



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1572 – Diagnosis of hypertension using ambulatory blood pressure monitoring in patients with clinic blood pressure \geq 140/90mmHg and \leq 180/110mmHg

Applicant: High Blood Pressure Research Council of Australia Inc.

Date of MSAC consideration: MSAC 78th Meeting, 3 April 2020

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

1. Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of ambulatory blood pressure monitoring (ABPM) for patients with a clinic blood pressure measure of \geq 140/90 mmHg and \leq 180/110 mmHg was received from the High Blood Pressure Research Council of Australia Inc by the Department of Health.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC supported MBS funding of diagnosis of hypertension using ambulatory blood pressure monitoring (ABPM) in patients with clinic blood pressure \geq 140/90 mmHg and \leq 180/110 mmHg on the basis that ABPM is the accepted gold standard for the diagnosis of high blood pressure in primary care. MSAC accepted that ABPM was cost-effective, but advised that the proposed fee should not include the cost of the consumables. MSAC was concerned with the potential for the proposed item to be used for monitoring purposes, and considered that this item be reviewed one year after listing to monitor utilisation and uptake. In addition, MSAC considered that implementation of the Extended Medicare Safety Net cap was appropriate for this item.

The MSAC-proposed descriptor was:

Category 2 – Diagnostic procedures and investigations – Group D1 – Miscellaneous Diagnostic Procedures and Investigations

Continuous ambulatory blood pressure recording for 24 or more hours (not in association with ambulatory ECG monitoring), with resting blood pressure and recording of parameters, using microprocessor-based analysis equipment, with interpretation and reporting of recordings by a medical practitioner, together with a treatment plan.

For a patient who has a clinic blood pressure measurement (CBPM) of systolic blood pressure between \geq 140 to \leq 180 mmHg, and/or diastolic blood pressure between 90 to \leq 110 mmHg., using a sphygmomanometer, and who has not yet commenced anti-hypertensive therapy.

Maximum one time per year

Consumer summary

The High Blood Pressure Research Council of Australia applied for public funding through the Medicare Benefits Schedule (MBS) to use ambulatory blood pressure monitoring (ABPM) to diagnose high blood pressure in certain people.

ABPM involves the person wearing a portable blood pressure measuring device usually for 24 hours. The device measures the person's blood pressure throughout the day and night. This is a more accurate way of measuring blood pressure than in a medical clinic, because it gives a range of reading over time and while people are doing different activities. It also allows for situations where a person is nervous about having their blood pressure measured, resulting in a misleading high blood pressure result.

ABPM is for people who have had their blood pressure measured in a medical clinic and the results are higher than 140/90 mmHg (millimetres of mercury, the measurement for blood pressure) and less than 180/110 mmHg. If a person's blood pressure is classified as high after wearing the ABPM device, it leads to a diagnosis of high blood pressure and the doctor and person can work out a treatment plan.

MSAC's advice to the Commonwealth Minister for Health

MSAC supported public funding for ABPM to diagnose high blood pressure. MSAC considered that ABPM is the gold standard for diagnosing high blood pressure, and that it is safe and good value for money (cost-effective) at the proposed MBS fee.

MSAC accepted that ABPM is used for diagnosing high blood pressure around the world and is the best available test (the "gold standard"). It is as safe and more effective than measuring blood pressure in a clinic. To encourage more doctors to use ABPM, MSAC recommended the cost of the equipment be covered by the MBS fee (except for the cost of the batteries needed to run the device). MSAC also recommended the Department and the applicant develop an education campaign for general practitioners (GPs) to help them understand how and when to use the device. MSAC decided to review the MBS item after 1 year to check whether GPs and specialists are using ABPM, and to review it again after another year to check that ABPM is only being used to diagnose high blood pressure and not for monitoring people who are already taking medication to treat high blood pressure.

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

MSAC noted this application for a Medicare Benefits Schedule (MBS) listing for diagnosis of hypertension using ambulatory blood pressure monitoring (ABPM) for adults with suspected hypertension; that is, those who have a clinic blood pressure measurement (CBPM) of $\geq 140/90$ mmHg and $\leq 180/110$ mmHg. MSAC noted the request that ABPM can be performed up to once every 12 months in people who have not commenced antihypertensive medication.

MSAC noted that the MSAC Executive had agreed that a full health technology assessment was not required, and instead requested the assessment group evaluate the National Institute for Health and Care Excellence (NICE) guidance from 2011 (relating to patient outcomes) and 2019 (relating to diagnostic accuracy) on clinical management of hypertension in adults, and focus on implementation issues for the Australian context.

MSAC noted the clinical need for ABPM, and accepted that ABPM is as safe and more effective than CBPM or home blood pressure monitoring (HBPM), noting that NICE guidance from 2019 on diagnostic accuracy used ABPM as the reference standard, and recommended that ABPM is used to confirm a diagnosis of hypertension after a CBPM of $\geq 140/90$ mmHg. MSAC accepted the economic evaluation that showed that ABPM is dominant (less costly and more effective) compared with CBPM and HBPM with an incremental cost-effectiveness ratio (ICER) that was robust in sensitivity analyses.

MSAC agreed it was appropriate for the proposed item descriptor to be silent on age. Although MSAC noted the population in the NICE assessments did not include patients younger than 18 years of age, MSAC considered that there was no reason to exclude adolescents from having access to this test, under the assumption that diagnostic accuracy is likely to be equivalent to that in adults. MSAC further agreed the device would be unlikely to be used in young children. MSAC noted this may lead to a small increase in utilisation.

MSAC advised the proposed item descriptor “for a patient who has a CBPM of systolic blood pressure between ≥ 140 to ≤ 180 mmHg, *and* diastolic blood pressure between 90 to ≤ 110 mmHg”, should be changed to “for a patient who has a clinic blood pressure measurement (CBPM) of systolic blood pressure between ≥ 140 to ≤ 180 mmHg, *and/or* diastolic blood pressure between 90 to ≤ 110 mmHg. This would ensure that people who are in the correct range for diastolic but not systolic, and vice versa, would not be excluded.

MSAC noted the Department’s advice that that the “medical practitioner” referred to in the proposed item descriptor includes any medical practitioner, not only general practitioners (GPs), MSAC also noted the applicant’s comments that a qualified person could perform part of the service under the supervision of the medical practitioner, and advised the Department deal with this issue in the same manner as for other similar MBS subsidised services.

MSAC discussed whether the item descriptor should incorporate preparation of a treatment plan. On the one hand, two MBS items could be established – one covering the test and report (with a reduced fee), and a separate one for the treatment plan (or this could use existing item 229) – which would allow GPs to refer patients to a cardiologist or other specialist to perform the test. On the other hand, encouraging GPs to perform the test and integrate the results into a treatment plan appropriately keeps the diagnosis and initial management of hypertension in primary practice. It also better supports the proposed costings in the application, which include an amount for the treatment plan (rather than revising costs for a test-only item number), thus supporting GPs to perform a sufficient number of services each year to cover the cost of the equipment. Overall, MSAC considered that GPs should be encouraged to perform ABPM in their practice, and advised that “together with a treatment plan” should remain in the item descriptor. MSAC therefore considered that basing the fee for this part of the service on item 229 was appropriate.

However, MSAC advised that a restriction should be added to prevent co-claiming with other treatment plans. MSAC also considered that an Extended Medicare Safety Net cap was appropriate for this item.

MSAC noted the proposed MBS fee for ABPM includes amounts for the cost of the equipment (on a pro-rata basis of \$10 per patient), and consumables (batteries at \$2 per patient). MSAC noted the Department’s advice that, with the exception of items on the pathology list, it is not usual practice to include the cost of equipment or consumables in the MBS item fee.

However, the applicant asserted in the pre-MSAC response that not including these costs in the fee would be a disincentive for medical practitioners, which could adversely affect uptake. The applicant also asserted that there is precedent for including consumables in the fee. After considering this issue, MSAC recommended the Minister include an amount towards the cost of the equipment in the MBS fee to encourage uptake, but not an amount towards the cost of consumables (batteries).

MSAC noted the financial analysis for ABPM looked at overall costs to the MBS (Table 7) of introducing an ABPM item (Table 7) taking into account the additional cost of the ABPM service and the reduction in costs of other services (both directly substituted diagnostic services and down-stream costs, for example, for cardiovascular events avoided). MSAC noted that when the cost of consumables is removed from the financial estimates, the inclusion of ABPM on the MBS is estimated to deliver a saving of \$4.7 million to the MBS over 5 years (see Table 7, *MSAC values*).

MSAC further noted that the inclusion of ABPM on the MBS is estimated to have cost consequences for the PBS and for hospitals (Table 8). An additional cost to the PBS of \$11 million over 5 years is estimated to result from more patients being diagnosed with hypertension and accessing PBS anti-hypertensive medicines. A small saving to hospitals arises because of some downstream cardiovascular events avoided, although MSAC noted this was small over the 5-year estimates. MSAC noted the overall cost to the health system of implementing ABPM (without including a cost for consumables) is \$6.3 million over 5 years (see Table 9, *MSAC values*).

MSAC noted that these financial estimates depend on optimistic assumptions about the uptake of ABPM in the first years after it is made available on the MBS. If those estimates of uptake are not realised in practice, then the overall cost to health systems over 5 years will likely be less.

MSAC considered that education for GPs would be important for implementation, and suggested that the Department work with the applicant to develop an education campaign relating to this item. MSAC also advised that utilisation of the item should be reviewed after one year and after two years. Reviewing after one year will allow assessment of whether the majority of services are being performed by GPs; if not, the GP education campaign could be revised or reinvigorated, or the item and fee could be revised to cover the diagnostic test only. Reviewing after 2 years will allow utilisation to be analysed in association with Pharmaceutical Benefits Scheme (PBS) data. This will enable monitoring of leakage to patients who are already receiving antihypertensive medication – that is, to evaluate whether the test is being used for monitoring rather than diagnosis. Including “once per year” in the item descriptor will also help minimise leakage.

4. Background

This is the first submission (Department-contracted assessment report [DCAR]) for ABPM for patients with a clinic blood pressure measure of $\geq 140/90$ mmHg and $\leq 180/110$ mmHg. MSAC has not previously considered this application.

MSAC Executive advised that “.. a full HTA [health technology assessment] is not necessary. The MSAC Executive advised that the HTA group should critique the existing National Institute for Health and Care Excellence (NICE) health technology assessment report for Ambulatory Blood Pressure Monitoring for relevance to the Australian population and develop an assessment report focussed primarily on implementation issues such as the

potential utilisation, the fee, financial impact, appropriateness of use and potential for leakage to use for monitoring”.

The DCAR stated for clarity, NICE has published a full guideline in August 2019. Owing to the specific review question and outcomes outlined in the confirmed PICO, the NICE 2019 full guideline (NICE, 2019c) and NICE 2011 full guideline (NICE, 2011) have been used in this DCAR.

5. Prerequisites to implementation of any funding advice

The DCAR provided the Australian Register of Therapeutic Goods details in Table 1. The DCAR did not provide any detail if there is a quality assurance program for the proposed test.

Table 1: Current ABPM available in Australia

Sponsor	Manufacturer	ARTG ID number
HealthStats Australia	HealthSTATS International Pte Ltd	221446
Atcor Medical Pty Ltd	SunTech Medical Inc	234055
Australian Sales and Trade Services (ASTS)	Andon Health Co Ltd	217021
Core Diagnostics Pty Ltd	DM Systems (Beijing) Co Limited	285458
Ecomed Pty Ltd	Statcorp Incorporated	198318
Cellmed Pty Ltd	SunTech Medical Inc	310020
Welch Allyn Australia Pty Limited	IEM GmbH Industrielle Entwicklung Medizintechnik und Vertriebsgesellschaft mbH	311921
Cardioscan Services Pty Ltd	IEM GmbH Industrielle Entwicklung Medizintechnik und Vertriebsgesellschaft mbH	227055
GE Healthcare Australia Pty Ltd	GE Medical Systems Information Technologies	134874
InMed Healthcare Pty Ltd	Meditech KFT	147014

Source: Table 11, p36 of the DCAR

6. Proposal for public funding

The applicant has proposed one new MBS item (Table 2) to cover the post-ABPM consultation service. This period would involve the medical practitioner creating a report (by downloading data from the ABPM device), reviewing and interpreting the report, and developing a patient management plan. The frequency of testing proposed is maximum one time per year.

Table 2: Proposed MBS item descriptor (fee corrected by DCAR in their Rejoinder- now incorporating MBS indexing, post PICO)

Category 2 – Diagnostic procedures and investigations – Group D1 – Miscellaneous Diagnostic Procedures and Investigations
Continuous blood pressure recording of ambulatory adult patient for 24 or more hours (not in association with ambulatory ECG monitoring), with resting blood pressure and recording of parameters, using microprocessor-based analysis equipment, with interpretation and reporting of recordings by a medical practitioner, together with a treatment plan. For a patient who has a clinic blood pressure measurement (CBPM) of: systolic blood pressure between ≥ 140 to ≤ 180 mmHg, and diastolic blood pressure between 90 to ≤ 110 mmHg, using a sphygmomanometer, and who has not yet commenced anti-hypertensive therapy. Maximum one time per year MBS Fee: \$107.60

Source: Table 1, p13 of the DCAR

The estimated fee as provided in the PICO and used in the economic model is the average fee based on the two costing two scenarios (costing scenario 1: based on MBS item 36 and costing scenario 2: based on MBS item 229) provided below. The DCAR noted in their Rejoinder, that since the ratified PICO (\$106.10), the proposed fee has increased to \$107.60 due to indexing of MBS fees (e.g. MBS items 36, 229).

Costing Scenario One (based on MBS Item 36):

Medical practitioner creation of report: 5 minutes*
Medical practitioner review and interpretation of report: 10 minutes*
Medical practitioner preparation of a management plan for the patient: 10 minutes*
MBS Fee = \$73.95 MBS Benefit: 100% = \$73.95 (based on MBS Item 36)

Cost of ambulatory blood pressure monitor: \$2,500 with a five-year life

- \$10.00 per patient (based on 50 patients per year)

Consumables: Two AA batteries per patient (\$2.00)

Total Fee = \$85.95

Costing Scenario Two (based on MBS Item 229):

Attendance by a medical practitioner, for preparation of a GP management plan for a patient (other than a service associated with a service to which any of items 735 to 758 and items 235 to 240 apply)

MBS Fee = \$117.25 Benefit: 75% = \$87.95 (admitted patient) 100% = \$117.25 (GP outpatient)

(See para AN.7.1, AN.7.17 of explanatory notes to this Category)

Cost of ambulatory blood pressure monitor: \$2,500 with a five-year life

- \$10.00 per patient (based on 50 patients per year)

Consumables: Two AA batteries per patient (\$2.00)

Total Fee = \$129.25

AVERAGE FEE = \$107.6

Justification by the applicant for including equipment costs in this service

The applicant stated that ABPM monitors are not currently owned by many medical practitioners, so they cannot offer this service to patients. The amount requested per service (\$10 for the monitor and \$2 for the batteries) represents the incremental cost of providing this equipment over the useful life of the device (5 years). The return on investment (ROI) for these devices is effectively zero if the devices are reimbursed at \$12 per measurement, with the ROI for these devices becoming negative if the cost of the device is not covered by the service fee. This would mean medical practitioners would need to subsidise the cost of these monitors, using revenue from other services. The cost of the monitor is not insignificant (\$2,500), and accelerated depreciation will not convince medical practitioners to purchase these devices if there is no fee for provision of these devices.

In their pre-MSAC response, the applicant stated that inclusion of an allowance for the equipment/consumables/disposables used is standard for diagnostic / pathology services on the MBS. This is not the case for therapeutic services since the cost of equipment/consumables/disposables for these services is covered by theatre banding /episodic payments.

In addition, the applicant stated that if the cost of the monitor and batteries were not included as part of the MBS Fee, the medical practitioner would need to charge the patient a co-payment.

Justification for a new item, as opposed to using current MBS items

The applicant believes a new item number is needed because:

1. Long consultation items on the MBS involving developing patient management plans currently refer to terminal diseases or other diseases such as diabetes. Hypertension is not terminal as it can be reversed with lifestyle measures and medication.
2. Other long consultation item numbers on the MBS do not include an allowance for the provision of ABPM monitors.
3. Without a specific item number referring to ABPM for the measurement of patients with clinic systolic blood pressure between ≥ 140 to ≤ 180 mmHg, and diastolic blood pressure between 90 to ≤ 110 mmHg, the MBS could be billed for long consultations for all patients regardless of their clinic BP.

Pre-MSAC response

The applicant stated that with the majority of patients requiring ABPM after their medical practitioner has used the standard blood pressure test, the medical practitioner or a qualified person under his/her supervision will fit the monitor onto the patient and explain how it is to be worn. The patient will return to the medical practitioner the next day with the data from the monitor being downloaded and interpreted by the medical practitioner. The medical practitioner will then put together a management plan (if required). The sponsor believes that the detailed wording of the proposed MBS Item makes this pathway very clear.

The applicant also noted that if MBS item 721 was more appropriate, this would raise the proposed fee for ABPM to \$122.25.

In addition, the applicant considered that the restrictions included proposed MBS item descriptor should be sufficient to limit leakage.

7. Summary of public consultation feedback/consumer Issues

The Department received 11 responses from researchers, hypertension specialists and general practitioners. All the comments received were positive, supporting the use of ABPM for diagnosing hypertension in the pre-specified patient population.

8. Proposed intervention's place in clinical management

Description of Proposed Intervention

ABPM involves the patient wearing a portable blood pressure (BP) measuring device for a specified period (usually for 24 hours), during which periodic BP measurements (usually every 15 to 30 minutes during the day and every 30 to 60 minutes during the night) are automatically taken via a cuff or sensor worn on the upper arm. ABPM systems provide measures of systolic, diastolic and mean BP as well as heart rate, during the daytime, night time, and sleep and awake (National Heart Foundation and High Blood Pressure Research Council of Australia Ambulatory Blood Pressure Monitoring Consensus Committee, 2011).

Description of Medical Condition(s)

The patient population for whom public funding of the proposed medical service is intended includes adult patients ≥ 18 years old with suspected hypertension, who have a clinic blood pressure measurement (CBPM) of: systolic blood pressure between ≥ 140 to ≤ 180 mmHg, and diastolic blood pressure between 90 to ≤ 110 mmHg, using a sphygmomanometer, and who has not yet commenced anti-hypertensive therapy. Those with a confirmed diagnosis of

hypertension based on an ABPM measurement in the last 12 months are excluded from the population for this assessment.

Place in clinical management

The DCAR stated that the current and proposed algorithm in is in line with the Australian guidelines and criteria for diagnosis of hypertension. ABPM is performed after initial clinic visit and as an alternative to repeat CBPM and HBPM (Figure 1). The treatments provided following diagnosis of grade 1 (systolic BP: 140 to 159 mmHg); or grade 2 (systolic BP:160 to 179 mmHg) hypertension are a simplification of the treatment guidance, based on discussions with the Department of Health and the applicant.

Once the diagnosis of hypertension with ABPM has been confirmed, a patient management plan to decrease blood pressure will be developed, which may include blood pressure lowering medication. While hypertension can be a lifelong disease, lifestyle modification (such as weight loss, exercise and healthy eating) can reduce blood pressure in hypertensive patients. Therefore, the DCAR stated that re-testing a patient with clinic-measured systolic blood pressure between ≥ 140 to ≤ 180 mmHg, and diastolic blood pressure between 90 to ≤ 110 mmHg (measured in the clinic), followed by ABPM to confirm the diagnosis of hypertension (and re-calibrate the patient management plan once per year) would be prudent.

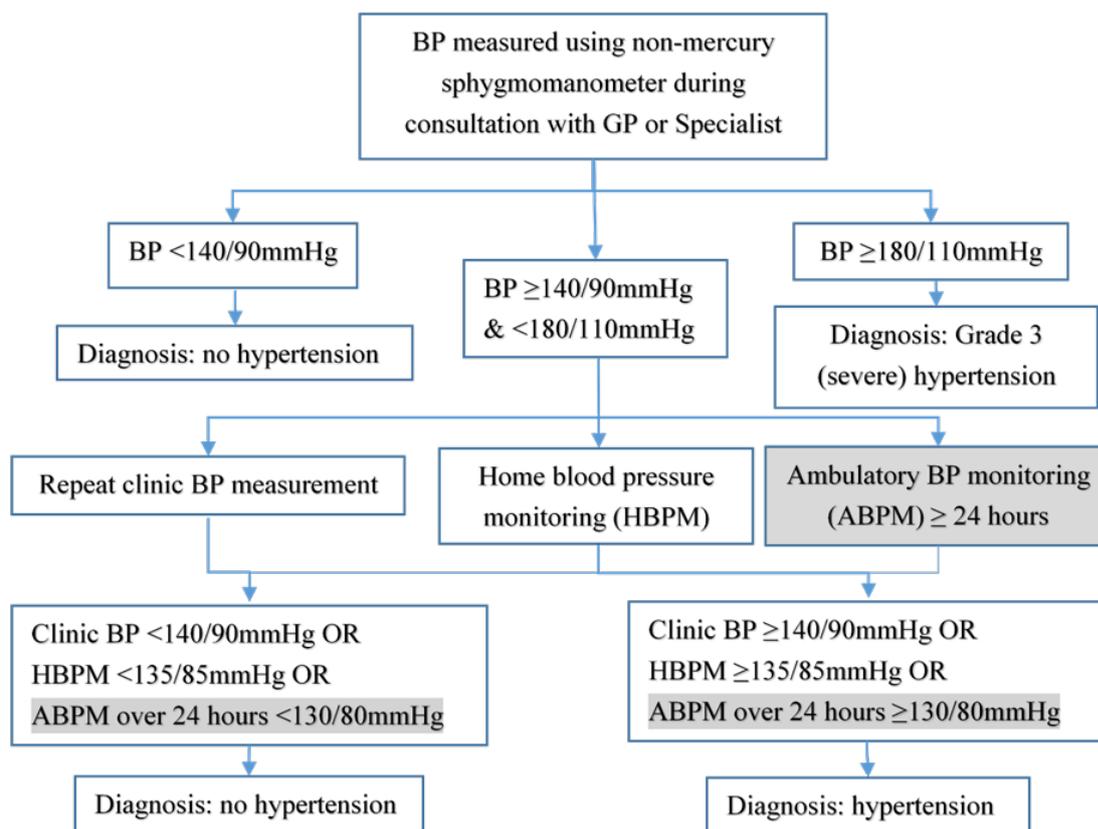


Figure 1: Clinical management algorithm for ambulatory blood pressure monitoring after clinic blood monitoring in the clinic (by GP or specialist). Shaded text refers to the proposed medical service

Source: Figure 2, p44 of DCAR

9. Comparator

The comparator(s) described in the confirmed PICO include:

1. Repeat CBPM using a validated and regularly maintained non-mercury sphygmomanometer, taken during a consultation at the doctor's office (e.g. MBS item 23) or in the patient's home (with a medical practitioner)
2. Home blood pressure monitoring (HBPM): Multiple non-ambulatory blood pressure measurements taken using a validated and automated device by the patient in their home (usually over a period of 1 week).

The DCAR stated that CBPM is known to give misleading results in the case of white-coat hypertension, so the current Australian guidelines for diagnosing hypertension recommends either ABPM and/or HBPM should be offered if CBPM $\geq 140/90$ mmHg (Gabb, 2016). Australian guidance also notes that HBPM and ABPM can be considered to provide complementary information (National Heart Foundation of Australia, 2016).

As the comparator:

CBPM: if three standard GP consultations are required to confirm the diagnosis of high blood pressure using clinic blood pressure, the cost of these consultations would be \$38.20 (MBS Item 23) *3 = **\$114.60**

HBPM: for an individual undergoing HBPM, it is assumed that two GP consultations following initial suspected hypertension will be applicable, and that the diagnosis will take one week to be completed with HBPM. The UK NICE guideline (National Clinical Guideline Centre UK, 2011) adopted a similar approach and it is assumed to be relevant in the Australian healthcare setting. Hence the estimated overall cost of diagnosis with HBPM would be: MBS fee = \$38.20 (MBS item number 23) Benefit: 100% = \$38.20
Total fee = \$38.20 * 2 = \$76.40

10. Comparative safety

Overall, the NICE 2019 and 2011 guidelines did not report any adverse events related to using ABPM. In addition, the included studies forming the systematic review did not report on these outcomes.

11. Comparative effectiveness

Patient outcomes (NICE 2011 guideline)

The systematic review underlying the evidence statements for cardiovascular outcomes was based on an updated search of the evidence from 2003 to 29 November 2011 in the NICE 2011 guideline. The guideline included evidence from three pooled analyses and eight cohort studies. The three pooled analyses (of cohort studies) and six cohort studies, involving 33,158 individuals, contributed data towards the comparison of ABPM vs. CBPM, while two cohort studies, involving 2,442 individuals, contributed data to HBPM vs. ABPM vs. CBPM.

The DCAR stated that of the 11 studies or pooled analyses in the NICE 2011 guideline (NICE, 2011), the population in 10 studies contained people who were on anti-hypertensive medications and in one study included people who were not on medication or had stopped one week prior to study entry. The proportion of the population medicated ranged from 9% to 61.9% in the 10 studies. The studies adjusted analysis based on anti-hypertensive therapy and other risk factors; however, results remained similar between adjusted or unadjusted values in the included studies. The applicant in their pre-ESC response considered this result to be important.

The DCAR also stated that nine of the 11 cohort studies or pooled analyses collected ABPM for 24 hours while two studies collected and reported daytime ABPM measures only. In terms of reporting of ABPM results, all studies that collected 24-hour ABPM measures reported data as daytime, night-time and 24-hour measures except for one study that reported daytime and night-time ABPM but not 24-hour values. The outcomes reported included cardiovascular morbidity (one study), all-cause mortality (six studies), cardiovascular mortality (five studies), major cardiovascular events (five studies), congestive heart disease (two studies), stroke (one study) and coronary events (one study). The median follow-up for assessing cardiovascular and survival outcomes ranged from 6.8 years to 10.9 years.

The DCAR stated that as the eligibility criteria of the NICE (2011) review question was closely aligned to the confirmed PICO, the findings of the NICE evidence review are probably generalisable to the Australian context.

The DCAR stated that the NICE 2011 guideline was deemed to be high quality, based on the modified AGREE tool, given the time point at which the guideline was developed. The risk of bias assessment, based on the ROBIS tool, for the systematic review underpinning the evidence statements was assessed to be at low risk of bias.

Based on the NICE 2011 guideline, for the comparison of ABPM vs. CBPM:

- **ABPM was superior to CBPM at predicting clinical events (based on eight studies involving 23,265 individuals);** however,
- **There was no difference between ABPM and CBPM in one study (based on a pooled analysis involving 5,682 individuals).**

Based on the NICE 2011 guideline, for the comparison of ABPM vs. HBPM:

- **HBPM was similar to ABPM, and both were superior to CBPM (based on one study involving 391 individual);** however,
- **There was no difference between HBPM, ABPM and CBPM in one study (based on one study involving 2,051 individuals)**

Clinical claim

Based on the NICE 2011 clinical statements, the DCAR suggested that ABPM is superior to CBPM for predicting cardiovascular outcomes, and ABPM or HBPM is a better predictor of cardiovascular outcomes compared to CBPM, but ABPM provided the most robust evidence thus far.

Diagnostic accuracy outcomes (NICE 2019 guideline)

The systematic review underlying the recommendations compared HBPM and CBPM to the reference standard of ABPM and included evidence from 2000 to October 2018 in the NICE 2019 guideline. The guideline included evidence from 13 studies; 11 of these were cross-sectional studies, one study was a retrospective analysis of a database and one study was a randomised cross-over study. Five studies, involving 2366 people, examined repeat CBPM against the reference standard ABPM and ten studies, involving 1914 people, examined HBPM compared to the reference standard, ABPM. Two studies contributed to both comparisons.

The DCAR stated that the pre-specified population in the NICE review was ‘suspected hypertension’ however in some of the included studies it was unclear whether individuals were already diagnosed with hypertension (in seven studies), may have been on anti-hypertensive medication during the study (3 studies; in one study 14% of the population were on treatment) or had been on anti-hypertensive medication up to four weeks prior to the study

(1 study). Most of the studies specified an eligibility criteria of ≥ 140 mmHg systolic and/or ≥ 90 mmHg diastolic with the exception of two studies (Mutlu et al., 2016; Ozdemir et al., 2000).

The confirmed PICO asked for data relating to ≥ 24 -hour ABPM and five of the 13 studies reported the analysis as per 24-hour ABPM measures. The other eight studies reported daytime averages of ABPM.

The DCAR stated that based on a modified AGREE II tool, the methodological quality of the NICE guideline was considered as high quality. The risk of bias assessment, based on the ROBIS tool, for the systematic review underpinning the evidence statements was assessed to be at low risk of bias.

CBPM vs. ABPM (reference standard)

Overall, four studies contributed data for the comparison of CBPM vs. ABPM. The DCAR stated that very low quality evidence from three studies (n = 1,250) showed that CBPM has a specificity of 76% and a sensitivity of 81% at a diagnostic threshold of $\geq 140/90$ mmHg, which did not meet the pre-specified threshold of 80% specificity set by the committee for possible recommendation. The certainty of evidence using the GRADE approach for CBPM (with differing days for BP readings, Gill et al., 2017) compared to the reference standard ABPM are presented in Table 3.

Clinical claim

Based on the NICE 2019 guideline, the evidence supports the clinical claim that CBPM is inferior in diagnostic accuracy to ABPM where ABPM is widely accepted to be the reference standard.

Table 3: Summary of findings for the accuracy of CBPM, relative to ABPM, in individuals with suspected hypertension

Index test (threshold)	Participants	Specificity % (95% CI)	Sensitivity % (95% CI)	Quality of evidence ^a	Comments
CBPM					
CBPM ($\geq 140/90$ mmHg)	1250 (3 studies)	76 (20 to 98)	81 (47 to 95)	⊕⊖⊖⊖	Due to serious risk of bias, very serious imprecision, serious inconsistency, serious indirectness
CBPM ($\geq 140/90$ mmHg using 2 nd and 3 rd readings over 3 days)	340 (1 study)	89.3 (83.8 to 93.4)	41.4 (33.7 to 49.4)	⊕⊕⊖⊖	Due to serious risk of bias, serious indirectness
CBPM ($\geq 140/85$ mmHg using 2 nd to 6 th readings over 3 days)	340 (1 study)	78.7 (71.9 to 84.4)	61.1 (53.1 to 68.7)	⊕⊕⊖⊖	Due to serious risk of bias, serious indirectness
CBPM ($\geq 140/90$ mmHg using 1 st reading on day 1 only)	203 (1 study)	59 (51.4 to 66.3)	44.4 (36.6 to 52.4)	⊕⊕⊖⊖	Due to serious risk of bias, serious indirectness

^a GRADE Working Group grades of evidence (Guyatt et al., 2013)

Source: data compiled from Table 4 (NICE 2019 evidence review)

⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimate of effect.

⊕⊕⊕⊖ **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

⊕⊕⊖⊖ **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

⊕⊖⊖⊖ **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

HBPM vs. ABPM

The DCAR stated that very low quality evidence from four studies (n=963) showed that HBPM without telemonitoring has a specificity of 84% and a sensitivity of 90% at a diagnostic threshold of $\geq 135/85$ mmHg, which met the pre-specified threshold of 80% specificity set by the NICE committee for possible recommendation. The certainty of evidence relating to HBPM (and multiple thresholds, including with or without telemonitoring) vs. ABPM are presented in Table 4.

Based on the NICE 2019 guideline, NICE recommended that to confirm the diagnosis of hypertension with a prior test in clinic of $\geq 140/90$ mmHg, ABPM should be used (preferably a daytime average) with the blood pressure threshold being $\geq 135/85$ mmHg. If ABPM is intolerable or unsuitable, based on the recommendations by NICE, offer HBPM to confirm diagnosis of hypertension ($\geq 135/85$ mmHg).

Table 4: Summary of findings for the accuracy of HBPM, relative to ABPM, in individuals with suspected hypertension

Index test (threshold)	Participants	Specificity % (95% CI)	Sensitivity % (95% CI)	Quality of evidence ^a	Comments
HBPM without telemonitoring					
HBPM ($\geq 135/85$ mmHg)	963 (4 studies)	84 (53 to 96)	90 (68 to 98)	⊕⊖⊖⊖	Due to very serious risk of bias, serious indirectness, serious imprecision
HBPM ($\geq 135/85$ mmHg)	340 (1 study)	62.4 (54.8 to 69.5)	84 (77.4 to 89.2)	⊕⊕⊖⊖	Due to serious risk of bias, serious indirectness
HBPM ($\geq 130/85$ mmHg)	203 (1 study)	81 (74 to 85)	71 (56 to 83)	⊕⊖⊖⊖	Due to very serious risk of bias, serious indirectness
HBPM ($\geq 135/80$ mmHg)	203 (1 study)	90 (85 to 94)	63 (48 to 76)	⊕⊖⊖⊖	Due to very serious risk of bias, serious indirectness
HBPM with wrist cuff ($\geq 135/85$ mmHg)	47 (1 study)	70 (45 to 84)	100 (82 to 100)	⊕⊕⊕⊖	Due to serious risk of bias
HBPM with wrist cuff & sensor ($\geq 135/85$ mmHg)	43 (1 study)	76 (47 to 87)	100 (83 to 100)	⊕⊕⊕⊖	Due to serious risk of bias
HBPM with telemonitoring					
HBPM (2 studies $\geq 135/85$ mmHg; 1 study ≥ 135 mmHg)	539 (3 studies)	63 (20 to 93)	80 (25 to 98)	⊕⊖⊖⊖	Due to serious risk of bias, very serious imprecision, serious inconsistency, serious indirectness

^a GRADE Working Group grades of evidence (Guyatt et al., 2013)

Source: data compiled from Table 4 (NICE 2019 evidence review)

⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimate of effect.

⊕⊕⊕⊖ **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

⊕⊕⊖⊖ **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

⊕⊖⊖⊖ **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

12. Economic evaluation

The DCAR stated the scope of this assessment was to critique the UK NICE guidance for ABPM and develop a relevant economic model and financial impact model to the Australian setting.

The DCAR stated that the population included in the UK NICE guideline were found to be representative of the patients who would be eligible to receive ABPM after the initial

suspected hypertension; however, noted some inputs to have applicability issues (diagnostic accuracy, probabilities of cardiovascular disease (CVD), distribution of coronary heart disease and stroke events, relative risk of the anti-hypertensive medications, standardised mortality ratios for CVD events, the cost parameters used in the UK NICE report and the transformation of utilities specific to each CVD event in the model.

The DCAR's cost-utility analysis informed by the Appendix J of UK NICE 2011 along with relevant Australian costs, and where available, other Australian relevant parameters is summarised in Table 5.

Table 5: Summary of the economic evaluation

Perspective	Australian healthcare system
Comparator	Clinical blood pressure monitoring (CBPM) and Home blood pressure monitoring (HBPM)
Type of economic evaluation	Cost-utility analysis (CUA)
Sources of evidence	Economic model in the UK NICE Hypertension guideline and published literature
Time horizon	Life-time (260 cycles for a starting age of 35 years)
Outcomes	LYG and QALYs gained
Methods used to generate results	Decision analytic Markov model
Health states	Condition positive, Condition negative, Non-fatal SA, Non-fatal UA, Non-fatal MI, Non-fatal TIA, Non-fatal Stroke, Post non-fatal SA, Post non-fatal UA, Post non-fatal MI, Post non-fatal TIA, Post non-fatal Stroke, Hypertension, Dead
Cycle length	3 months
Discount rate	5% annual, per cycle discount rate of 1.25%
Software packages used	TreeAge Pro 2019 (Full version), 19.2.1-v20190821

Source: Table 4, p22 of DCAR

LYG=Life-years gained; QALYs=Quality adjusted life years; SA=Stable angina; UA=Unstable angina; MI=Myocardial infarction; TIA=Transient ischaemic attack

The DCAR stated that most assumptions made in the UK NICE 2011 guideline were considered reasonable and adopted in this model for the Australian setting. It was assumed:

- that people with hypertension will have a higher risk of cardiovascular events than people without hypertension;
- once a diagnosis of hypertension has been made (true positives and false positives), individuals receive treatment with anti-hypertensive medications;
- only people who are truly hypertensive (true positives) receive benefit in terms of cardiovascular risk reduction due to treatment and the false positives receiving unnecessary anti-hypertensive treatment would have risk similar to that of the general population;
- individuals who are normotensive but are treated (false positives) do not receive any health benefits;
- people who are truly normotensive at entry to the model may develop hypertension over time; and
- people who have had a cardiovascular event experienced reduced quality of life and have an increased risk of death.

However, the DCAR did deviate from the UK NICE guideline 2011 for the following assumptions associated with the model structure:

- Modelled true negative individuals can move to the hypertensive state in any cycle based on the risk of hypertension and at this stage they would be suspected as hypertensive again with CBPM and will receive confirmed diagnosis (i.e. true

positive) with the test used previously and move to the hypertension health state. This is a conservative assumption as these individuals might still receive an incorrect diagnosis especially if the previous test used were CBPM and HBPM;

- Modelled false negative individuals were assumed that their hypertensive status could be detected (with CBPM and diagnostic test used previously) within the same cycle based on an assumed probability of 10% in the base case. These patients would receive confirmed diagnosis (i.e. true positive) and move to hypertension health state. This approach was adopted to avoid complexity in the model structure on reintroducing false negative patients after some years (as per the UK assumption they were reintroduced after 5 years). An assumption of a retest probability of 10% was tested in the sensitivity analysis; and
- Failure rate of 5% associated with ABPM and HBPM from UK model was not included in DCAR’s model, as they stated it uncertain how a diagnostic test failure would be actioned by the clinician.

The overall costs and outcomes, and incremental costs and outcomes as calculated for the testing strategy and comparative testing strategy in the model, and using the base case assumptions, are shown in Table 6.

Table 6: Base case incremental costs and effectiveness (QALYs) of ABPM vs HBPM and ABPM vs CBPM

	Cost	Incremental cost	Effectiveness (QALYs)	Incremental effectiveness	ICER
ABPM	\$7600	-	12.94	0.02 vs. HBPM 0.02 vs. CBPM	Dominant (less costly, more effective)
HBPM	\$8725	\$1125	12.92	-	Dominated (more expensive, less effective)
CBPM	\$9264	\$1665	12.92	-	Dominated (more expensive, less effective)

ABPM=Ambulatory blood pressure monitoring; HBPM=Home blood pressure monitoring; CBPM=Clinical blood pressure monitoring; QALYs=Quality adjusted life-years; ICER = Incremental Cost Effectiveness Ratio

The DCAR stated that the modelled results were most sensitive to utility gains amongst normotensive patients (i.e. true negative patients) and the utility accrued by patients treated with hypertensive medications (Figure 21 and Figure 22 in both the ABPM vs. HBPM model and the ABPM vs. CBPM model). In every scenario tested (with the exception of the utility value for normative patients at 55 years), ABPM remained cost-effective.

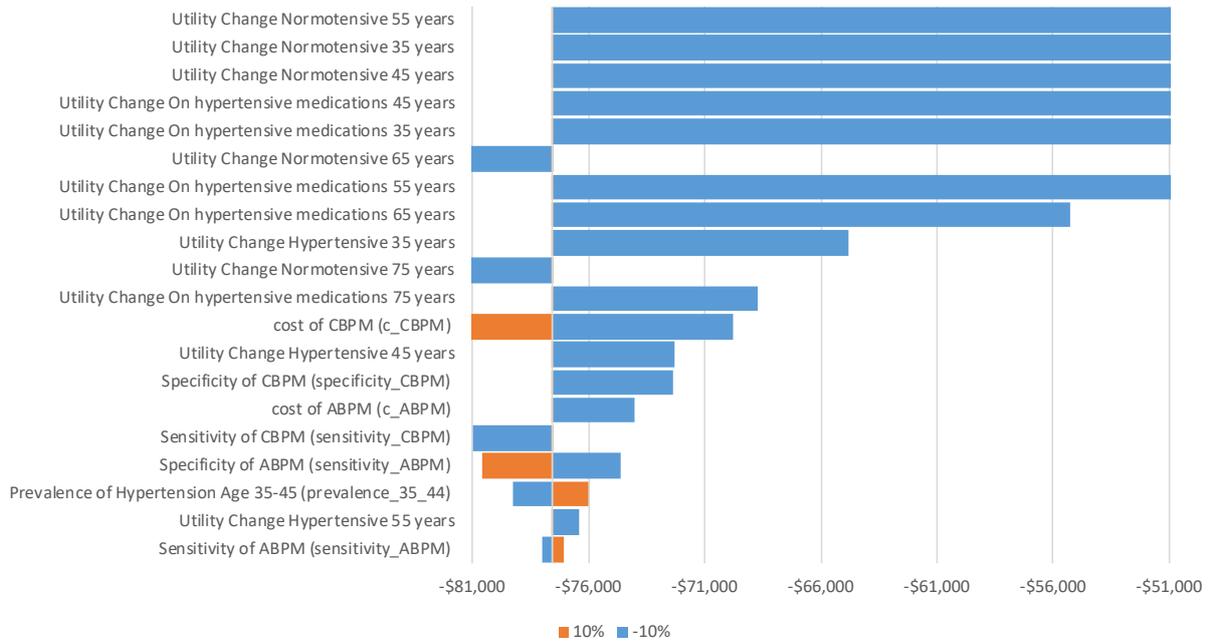


Figure 2: Tornado diagram of main drivers of economic model – ABPM v HBPM

Source: Figure 21, p133 of the DCAR

*axis has been shortened. A more accurate identification of the change in ICER is shown in Table 45

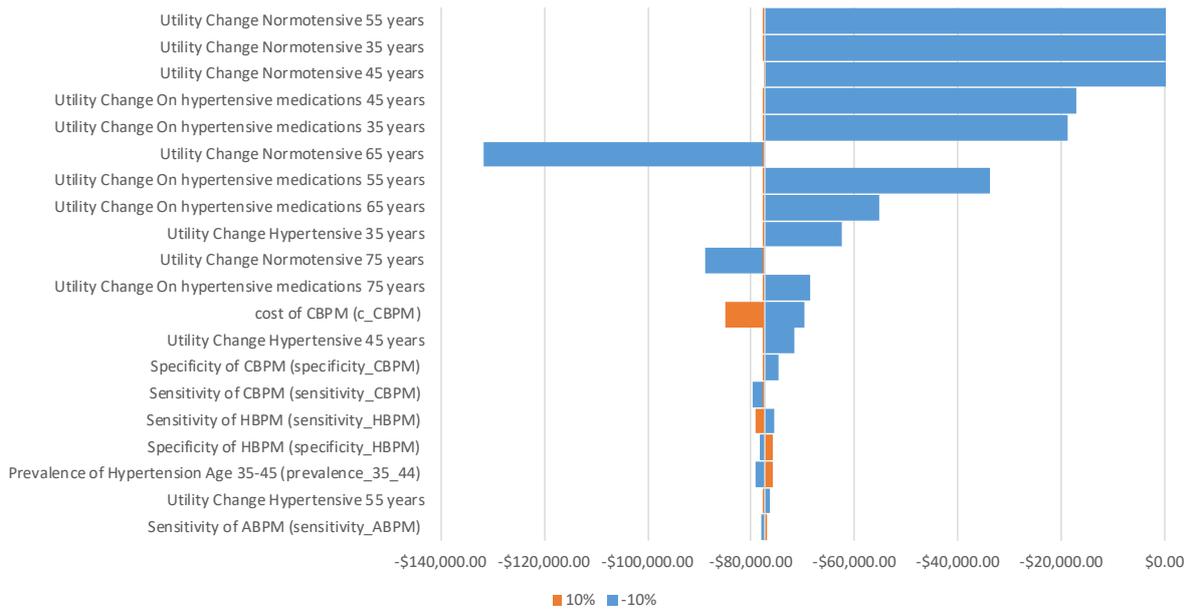


Figure 3: Tornado diagram of main drivers of economic model – ABPM v CBPM

Source: Figure 22, p133 of the DCAR

*axis has been shortened. A more accurate identification of the change in ICER is shown in Table 45

13. Financial/budgetary impacts

An epidemiological approach has been used by the DCAR to estimate the financial implications of the introduction of ABPM. The cost of ABPM was determined by calculating the number of patients eligible for testing, assuming a 50% uptake rate and 10% retest rate (i.e. how many patients will be tested in subsequent years), and applying the cost of the test to these patients over five years. Indirect costs to the MBS, PBS and hospital systems were attributed to cost of cardiovascular events (myocardial infarction, angina [stable and unstable] transient ischaemic attack, and stroke [intracerebral haemorrhage]), with the number of events sourced from Australian Institute of Health and Welfare (AIHW) data, and costing data of each event sourced from local (Ioannides-Demos et al. 2010; Access Economics 2009) and international publications (UK NICE 2011 guideline; Kaambwa et al. 2017). Cost offsets from cardiovascular events avoided (calculated in the economic model) were then applied to assess the overall savings to the health care budgets. However, while the model was structured to capture these cost offsets, as these events occur in greater frequency over a longer period of time, no events were identified over the first five years.

The DCAR stated that the cost of CBPM and HBPM currently is absorbed in the MBS code for GP services, and as such has a 100% benefit. ABPM would be performed out-of-hospital, and generally in a GP clinic and therefore would be an out-of-hospital fee and attract an 85% benefit. The financial implications of listing ABPM to the MBS are summarised in Table 7 and other Government budgets is summarised in Table 8. Note, the applicant in their pre-ESC response updated the financial implications using the proposed 85% rebate (\$90.20 rather than \$97.40 used by DCAR) for ABPM. However, in their Rejoinder, the DCAR updated all financial estimates correcting:

- the proposed fee for ABPM resulting in the 85% rebate of \$91.45;
- the proposed fee of CPPM resulting in the 100% rebate of \$114.60; and
- the application of the uptake rate of ABPM.

Note, all financial estimates are from the Rejoinder, which were informed by the DCAR's updated financial spreadsheet.

The applicant also highlighted that there will also be some cases where ABPM will be used in hospital setting (75% rebate). The Rejoinder acknowledged this, although noted there was uncertainty what the proportion treated in hospital with ABPM would be, and thus considered that the financial estimates provided were conservative.

Table 7: Total costs to the MBS associated with Ambulatory Blood Pressure Monitoring (Rejoinder corrected values; and ESC (equipment and consumables removed) and MSAC (consumables removed) revised values for ABPM italicised

	Year 1	Year 2	Year 3	Year 4	Year 5
Number of Services	401,566	208,495	108,136	58,013	32,959
Total Cost of ABPM (incl. equipment+consumables) <i>Rejoinder 85% rebate (\$91.45)</i>	\$36,723,184	\$19,066,909	\$9,889,027	\$5,305,325	\$3,014,107
<i>ESC values: equipment and consumables removed (\$81.25)</i>	\$32,627,213	\$16,940,256	\$8,786,041	\$4,713,588	\$2,677,924
<i>MSAC values: consumables removed (\$89.75)</i>	\$36,040,521.85	\$18,712,466.99	\$9,705,195.58	\$5,206,702.21	\$2,958,076.56
Total over 5 years (including equipment and consumables)	\$73,998,551				
<i>ESC values</i>	\$65,745,022				
<i>MSAC values</i>	\$72,622,963				
Total Cost with ABPM ^a	\$377,820,293	\$366,183,100	\$363,041,967	\$364,547,795	\$368,373,582
<i>ESC values</i>	\$373,724,323	\$364,056,447	\$361,938,981	\$363,956,058	\$368,037,400
<i>MSAC values</i>	\$377,137,631	\$365,828,658	\$362,858,136	\$364,449,172	\$368,317,552
Total Cost without ABPM ^b	\$379,449,033	\$367,029,906	\$363,482,317	\$364,785,149	\$368,509,466
Difference	-\$1,628,740	-\$846,806	-\$440,350	-\$237,354	-\$135,884
<i>ESC values</i>	-\$5,724,711	-\$2,973,460	-\$1,543,336	-\$829,090	-\$472,066
<i>MSAC values</i>	-\$2,311,402	-\$1,201,248	-\$624,181	-\$335,976	-\$191,914
Total over 5 years	-\$3,289,133				
<i>ESC values</i>	-\$11,542,662				
<i>MSAC values</i>	-\$4,664,722				

Source: Table 9, p30 of the DCAR and Budget impact model_MSAC1572 CA

^a Inclusive of test cost of ABPM (85% rebate), and modelled costs (from economic model) of cardiovascular events: myocardial infarction, stable angina, unstable angina, transient ischaemic attack, and stroke per year

^b Inclusive of cost of alternative tests (average of CBPM, HBPM; 100% Fee = \$95.50) and modelled costs (from economic model) of cardiovascular events: myocardial infarction, stable angina, unstable angina, transient ischaemic attack, and stroke per year

The DCAR stated that ABPM would impact the PBS the most, by identifying patients needing hypertensive medication. However, the costs of hypertensive medication may be overestimated in the model, due to a paucity of evidence in the literature. In their pre-ESC response, the applicant stated it is unclear if the DCAR takes into account the savings to the PBS from patients who would have been prescribed antihypertensive drugs based on a false positive result from CBPM if ABMP was not available. In their Rejoinder, the DCAR acknowledged this, but also indicated that there is also a significant proportion of patients who do not receive medication in the false negative population (when CBPM is used subsequent to an initial CBPM), which also needs to be accounted. It is this false negative population which decreases PBS costs when ABPM is not MBS listed. The model assumes 100% sensitivity and specificity for ABPM (and therefore no false positive or false negative patients), while for CBPM, the sensitivity is 0.78 and the specificity is 0.72. Based on the first year expected number of services, 401,566, a secondary CBPM would result in 35,980 false positive patients and 60,074 false negative patients. If the specificity of CBPM were higher than the sensitivity CBPM, then a greater offset in patients avoiding medication would be observed, and a greater savings in PBS medication.

In addition, the DCAR stated that due to polypharmacy, the complexity of how many different types of medications used and frequency of use is difficult to quantify. The cost for pharmacological treatment of hypertension has been sourced from an Australian source

(Chowdhury et al. 2018); however, the population was specifically hypertensive-resistant which would overestimate utilisation compared with the mean hypertensive population; the PBS costs used in the model are for a higher utilising hypertension population (treatment-resistant) and therefore are overestimated.

Table 8 Financial implications to the PBS and Hospital budgets with Ambulatory Blood Pressure Monitoring (Rejoinder corrected values)

	Year 1	Year 2	Year 3	Year 4	Year 5
PBS					
Total Cost with ABPM ^a	\$217,402,480	\$218,147,001	\$220,427,831	\$223,515,253	\$226,983,509
Total Cost without ABPM ^b	\$211,574,446	\$215,307,914	\$219,052,340	\$222,829,504	\$226,623,711
Difference	\$5,828,033	\$2,839,087	\$1,375,492	\$685,749	\$359,799
Total over 5 years	\$11,088,160				
Hospitals					
Total Cost with ABPM ^c	\$2,530,712,412	\$2,575,370,059	\$2,620,158,790	\$2,665,339,113	\$2,710,723,288
Total Cost without ABPM ^d	\$2,530,735,070	\$2,575,392,716	\$2,620,181,448	\$2,665,361,770	\$2,710,745,945
Difference	-\$22,657	-\$22,657	-\$22,657	-\$22,657	-\$22,657
Total over 5 years	-\$113,287				

Source: Table 10, pp30-31 of the DCAR

^a Inclusive of modelled costs using ABPM (from economic model) of additional patients on hypertensive drugs and cardiovascular events: myocardial infarction, stable angina, unstable angina, transient ischaemic attack, and stroke per year

^b Inclusive of modelled costs using alternative tests (CPBM, HBPM) (from economic model) of cardiovascular events: myocardial infarction, stable angina, unstable angina, transient ischaemic attack, and stroke per year

^c Inclusive of modelled costs using ABPM (from economic model) of cardiovascular events: myocardial infarction, stable angina, unstable angina, transient ischaemic attack, and stroke per year

^d Inclusive of modelled costs using alternative tests (CPBM, HBPM) (from economic model) of cardiovascular events: myocardial infarction, stable angina, unstable angina, transient ischaemic attack, and stroke per year

The DCAR stated that the overall cost to Australian healthcare budget, combining the cost to the MBS, PBS and hospital budgets is estimated to be between \$201,258 and \$4,176,636 over five years, per year (Table 9).

Table 9 Overall financial implications of Ambulatory Blood Pressure Monitoring to the Australian healthcare budget (Rejoinder corrected values; and ESC (equipment and consumables removed) and MSAC (consumables removed) revised values for ABPM italicised

	Year 1	Year 2	Year 3	Year 4	Year 5
MBS, PBS and Hospital combined					
Total Cost with ABPM ^a	\$3,125,935,185	\$3,159,700,160	\$3,203,628,589	\$3,253,402,161	\$3,306,080,380
<i>ESC values</i>	<i>\$3,121,839,215</i>	<i>\$3,157,573,506</i>	<i>\$3,202,525,603</i>	<i>\$3,252,810,425</i>	<i>\$3,305,744,197</i>
<i>MSAC values</i>	<i>\$3,125,252,523</i>	<i>\$3,159,345,718</i>	<i>\$3,203,444,758</i>	<i>\$3,253,303,539</i>	<i>\$3,306,024,349</i>
Total Cost without ABPM ^b	\$3,121,758,549	\$3,157,730,536	\$3,202,716,105	\$3,252,976,423	\$3,305,879,122
Difference	\$4,176,636	\$1,969,624	\$912,484	\$425,738	\$201,258
<i>ESC values</i>	<i>\$80,665</i>	<i>-\$157,030</i>	<i>-\$190,502</i>	<i>-\$165,998</i>	<i>-\$134,925</i>
<i>MSAC values</i>	<i>\$3,493,974</i>	<i>\$1,615,182</i>	<i>\$728,653</i>	<i>\$327,116</i>	<i>\$145,227</i>
Total over 5 years					\$7,685,740
<i>ESC values</i>					-\$567,789
<i>MSAC values</i>					\$6,310,152

Source: Table 58, p145 of the DCAR

^a Inclusive of modelled costs using ABPM (from economic model) of additional patients on hypertensive drugs and cardiovascular events: myocardial infarction, stable angina, unstable angina, transient ischaemic attack, and stroke per year

^b Inclusive of modelled costs using alternative tests (from economic model) of cardiovascular events: myocardial infarction, stable angina, unstable angina, transient ischaemic attack, and stroke per year

The DCAR's sensitivity analysis (from updated financial spreadsheet provided in DCAR's Rejoinder) focused on the two variables based on assumption and thus high uncertainty: uptake rate of ABPM, and the retest rate. The bivariate sensitivity analysis of the variation to the impact of uptake rate and retest rate to the total accumulated cost to:

- MBS over 5 years: from **-\$1,233,916** (10% uptake, 0% retest rate) to **-\$6,391,351** (100% uptake, 100% retest rate);
- PBS over 5 years: from \$3,932,893 (10% uptake, 0% retest rate) to \$22,577,403 (100% uptake, 100% retest rate);
- hospital budgets over 5 years: from **-\$331** (10% uptake, 0% retest rate) to **-\$158,000** (100% uptake, 100% retest rate); and
- overall financial impact to Australian healthcare budget over 5 years: from \$2,698,646 (10% uptake, 0% retest rate) to \$16,028,052 (100% uptake, 100% retest rate).

However, the DCAR requested further discussion is needed by clinicians and relevant stakeholders to ascertain the expected proportion of patients that would be retested and also the estimated uptake rate.

14. Key issues from ESC for MSAC

ESC key issue	ESC advice to MSAC
Justification of proposed fee-personnel included in proposed service	ESC considered that the submission does not adequately explain or justify the exclusive use of medical practitioners to conduct all aspects of the service, rather than non-medical practitioner staff, or software, to perform certain steps in the process.
Justification of proposed fee-device costs and consumables should be removed	ESC noted that the submission does not sufficiently justify the proposed fee- costs for the device and consumables should not be included as these are not reimbursable as a service under the MBS. In addition, MSAC may wish to consider the appropriateness of using MBS item 229 as the basis of costs for preparing a GP management plan, as most GPs use item 721 for this purpose.
Economic evaluation and financial estimates	ESC considered that the economic evaluation and financial estimate should be revised, so the cost of device and consumables removed from ABPM. However, ESC noted that for the economic evaluation, this is unlikely to change the ICER decision (i.e. ABPM likely to remain dominant).
Potential for leakage	ESC advised the submission does not explore the potential for leakage outside the restriction (such as ABPM used for monitoring, or clinicians relying on different diagnostic criteria for ABPM and HBPM).

ESC discussion

ESC noted the purpose of this application was to consider MBS listing for ABPM in adults with suspected hypertension who have a CBPM of $\geq 140/90$ mmHg and $\leq 180/110$ mmHg. The MSAC Executive had determined that a full health technology assessment was not required, and the assessment group instead provided a critique of the NICE guidance from 2011 on clinical management of hypertension in adults, and focused on implementation issues for the Australian context.

ESC considered that the NICE clinical management guidance from 2011 was high quality with a low risk of bias. Comparative safety was not assessed in the NICE guidance, but the assessment report considered ABPM to have non-inferior safety to CPBM. Based on NICE clinical statements on comparative effectiveness, the assessment report concluded that ABPM is superior to CBPM or HBPM, and a better predictor of cardiovascular outcomes. In addition, NICE guidance from 2019 on diagnostic accuracy used ABPM as the reference standard, and recommended that ABPM is used to confirm a diagnosis of hypertension after a CBPM of $\geq 140/90$ mmHg.

Australian guidelines (National Heart Foundation 2016) also recommend that ABPM or HBPM are used to confirm a diagnosis after a CBPM of $\geq 140/90$ mmHg. ESC noted that these guidelines also specify the criteria to confirm a diagnosis of hypertension as being $\geq 130/80$ mmHg for ABPM (over 24 hours), and $\geq 135/85$ mmHg for HBPM. ESC considered that different diagnostic criteria between ABPM and the comparators may create the potential for leakage.

ESC considered that the inclusion of costs for equipment purchase and maintenance is not justified in the proposed fee, and also that costs for the device and consumables were not supported under the MBS. ESC queried why the test and the consultation were combined (given that patients rarely attend for a blood pressure measurement alone), and considered that this made it difficult to differentiate the costs at each step. An item number that combines

a test and consultation also represents a new business model for GPs. If these were separated, ESC considered it would be easier to monitor utilisation and would discourage gaming or duplication of other consultation services.

ESC questioned whether the proposed service would be restricted to GPs, and whether staff other than medical practitioners (such as nurses or assistants), or even software, could be involved in various steps of the process (such as downloading data). ESC considered that the justification of the personnel required for the proposed service was not adequately explained or justified in the submission.

ESC also queried the use of MBS item 229 as the basis of costs for preparing a GP management plan, as most GPs use item 721 for this purpose. Furthermore, patients with hypertension alone are not currently eligible for a chronic disease care plan item (721) unless they have other chronic illness.

ESC noted that the economic evaluation was a cost-utility analysis based on the published NICE model, comparing ABPM with CBPM and HBPM. ESC considered there were several uncertainties in the modelled economic evaluation:

- Prevalence of ‘hypertension’ (using ABPM and HBPM) may be higher than estimated, depending on diagnosis tool used (favours ABPM)
- Proposed fee includes device cost and consumables (favours comparator); ESC considered the economic evaluation should be redone with a respecified base case model with the cost of consumables removed from ABPM (although unlikely to have change ICER decision; ABPM likely to remain dominant)
- Cost of comparators likely to be higher than estimated, for example GP incentives for bulk billing HBPM likely to be similar cost to CBPM (favours comparator).

However, ESC noted the ICER was robust in sensitivity analyses, and ABPM was dominant (i.e. less costly and more effective).

ESC considered that the modelling uncertainties flowed on into the financial estimates. ESC noted the applicant’s pre-ESC response, and the assessment group’s rejoinder, that included correction of some costs and calculation errors in the original assessment report. ESC also noted the financial estimates does not consider any change in monitoring costs. Using the rejoinder estimates, the total cost to the MBS of listing ABPM would be a cost saving \$3.3 million over 5 years. ESC noted removing the cost of the device and consumables from ABPM in the rejoinder estimates resulted in a cost saving of \$11.5 million to the MBS over 5 years (see Table 7). The largest impact would be to the PBS (\$11 million over 5 years; see Table 8), by identifying patients who need anti-hypertensive medication. The potential PBS cost savings due to lower false positive rates was not assessed in the application, but ESC considered this would likely be offset by the lower rates of false negatives.

Potential leakage (such as using ABPM for monitoring or clinicians relying on different diagnostic criteria for ABPM and HBPM) was not explored in the submission. ESC considered that capping the fee would reduce the use of ABPM for monitoring. ESC noted there were 11 responses to this application from health professionals (all supportive), and no responses from consumers.

ESC also discussed the potential impacts of technological changes in the future, with potential combination of patient monitoring devices with electronic health products.

15. Other significant factors

Nil

16. Applicant comments on MSAC's Public Summary Document

The Executive Subcommittee of the High Blood Pressure Research Council of Australia is very pleased with MSAC's recognition of ABPM as the gold standard for measuring blood pressure and determining the correct diagnosis for hypertension. The listing of ABPM on the MBS is an important step forward in the management of this condition that affects approximately one third of adult Australians. The Executive Subcommittee found the decision by MSAC to accept the clinical case supports the use of ABPM in the clinical settings of general practice and specialist care and brings Australia in line with the rest of the world. Additionally, the recognition that ABPM is cost-effective in Australia is also important in a climate of increasing health care costs.

17. Further information on MSAC

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