% swich from laboratory to PoC testing would associated with an increase in the cost of Government of approximately **\$redacted** per annum. Additionally, if the adoption of PoC HbA1c testing lead to an **redacted**% overall increase in the number of HbA1c tests conducted each year, the cost to Government would increase by between **\$redacted** (at MSAC recommended price) and **\$redacted** per annum, without evidence of improvements in health outcomes.

Table 3 (addendum): Estimated Cost to Government of adding HbA1c test to MBS

Estimated total number HbA1c per annum (2018)	Price requested by applicant	Cost	Price recommended by MSAC	Cost	Differential Cost
2,936,812	\$19.50		\$11.77		
Proportion PoC					
redacted%		\$redacted		\$redacted	\$redacted
redacted%		\$redacted		\$redacted	\$redacted
redacted%		\$redacted		\$redacted	\$redacted
Add New tests by POC only					
redacted%		\$redacted		\$redacted	
redacted%		\$redacted		\$redacted	
redacted%		\$redacted		\$redacted	

December 2019 MSAC Executive

The MSAC executive recalled that in December 2019, it had noted that PoC HbA1c testing will only be cost-effective (value for money) if the cost of delivering testing with this approach is no more than the cost of delivering testing through a laboratory based approach.

In December 2019, the MSAC Executive also noted the key input variables for determining a cost-effective price for PoC HbA1c are the number of tests conducted each year and the extent to which laboratory tests are coned.

At that time, the MSAC executive considered it was reasonable to assume that on average, a patient would receive 2.5 HbA1c tests each year for the management and monitoring of diabetes, with, in the case of PoC testing, 1.5 tests done at the GP and one in a laboratory. This is less than the 4 annual tests (PoC or laboratory) proposed by the applicant to the March 2019 MSAC meeting.

In December 2019, the MSAC Executive further considered it was reasonable to use the available Department of Veteran Affairs data on number of HbA1c tests (un-coned) to estimate the proportion of coned GP requested HbA1c tests under the MBS. The MSAC noted this proportion was 60%.

The MSAC executive deferred making a recommendation at its December 2019 executive meeting to allow the applicant to update its cost-minimisation analysis and financial analysis in response to this advice.

March 2019 MSAC Consideration

MSAC noted that this is a resubmission of Application 1431. MSAC recalled that, in July 2017, MSAC considered the safety, clinical effectiveness and cost-effectiveness of HbA1c PoC testing as an alternative to HbA1c testing in an accredited pathology laboratory for the diagnosis and management of diabetes. MSAC recalled that it did not support public funding for HbA1c PoC tests for the diagnosis of diabetes and deferred its advice for the monitoring of glycaemic management in patients with established diabetes, pending:

- further data and advice on an accreditation framework;
- a reduction in, or further justification of, the proposed fee for HbA1c PoC testing compared with the laboratory test fee; and
- an updated economic evaluation.

MSAC noted that no new literature has been identified since the original submission and that therefore the clinical claim (non-inferior clinical safety and non-inferior effectiveness) remains unchanged from the original submission.

MSAC noted the proposed item descriptor in this resubmission sets out test performance and accreditation requirements aimed at quality service provision which are discussed below. The proposed item is consistent with existing MBS HbA1c items.

In contrast to testing for diagnosis of diabetes where diagnostic accuracy of the test is critical, MSAC noted that the accuracy of the test in monitoring patients with established diabetes is not critical as long as the patient continues to be monitored by the same method. However, MSAC noted that the applicant had advised requirements for test performance and these appeared reasonable.

MSAC noted that compared to pathology laboratory testing, key issues are whether the cost of PoC test can be offset by reduced numbers of consultations because attendance to discuss the outcome of testing are no longer required. Further benefits to patients flow from not having to return for another appointment. As well as improving convenience, PoC testing provides an opportunity for more timely change in management and the prospect of better diabetes management, although there are, as yet, no data to support the latter. MSAC noted that, although patient convenience alone should not drive decisions, consumers value ready access to health care professionals where decisions can be made at the point of care.

In response to MSAC's request for further economic analysis, the resubmission presented a cost-minimisation analysis (base case) with a cost-utility analysis presented as a sensitivity analysis. ESC considered the cost-minimisation approach to be appropriate. However, MSAC noted that at the proposed MBS fee, the applicant's claim that the PoC test will cost no more than laboratory testings is only valid if the assumption is accepted that only one laboratory test per year is currently coned. If more than one laboratory HbA1c test is subject to coning in a year, then PoC testing becomes more expensive than laboratory testing. MSAC considered that the applicant's claim that only one laboratory HbA1c test per year would be subject to coning to be poorly justified. The MSAC requested further work be undertaken to determine the extent to which HbA1c tests are currently coned.

The resubmission addressed MSAC's concerns about the proposed MBS fee by reducing the fee \$27.57 to \$22.60; however, MSAC noted that the fee has been largely determined based on expert opinion and assumptions that cannot be verified. Training costs associated with accreditation were estimated by the applicant to be \$240 per year per general practitioner (GP), calculated over a 5-year period (\$400 in Year 1 and \$200 in Years 2–5). The resubmission states the costs attributed to the quality assurance (QA) program have reduced from \$420 in the original submission to \$330 based on updated costs for enrolment in a PoC testing QA program. There is no indication of whether there are costs beyond the initial training years or ongoing QA. These costs have been incorporated into the fee; however, no data were provided to justify these estimates.

MSAC also noted the uncertainty in claimed financial impact of adding PoC HbA1c testing to the MBS. There are no data to support the claim that 5% of unconed laboratory HbA1c tests will be replaced with PoC tests after 5 years. In addition, the amortisation costs were calculated based on the machine being used six times per week, but most machines will be used by group practices, not by an individual GP, and therefore may well be used more often.

If the assumption around practice usage (6 times per week or 350 times per year) is considered in the context of the estimated uptake rate (5% or 103,306 tests per year), it would appear the applicant expects only around 295 medical practices will take up PoC. If usage per GP practice is higher, the number of practices taking up PoC would need to be considerably less than 295 for overall usage to remain within the 103,306 PoC tests estimated by the submission. Overall, MSAC considered the applicant's assumptions around practice usage and uptake rates to be poorly justified.

MSAC noted that if both the uptake rates for PoC HbA1c and the number of currently coned laboratory HbA1c services are underestimated, then the inclusion of a PoC test in the MBS will be associated with a large additional cost.

MSAC noted that one of the primary issues identified in the original application was the lack of a quality framework for PoC testing on which accreditation could be based. The resubmission proposes using the Royal Australian College of General Practitioners (RACGP) PoC testing standards that were published in October 2018. This is a voluntary accreditation

module that medical practices can seek to be accredited to in addition to the main GP accreditation standards. Although ESC (at its meeting in February 2019) indicated that they considered the RACGP PoC testing standards to be appropriate, MSAC recommended that further consultation be undertaken to gain insight into how the standards are being used. Since the publication of the RACGP standards in October 2018, there has yet to be a medical practice seek accreditation under the standards. However, MSAC support for this application may incentivise medical practices to seek accreditation to the RACGP PoC testing standard.

MSAC also noted that the National Pathology Accreditation Advisory Council (NPAAC) published its own *Guidelines for point of care testing*, in 2015, for users of PoC testing in both laboratory and non-laboratory settings. NPAAC recently started a review of these guidelines, with the aim of revising them into accreditation standards that can be used to assess laboratories that use PoC testing devices. NPAAC has advised that the guidelines could also provide a model for minimum best practice standards for the use of PoC testing devices in other health care settings. MSAC questioned whether there should be two separate accreditation standards and supports the view that a single set of standards would be preferable. NPAAC advised and MSAC noted that the accrediting body need not be the same across the system. This function is currently undertaken by NATA for the pathology sector.

MSAC noted that the Department has recently engaged a consultant to undertake an independent mapping analysis of the pathology quality standards and RACGP standards, in addition to some further exploration and analysis of PoC testing in laboratory and non-laboratory health care settings, which is expected to inform the Department's policy consideration. In addition, there are different costs associated with accreditation assessments of pathology laboratories as opposed to medical practices, which can be attributed, in part, to the number of recognised accreditation assessment bodies. This is an issue related to PoC testing that is under consideration by the Department.

4. Background

This is the first resubmission of Application 1431.

At its July 2017 meeting, MSAC:

- deferred its advice for the monitoring of glycaemic management in patients with established diabetes (including in pregnancy) [1431 Public Summary Document (PSD) 2017, pp2-3]; and
- did not support public funding for HbA1c PoC testing for the diagnosis of diabetes based on insufficient evidence demonstrating accuracy in terms of analytical or clinical validity for diagnostic purposes [1431 PSD 2017, p1].

The MSAC also noted that the application presented limited information on the use of HbA1c PoC testing for the diagnosis of diabetes, and no evidence for the use of HbA1c PoC testing in pregnant women with established diabetes [1431 PSD 2017, p2].

Further information is available in the Public Summary Document on the MSAC website.

5. Prerequisites to implementation of any funding advice

HbA1c tests are Class 2 *in vitro* diagnostics (IVD) and must be included on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA) before being supplied in Australia. All PoC test instruments undergo mandatory technical review by the TGA which assesses the test's analytical performance and suitability for use at the point of care.

It is proposed that accreditation to the Royal Australian College of General Practitioners (RACGP) PoC testing Standards (requesting medical practitioner or medical practitioner's organisation) will be required to claim the MBS item.

6. Proposal for public funding

The proposed MBS item descriptor for HbA1c PoC testing in the management of patients with established diabetes (with a maximum of three tests per patient in 12 months) is presented in Table 1, with the descriptor notes provided below the descriptor.

Table 1 Proposed MBS item descriptor

Category 6 – PATHOLOGY SERVICES	Group P9 – SIMPLE BASIC PATHOLOGY TESTS
MBS [item number]	
Quantitation of glycated haemoglobin (HbA1c) via Point of Care testing performed using a National Glycohemoglobin Standardization Program (NGSP) certified instrument with a total coefficient of variation (CV) <3.0% at 48 mmol/mol (6.5%) in the management of established diabetes; a maximum of three Point of Care tests in a 12 month period and a maximum of four glycated haemoglobin tests in total (Point of Care and laboratory) in a 12 month period. (Item is subject to rule 25).	
(Item is subject to RACGP Point of Care Testing Standards accreditation requirements. Item is subject to restrictions in rule PR.9.X of explanatory notes to this category)	
Fee: \$22.60 Benefit: 75% = \$16.95 85% = \$19.20	

Proposed Use Rule and Explanatory Note:

Rule 25(##): For any particular patient, item XXXX (HbA1c Point of Care testing) and item 66551 are not applicable more than four times in total in a 12 month period, and item XXXX (HbA1c Point of Care testing) is not applicable more than three times in a 12 month period.

PR.9.## Point of Care in General Practice item

Item number XXXX (HbA1c Point of Care testing) can only be performed in the following circumstances:

- the service is rendered by or on behalf of a medical practitioner;
- the practitioner referred to in paragraph (a), or the organisation for which the practitioner works, is accredited to the RACGP Point of Care Testing Standards; and
- the service is provided in accordance with that accreditation; and
- the practitioner referred to in paragraph (a) has determined the service to be necessary for his or her patient.

The resubmission suggested the proposed item is placed in Group P9 of the MBS. Services in this Group may be performed by a medical practitioner in the practitioner's surgery without the need to obtain Approved Pathology Authority, Approved Pathology Practitioner or Accredited Pathology Laboratory status.

7. Summary of Public Consultation Feedback/Consumer Issues

See Application 1431 - Public Summary Document on the MSAC website.

8. Proposed intervention's place in clinical management

In summary, practitioners would perform the proposed medical service under the same circumstances as they would order the existing HbA1c tests and hence the clinical management algorithm will remain the same as current practice. Use of HbA1c PoC testing is expected to replace HbA1c pathology laboratory testing. This was unchanged compared with the previous application.

9. Comparator

The comparator for HbA1c PoC testing is HbA1c testing performed in a laboratory, i.e. HbA1c pathology laboratory testing.

MBS item 66551 was listed on 1 November 1998 for management of established diabetes. In addition, MBS item 66554 was listed on the same date for the management of pre-existing diabetes where the patient is pregnant.

10. Comparative safety

No new evidence was presented in the resubmission evaluating the safety or effectiveness of HbA1c PoC testing compared with laboratory testing in the proposed patient population. The MSAC considered that there were no significant acute differences in the safety of the HbA1c PoC testing technique over standard laboratory testing [1431 PSD 2017, p2].

11. Comparative effectiveness

The resubmission presented an updated and more detailed framework in accordance with advice from MSAC [1431 PSD 2017, p1] which was based on the draft RACGP PoC testing Standards. Note, the final Standards were provided by the applicant during the Critique; the applicant advised that no relevant changes were found between the draft and final RACGP standards, and therefore stated no changes to the test cost were necessary.

Clinical Claim

The clinical claim previously reported remains the same for the purpose of this resubmission. Specifically, the clinical claim was that relative to laboratory HbA1c testing, HbA1c PoC testing has non-inferior safety and effectiveness for the management of established diabetes.

12. Economic evaluation

The summary of the resubmission's economic evaluation is presented in Table 2.

Table 2 Summary of the resubmission's economic evaluation

Perspective	Australian government
Comparator	HbA1c pathology laboratory testing
Type of economic evaluation	Cost-minimisation (base case); cost utility provided in sensitivity analysis
Sources of evidence	RCT of PoC testing in Australia; systematic review of economic evaluations
Time horizon	3 years
Outcomes	Incremental cost
Methods used to generate results	Cost comparison
Cycle length	3 months
Discount rate	5% per annum
Software packages used	Microsoft Excel 2016

Source: Extracted from Table 6, p19 of the resubmission

HbA1c = glycated haemoglobin; PoC = Point of Care; RCT = randomised controlled trial

The overall costs and incremental costs as calculated for the testing strategy and comparative testing strategy in the model, and using the base case assumptions are shown in Table 3.

Table 3 Results of cost-minimisation analysis for HbA1c testing

Step	PoC testing ^a	Pathology laboratory testing ^a	Incremental difference
Step 1: 18 months (Trial-based)^b			
Cost	\$147.18	\$148.18	-\$1.00
Cost (discounted)	\$141.80	\$142.76	-\$0.96
Step 2: 3 years (base-case)^b	(modelled)		
Cost	\$271.75	\$273.55	-\$1.80
Cost (discounted)	\$252.83	\$254.50	-\$1.67

Source: Table 12, p31 of the resubmission

GP = general practitioner; HbA1c = glycated haemoglobin; PoC = Point of Care

^a In each model arm, 1 coned (34% taken from PoC test GP trial) pathology laboratory testing was applied annually to reflect item descriptor

^b Note the costing of HbA1c in both arms is based on the assumption that 4 HbA1c tests would be performed per patient per year (same as limits on item descriptor claims in 12 months for PoC and pathology laboratory testing)

The resubmission stated that the model was most sensitive to changes related to the number of tests coned, i.e. if two pathology laboratory tests are assumed to be coned at 34% rather than one in the pathology arm alone, HbA1c PoC testing is no longer a cost saving (incremental cost +\$14.46 over 3 years). However, the resubmission stated that a more reasonable assumption was that the majority of patients would have a complete comprehensive pathology review (involving more than 3 tests) per 12 months.

13. Financial/budgetary impacts

The resubmission provided a brief update of the financial implications of listing HbA1c PoC testing on the MBS for the management of established diabetes. Using the same patient numbers from the previous application for the management population (MBS utilisation of item 66551 and coning and uptake rate assumptions), the resubmission updated the budget impact with the revised MBS item fee. Using the MBS Schedule Fees for HbA1c testing, the average cost of PoC testing is \$21.22 per quarter (3 PoC tests plus 1 pathology laboratory test (coned)) and the average cost of pathology laboratory testing is \$21.37 (3 pathology laboratory tests (unconed) plus 1 test (coned)) (Table 4).

Table 4 Budget impact estimations for HbA1c testing (using average yearly MBS Schedule fee; 100% rebate)

Net cost to MBS	Year 1	Year 2	Year 3	Year 4	Year 5
-	2018	2019	2020	2021	2022
Uptake rate (switch to PoC, from PATH)	1% ^a	2%	3%	4%	5%
Number of HbA1c PoC test services substituted from PATH	18,662	38,285	58,908	80,568	103,306
Total cost of HbA1c PoC test	\$396,036 <i>\$396,045</i>	\$812,487 <i>\$812,484</i>	\$1,250,145 <i>\$1,250,146</i>	\$1,709,823 <i>\$1,709,814</i>	\$2,192,368 <i>\$2,192,360</i>
Number of HbA1c PATH tests performed	1,213,002	1,225,125	1,237,067	1,248,811	1,260,338
Total cost of HbA1c pathology laboratory test	\$25,924,288	\$26,183,368	\$26,438,597	\$26,689,580	\$26,935,936
Total number of services (PoC and PATH)	1,231,664	1,263,410	1,295,975	1,329,379	1,363,644
Total costs associated with HbA1c tests (PoC and PATH)	\$26,320,324 <i>\$25,924,279</i>	\$26,995,856 <i>\$26,183,372</i>	\$27,688,742 <i>\$27,688,742</i>	\$28,399,403 <i>\$26,689,589</i>	\$29,128,304 <i>\$26,395,944</i>
Net change in test cost (PoC: -\$0.15 per test)	-\$2,799	-\$5,743	-\$8,836	-\$12,085	-\$15,496
Total net change to the MBS	-\$2,799	-\$5,743	-\$8,836	-\$12,085	-\$15,496

Source = Table 18, p36 of the resubmission

HbA1c = glycated haemoglobin; MBS = Medicare Benefits Schedule; PATH = pathology laboratory testing; PoC = Point of Care

^a MBS utilisation of item 66551 in 2015/16 (coned: 1,200,715; coned & unconed: 1,866,158), with annual growth applied of 2.6%

Values in italics represents calculated during Critique

The 85% rebate level for HbA1c testing (PoC and pathology; Table 5) was considered more appropriate, based on average MBS benefits paid from utilisation of MBS item 66551 over 2013/14 to 2017/18. However, this made negligible impact to the total net cost to the MBS (compared with resubmission's approach using 100% rebate level).

Table 5 Budget impact estimations for HbA1c testing (using average yearly 85% rebate for HbA1c testing^a)

Net cost to MBS	Year 1	Year 2	Year 3	Year 4	Year 5
-	2018	2019	2020	2021	2022
Uptake rate (based on assumption)	1%	2%	3%	4%	5%
Number of HbA1c PoC test services substituted from pathology laboratory testing	18,662	38,285	58,908	80,568	103,306
Total cost of HbA1c PoC test	\$336,849	\$812,484	\$1,250,146	\$1,709,814	\$2,192,360
Number of HbA1c PATH tests performed	1,213,002	1,225,125	1,237,067	1,248,811	1,260,338
Total cost of HbA1c PATH test	\$22,049,452	\$22,269,819	\$22,486,896	\$22,700,374	\$22,909,907
Total number of services (PoC and PATH)	1,231,664	1,263,410	1,295,975	1,329,379	1,363,644
Total costs of HbA1c tests (PoC and PATH)	\$22,386,302	\$22,960,864	\$23,550,186	\$24,154,627	\$24,774,581
Net change in test cost (-\$0.13 per test)	-\$2,381	-\$4,884	-\$7,515	-\$10,279	-\$13,180
Total net change to the MBS	-\$2,381	-\$4,884	-\$7,515	-\$10,279	-\$13,180

Source = Compiled during Critique from Table 18, p36 of the resubmission

HbA1c = glycated haemoglobin; MBS = Medicare Benefits Schedule; PATH = pathology laboratory testing; PoC = Point of Care

^a Based from MBS utilisation for 66551 (HbA1c pathology testing in management population) from 2013/14 to 2017/18

14. Key issues from ESC for MSAC

ESC key issue	ESC advice to MSAC
Including pregnant patients in the item descriptor	This is acceptable.
Should the item descriptor for the PoC machine refer to the National Glycohemoglobin Standardization Program (NGSP) standards and the coefficient of variance?	Yes, it is important that the most appropriate machines are used for PoC testing.
Are the RACGP standards acceptable for PoC testing?	The RACGP standards are acceptable; however, since they have only recently been released, further consultation will be helpful to see how they are being used.
Cost of accreditation	Resubmission now has \$240 per year for training, \$167 per year for accreditation (part of general costs, not included) and \$330 per year for quality assurance. The Critique estimated incremental costs over 3 years of – \$0.59 to –\$2.51.
Cost-minimisation analysis	From this cost-minimisation analysis, the PoC test would only be cheaper than the laboratory test if MSAC accepts the assumption that only one laboratory test per year is subject to coning.
MBS rebate (85% or 100%)	There will be cost saving to the budget of ~\$13,000 by 2022 if the 85% rebate is applied (broadly similar to resubmission’s original financial estimates using 100% rebate level) and MSAC accepts the assumption that only one laboratory test per year is subject to coning.
Restriction to testing three times per year	Compliance will be an issue.

ESC Discussion

ESC noted that this is a resubmission of Application 1431 requesting MBS listing of HbA1c point-of-care (PoC) testing as an alternative to HbA1c testing in an accredited pathology laboratory for the diagnosis and management of diabetes.

ESC recalled that when Application 1431 was first considered in July 2017, MSAC did not support public funding for HbA1c PoC tests for the diagnosis of diabetes based on insufficient evidence demonstrating accuracy in terms of analytical or clinical validity for diagnostic purposes. MSAC noted at the time that many clinicians would request a confirmatory HbA1c laboratory test as well as blood tests for other risk factors associated with diabetes.

MSAC noted that a resubmission for diagnosis of diabetes would need to be considered by ESC with new assay performance data to support a conclusion of improved accuracy.

ESC recalled that MSAC deferred its advice regarding funding for the monitoring of glycaemic management in patients with established diabetes. This was pending further data and advice on an accreditation framework, a reduction in or further justification of the proposed fee for HbA1c PoC testing compared to the laboratory test fee, and an updated economic evaluation. MSAC requested that the base-case of the revised economic analyses for management of diabetes should:

- be for management alone
- include reducing the HbA1c PoC test fee down to the laboratory test cost or below
- account for updated accreditation costs
- factor in a frequency of 3-monthly HbA1c PoC tests
- factor in alignment with laboratory tests conducted for patients on an annual basis.

ESC noted that the resubmission focused on a single patient population (i.e. the management of diabetes) in a fit-for-purpose report specifically addressing key areas outlined by MSAC. The key changes in this resubmission were:

- a revised item descriptor (see **Table 1**).
- an updated and more detailed accreditation standards framework
- revision of the cost of the test
- an updated economic model and cost-minimisation model, and updated assumptions
- updated budgetary impact modelling.

ESC noted that the resubmission's updated literature review did not identify any new evidence and the clinical claim remained unchanged from the original submission.

ESC noted that no evidence was presented in the original submission for the use of HbA1c PoC testing in pregnant women with established diabetes. However, ESC did not consider it problematic to include pregnant women in the revised descriptor, as this population could benefit from PoC testing.

ESC noted the statement in the resubmission that MSAC's concerns with the previous SBA (that proposed patients could receive four tests per year) indicated that this item descriptor is subject to episode coning. Episode coning occurs generally when more than three MBS item numbers are requested for a patient in the same day. This is usually via a comprehensive pathology assessment that is generally ordered for patients once every 12 months to assess other risk factors associated with the condition, such as kidney function tests, lipid levels and liver function tests. In such situations, Medicare only pays for the three most expensive items.

ESC noted that including a cap of three PoC tests per 12 months in the item descriptor will avoid duplication of HbA1c PoC testing and the HbA1c pathology test ordered within the routine yearly assessment.

ESC noted that limiting PoC testing to three times per year could result in a compliance issue. Currently, general practitioners (GP's) can try to claim for the test, only to be denied reimbursement because the patient has already been tested three times by other practitioners. Patients may not recall the previous tests or may not be forthcoming in sharing this information.

ESC noted that the definition of the proposed medical service remains unchanged from the original submission. The proposed item descriptor has been updated to incorporate a restriction based on the PoC test device meeting generally acceptable performance criteria (i.e. a National Glycohemoglobin Standardization Program (NGSP) manufacturer

certification and a total coefficient of variation (CV) <3.0% at 48 mmol/mol). ESC agreed with the Assessment Group that including the CV was a useful way to ensure that only suitable machines are used in this test, given the range of machines available on the market.

ESC noted that the Royal Australian College of General Practitioners (RACGP) PoC testing standards have recently been published; further consultation with the College will be required to see how these standards are working in practice. PoC accreditation will be conducted as part of overall GP accreditation as an optional module. ESC noted that the requirements of the current version of the RACGP PoC testing standards were compared with the National Pathology Accreditation Advisory Council (NPAAC) PoC testing guideline. Although the language, presentation and style are different between the two, the actual requirements are comparable and provide assurance of consistent quality.

ESC noted that the base-case result in the original submission showed HbA1c PoC testing to be dominant (i.e. more effective and less costly) than HbA1c pathology laboratory testing (ICER -\$31,747 per QALY gained). However, MSAC considered that there was uncertainty around the assumption that HbA1c PoC testing would lead to a reduction in GP visits. ESC recalled that the additional analysis of the economic model run by MSAC during its consideration of the original submission showed no differences in hospital and pharmaceutical costs based on the non-significant cost difference results from the PoC test GP trial.

ESC noted that MSAC requested the economic model in the original submission be updated to incorporate a reduced test fee. In response to MSAC's request, the economic evaluation has been amended in the resubmission to a cost-minimisation analysis. A cost-utility analysis was also presented as a sensitivity analysis, as PoC HbA1c testing has been proven to increase control of diabetes. Key changes to the model included:

- for the PoC testing arm, the number of tests per year was modified to align with the cap of three PoC tests per year in the updated proposed MBS item descriptor and included costs for a fourth HbA1c test taking place via pathology laboratory testing; as such, the 34% coning rate was applied to one HbA1c pathology laboratory test per year
- in the original submission, all pathology laboratory tests (MBS item 66551) were assumed to be subject to coning; however, in the resubmission it was assumed that only one of these tests per year was subject to coning, resulting in the MBS-listed price of \$16.80 reduced by 34% for one of the pathology laboratory tests of each model arm (per advice from the post-MSAC debrief in November 2017).
- costs associated with GP visits were removed as these were assumed to be neutral across both groups
- pharmaceutical- and hospital-related costs were removed.

The updated economic evaluation was simplified to two steps:

- Step 1 – a trial-based cost-minimisation model (i.e. derived from the PoC test GP trial results over 18 months) yielding an incremental cost
- Step 2 – a cost-minimisation model (i.e. derived from the PoC test GP trial results over 18 months and extrapolated to 3 years) yielding an incremental cost.

ESC confirmed that the cost-minimisation approach was appropriate, as requested by MSAC. ESC advised that, from this cost-minimisation analysis, the PoC test would only be cheaper than the laboratory test if MSAC accepts the assumption that only one laboratory test per year is subject to coning.

ESC recalled that MSAC suggested a reduced fee (or further justification of the proposed test fee compared to the laboratory test fee) be presented in the resubmission. In alignment with this recommendation, the new test cost was reduced to \$22.60, a \$0.20 saving compared to the current pathology laboratory testing fee (pathology test fee = \$22.80). ESC noted that the proposed fee was calculated based on the costs of meeting quality assurance (QA), training and accreditation requirements.

However, the Critique noted that although this might be appropriate, the majority of these costs were not evidence-based estimates (rather, based on assumptions, which could not be verified).

ESC noted the rationale used for estimating the updated test costs, as follows:

- it was assumed that GPs open 6 days a week rather than 5 days and would use the HbA1c PoC test once daily, thereby increasing the number of tests conducted per year to 312 in the resubmission (compared with 260 in previous SBA)
- the cost of the device was amended to be amortised over 5 years (i.e. \$600 annually) based on the real-world life cycle of the PoC testing machines
- training costs were reduced to \$240 (from \$280 in the previous SBA)
- QA program costs were reduced to \$330 (from \$420 in the previous SBA)
- cost of consumables per test was reduced to \$10 (from \$11 in previous SBA).

However, ESC noted that amortising the cost of the device over 5 years was not appropriate for the base-case economic evaluation as the full cost of the device would not be captured in the model's 3-year time horizon (which favoured HbA1c PoC testing). Amending the cost of the device to be amortised over 3 years (e.g. \$1,000 annually; same as previous SBA) resulted in \$1.28 higher HbA1c PoC test cost (\$23.88 vs proposed test cost of \$22.60).

ESC noted that the resubmission's economic evaluation showed that HbA1c PoC testing resulted in a cost saving of \$1.67 per person over the 3-year time horizon (relative to pathology laboratory testing). However, this cost saving is likely to be overestimated due to the model assumptions that excluded the full cost of the PoC machine and the volume assumption that GPs would work on average 6 days/week (312 tests/year). ESC noted that the sensitivity analysis showed that varying these cost inputs for PoC testing resulted in an additional cost of about \$9 to \$36 over the 3-year base-case model.

ESC noted that different percentages for the MBS rebate were used in the resubmission and the Critique. The resubmission used 100% for HbA1c testing (PoC and laboratory), compared with the Critique which used 100% for PoC (as PoC testing would typically be performed by a GP), and 85% for pathology laboratory testing (based on average MBS benefits paid from utilisation of item 66551 over 2013/14 to 2017/18). ESC considered the 85% rebate level to be appropriate for both PoC and pathology laboratory testing, resulting in cost savings to the MBS of approximately \$2,000 in Year 1, increasing to \$13,000 in Year 5 (similar to resubmission's original financial estimates).

ESC noted the uncertainty around utilisation of PoC testing. ESC considered that PoC testing is only of benefit if the patient needs immediate results and subsequent discussion (noting that the value of this cannot be underestimated). However, if the patient needs a number of blood tests and needs to come back to see their GP anyway, then the question remains as to whether PoC testing provides a benefit. From an economic perspective, the most expensive pathway would be for the GP to do the PoC test and then also request other tests from the pathology laboratory.

ESC noted the resubmission's claim that the average yearly cost of laboratory testing is \$21.37 per quarter with three tests unconed and one coned, and for PoC is \$21.22 per quarter with three PoC and one coned laboratory test. ESC noted that the current laboratory-based MBS item 66551 (i.e. HbA1c testing for the management of established diabetes) is routinely requested with items that have a higher schedule fee. As items that are subject to coning are funded as part of the fee for the third item, the true rates at which they are requested are unknown and therefore the true number of HbA1c tests are not reflected in the data. This means that predicted utilisation of HbA1c PoC will be underestimated.

ESC also noted that, in circumstances where HbA1c is tested by PoC instead of a pathology laboratory, it will not always amount to a saving in pathology laboratory testing costs equivalent to the fee for the HbA1c test. Coning arrangements will mean that where multiple items are requested, the HbA1c laboratory test will be substituted by another pathology test, which would result in little to no saving to the MBS.

ESC noted that PoC may also drive test utilisation by providing immediate access to the service for patients, which needs to be taken into account. ESC noted that Diabetes Australia would be likely to support this resubmission; however, they were not consulted because there was no PASC process for this application.

15. Other significant factors

Nil

16. Applicant's comments on MSAC's Public Summary Document – March 2019

We are happy that the MSAC is supportive of MBS listing of HbA1c PoC testing for the management and monitoring of established diabetes mellitus, including in pregnancy, on the basis of its ability to improve patient health outcomes and generate cost savings to the Government. We are however, concerned that timely access to this service will be compromised if the recommendation to await the outcomes of the NPAAC review and update of its 2015 *Guidelines for point of care testing* into accreditation standards is enforced, particularly given the RACGP have developed Standards for PoC testing which are current, are largely comparable with the NPAAC Guidelines, and provide assurance of consistent quality.

We note that the economic evaluation presented in the resubmission was a conservative cost-minimisation analysis. While the ESC noted that an amendment to the amortisation of the device cost across three rather than five years would lead to an increase in the proposed cost of PoC by \$1.28, this is not reflective of real-world practice. Anecdotal evidence suggests that there are PoC devices effectively used for five years and beyond, in which case the cost of PoC would be reduced further than that proposed in the submission.

17. Applicant's comments on MSAC's Public Summary Document – March 2020

Pathology Technology Australia Limited (PTA) welcomes the MSAC recommendation supporting the public funding for glycated haemoglobin (HbA1c) Point of Care (PoC) testing for the management of patients with diabetes mellitus.

The applicant has continually rejected the assertion by MSAC that there is no difference in healthcare outcomes between laboratory and PoC tests. The applicant has provided evidence

of studies performed internationally (which MSAC has not recognised) and in Australia by Laurence 2009 (which MSAC interprets differently).

The applicant does not agree with the notion that HbA1c testing at the POC will increase total tests. Data that we presented from the RACGP annual survey indicates that GPs see their diabetes patients less than twice per year on average. Studies in Europe have shown that HbA1c testing actually declines when POCT is introduced.

The applicant reject the assertion that POC HbA1c will significantly increase the cost of funding this service, based on the international and local evidence. Further, there is no consideration of healthcare equity and access for people who cannot easily access traditional pathology services.

The applicant wishes it be recognised that even without a proven causal link between the reduced hospitalisations and POC HbA1c testing, there is a plausible relationship that must be considered here. It is wrong, in our opinion, to dismiss this possibility out of hand and wrong not to include some measure of the reduced hospitalisation in the calculations.

The applicant has experience from the uptake of other POC tests to guide our expectations of a low initial uptake. The applicant has provided evidence from the QAAMS HbA1c program which has been established for 20 years and still has an extremely low uptake at around 2%. The applicant have also presented information on the most successful uptake of POCT, being POC INR, where the uptake is just over 10%. The barriers to entry are high, a reasonable reimbursement notwithstanding.

PTA considers the reimbursement of the item through the MBS should not be dependent on an NPAAC and NATA quality framework and audit process. PTA contends that while this framework may work in a small number of PoC settings, for the vast majority of settings the RACGP and AGPAL framework is fit for purpose and better matches the operational environment. PTA considers that without the RACGP and AGPAL quality framework option, there will be almost no uptake of PoC in general practice.

PTA considers the MSAC recommended reimbursement rate for HbA1c PoC testing to be too low and is likely to act as a disincentive to uptake, potentially negating any benefits the item is intended to deliver.

18. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)