Australian Government

Department of Health

Application 1572:

Diagnosis of hypertension using ambulatory blood pressure monitoring in patients with clinic blood pressure ≥ 140/90mmHg and ≤ 180/110mmHg

Ratified PICO Confirmation

(To guide a new application to MSAC)

(Version 1.0)

Summary of PICO/PPICO criteria to define the question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Component	Description
Patients	Adults ≥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 ≤110mmHg, using a sphygmomanometer, and who have not yet commenced anti-hypertensive therapy. Exclusions: Pregnant women, those with a confirmed diagnosis of hypertension as diagnosed by ABPM within the last 12 months
Prior tests (for investigative medical services only)	Clinic blood pressure measurement (CBPM), taken using a validated and regularly maintained non-mercury sphygmomanometer, during a consultation at the doctor's office or in the patient's home, with a medical practitioner.
Intervention	Ambulatory blood pressure monitoring (ABPM) in the patients home/daily activities for ≥ 24 hours, after which a medical practitioner downloads the data from the monitor; interprets and reviews the results; creates a report; and puts together a patient management plan.
Comparator	1. CBPM/Repeat CBPM using a validated and regularly maintained non-mercury sphygmomanometer, during consultation at the doctor's office or in the patient's home with a medical practitioner. 2. Home blood pressure monitoring (HBPM): Multiple non-ambulatory blood pressure measurements taken by the patient in their home. HBPM involves the patient self-measuring BP at home, usually over a period of 1 week. It is often measured at approximately the same time in the morning or evening. The patient records the measurements and then returns to the doctor.
Outcomes	<u>Efficacy/effectiveness</u> • Adverse events from anti-hypertensive medication, such as orthostatic hypotension and related events including falls, hospital admissions and cardiovascular outcomes. • Composite outcomes: Major adverse cardiovascular and cerebrovascular events (MACCE) or Major adverse cardiovascular events (MACE) • Cardiac events/conditions (e.g. coronary heart disease/myocardial infarction, stroke, heart failure/cardiomyopathy) • All-cause mortality • Cardiovascular-specific mortality • Health-related quality of life

	• Diagnostic accuracy (e.g. sensitivity; specificity; area under the curve (AUC); false positives (FP); false negatives (FN); true positives (TP); true negatives (TN)). <u>Safety</u> Adverse effects of using ABPM such as; skin irritation, haematoma, sleep quality. <u>Cost-effectiveness</u> • Cost of doctor consultation/s • Cost of medication cost • Cost of treating adverse events resulting from medication including hypotension related events. • Cost per life year gained • Cost per quality-adjusted life year (QALY) gained • Cost of treating cardiac events/conditions • Cost of treating cardiac events/conditions occurring in the 2-3 week period after confirmed diagnosis of Hypertension <u>Healthcare resources</u> • Cost of ABPM • Cost of clinical consultation/s • Cost associated with changes in clinical management <u>Total Australian Government Healthcare costs</u> • Total cost to the Medicare Benefits Schedule (MBS) • Total cost to the Pharmaceutical Benefits Scheme (PBS) • Total cost to other healthcare services

PICO or PPICO rationale for therapeutic and investigative medical services only

Population

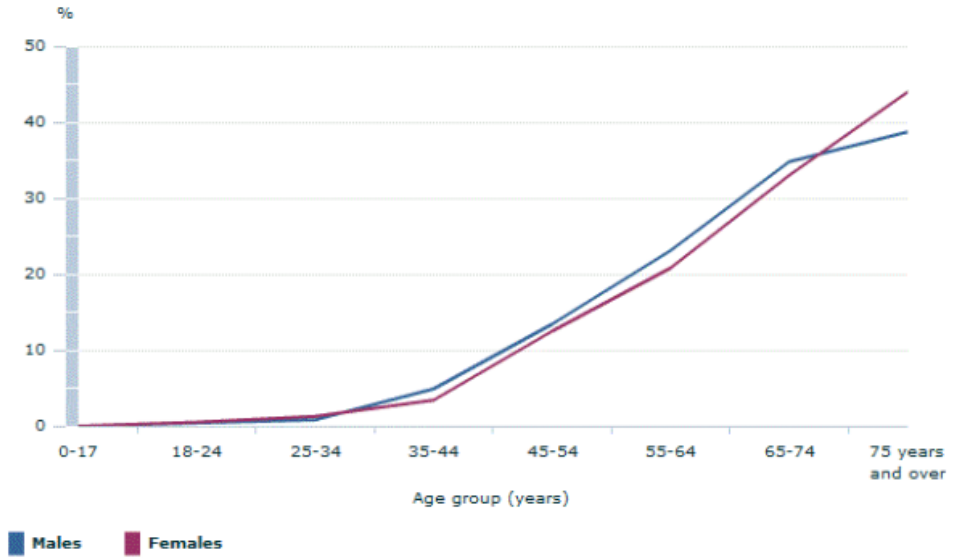
The patient population for whom public funding of the proposed medical service is intended includes adult patients ≥18 years old with suspected hypertension, who have a clinic blood pressure measurement (CBPM) of: systolic blood pressure between ≥140 to ≤180 mmHg, and diastolic blood pressure between 90 to ≤110mmHg, 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 proposed assessment.

The population for the proposed assessment includes patients with suspected hypertension who have CBPM of ≥140/90mmHg and ≤180/110mmHg (Grade 1: ≥140/90mmHg - <160/100mmHg, and Grade 2: ≥160/110mmHg - ≤180/110mmHg).

Although use of ABPM may be useful for diagnosis of 'white coat hypertension' in pregnant women (National Heart Foundation and High Blood Pressure Research Council of Australia Ambulatory Blood Pressure Monitoring Consensus Committee 2011), they are excluded from the population for this proposed assessment, as they would follow a different clinical pathway to the proposed population. For example, an outcome such as pre-eclampsia or the contraindication of certain treatment options for hypertension during pregnancy (Gabb 2016).

In 2017-18, 1 in 10 (10.6%) people in Australia had hypertension (Figure 1). The prevalence is balanced amongst gender and has remained similar over the prior 10 years (ABS 2018).

Figure 1: Proportion of people in Australian with hypertension, 2017-2018



Source: Australian Bureau of Statistics, Commonwealth of Australia, 2018(ABS 2018).

Table 1 and Table 2 (below) provide some content of the burden of high blood pressure in Australian adults and its prevalence in Australian states/territories.

Table 1: Percentage of Australian population with high/very high blood pressure

% of population	Males	Females	Persons
Taking hypertension medication	6.9	7.0	7.0

% of population	Males	Females	Persons
Not taking hypertension medication	15.3	11.3	13.3
Total high/very high measured blood pressure	22.2	18.3	20.2

Source: Australian Health Survey: Health Service Usage and Health Related Actions, 2011–12(ABS 2013)

Table 2: Prevalence of uncontrolled or unmanaged high blood pressure in Australia

State/territory	%
Tasmania	25.2%
South Australia	22.6%
Victoria	22.8%
New South Wales	21.3%
Western Australia	20.4%
Australian Capital Territory	23.7%
Queensland	22.5%
Northern Territory	21.5%

Source: Australian Bureau of Statistics. Australian Health Survey 2014/15(ABS 2015)

Rationale

The population described above is consistent with the population described in the current Australian guidelines for diagnosing hypertension, which recommends either ABPM and/or home blood pressure monitoring (HBPM) should be offered if CBPM ≥140/90mmHg (Gabb 2016, National Heart Foundation of Australia 2016). As those with BP ≥180/110mmHg are considered to have Grade 3 (severe) hypertension, they are not considered part of the population for this application. The application focuses on those who may have 'white coat hypertension' and do not have a diagnosis of hypertension, these patients are likely to have a CBPM <180/110mmHg.

High blood pressure contributed 42.1% the burden of cardiovascular disease in Australia in 2003, which was the highest contributor to the burden of cardiovascular disease. Cardiovascular disease contributed to 15% of the total burden of disease in Australia, coming behind cancers which consist of 19% of the total burden (AIHW 2011). Health care expenditure for patients admitted with cardiovascular disease was $5.0 billion in 2012-13, accounting for 11.1% of total admitted health expenditure, which was the greatest expenditure for any disease group (Heart Foundation 2018).

High blood pressure is defined by the Australian guidelines as a CBPM ≥ 140/90mmHg (Gabb 2016). However, patients with 'white-coat hypertension' (isolated clinic hypertension) are known to give misleading results. White-coat hypertension refers to the condition in which a person meets criteria for hypertension when measured in the clinic (i.e. CBPM) but shows normal BP levels when measured at HBPM or ABPM, which occurs in up to 32% of the population: (Brown et.al 2001).

The NICE guideline on 'Hypertension in adults: diagnosis and management' exclusively recommends ABPM for patients with a CBPM ≥140/90 mmHg, to confirm the diagnosis of hypertension (NICE 2011).

The Canadian guidelines (Nerenberg KA, Harris KC et al. 2018) follow similar recommendations to Australia, stating that ABPM "can be used in the diagnosis of hypertension" and "should be considered" in the case of suspected 'white coat hypertension'.

Prior test (investigative services only - if prior tests are to be included)

CBPM using a validated and regularly maintained non-mercury sphygmomanometer, during consultation with a medical practitioner, in line with current Australian guidelines on diagnosis of hypertension (Gabb 2016).

Intervention

Patients with a confirmed CBPM ≥ 140/90mmHg and ≤ 180/110mmHg will be fitted with an ABPM, including giving instructions to the patient about wearing the device, as part of another medical service. The new medical service starts when the patient returns to the medical practitioner after ≥ 24 hours and the monitor is removed. The medical practitioner, who is adequately skilled in interpreting this data, downloads the data from the monitor, interprets and reviews the results, creates a report and develops a patient management plan. The results should be interpreted with care, taking into account measures such as BP load, BP variability, maximum systolic BP and morning BP surge (National Heart Foundation of Australia 2016).

The device consists of a portable monitor, which is connected to a standard cuff on the upper arm and measures, at regular intervals of around 20–30 minutes over a period of ≥ 24 hours; systolic, diastolic and mean BP as well as heart rate, during the day time, night time, and sleep and awake (National Heart Foundation and High Blood Pressure Research Council of Australia Ambulatory Blood Pressure Monitoring Consensus Committee 2011).

Currently there are ten different brands of ABPM available in Australia (Table 3).

Table 3: 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

Rationale

Clinic, home and ambulatory BP all predict the risk of a cardiovascular event. The current Australian guidelines for diagnosing hypertension in adults recommends either ABPM and/or home blood pressure monitoring (HBPM) should be offered if CBPM ≥140/90 mmHg (Gabb 2016).

Stakeholder consultation on this application indicated the importance of using a validated device against standard sphygmomanometry, which is the validity of the device to accurately measure BP as well as the safety of the device. The need for reporting requirements to ensure the validated device is regularly maintained was also suggested.

The NICE Quality Statement, reviewed every year, concluded that: "ABPM is the most accurate method for confirming a diagnosis of hypertension, and its use should reduce unnecessary treatment in people who do not have true hypertension. ABPM has also been shown to be superior to other methods of multiple blood pressure measurement for predicting blood pressure-related clinical events."(NICE 2013) NICE also conducted an evidence update (NICE 2013) of their hypertension guideline in 2013, which concluded that: "Automated clinic blood pressure measurement providing a series of readings may result in more accurate blood pressure measurement than manual blood pressure measurement, but may still overestimate blood pressure in some patients when compared with ambulatory blood pressure monitoring."

Comparator

1. Repeat CBPM using a validated and regularly maintained non-mercury sphygmomanometer, taken during a consultation at the doctor's office or in the patient's home (with a medical practitioner).
2. HBPM: Multiple non-ambulatory blood pressure measurements taken using a validated and automated device by the patient in their home.

HBPM involves the patient self-measuring BP at home, usually over a period of 1 week using a validated and automated device. It is often measured at approximately the same time in the morning or evening. Training should be provided to patients on how to appropriately take BP measurements at home. The patient records the measurements and then returns to the doctor (Sharman, Howes et al. 2015)

Rationale

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 home blood pressure monitoring (HBPM) should be offered if CBPM ≥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). There have been a number of studies published that suggest ABPM may be the preferred option over HBPM (Sega, Facchetti et al. 2005, Fagard, Thijs et al. 2008, Hodgkinson, Mant et al. 2011, Muntner P, Myers MG et al. 2019).

Outcomes

Efficacy/effectiveness

- Adverse events from anti-hypertensive medication, such as orthostatic hypotension and related events including falls, hospital admissions and cardiovascular outcomes.
- Composite outcomes: Major adverse cardiovascular and cerebrovascular events (MACCE) or Major adverse cardiovascular events (MACE)

- Cardiac events/conditions (eg. coronary heart disease/myocardial infarction, stroke, heart failure/cardiomyopathy)
- All-cause mortality
- Cardiovascular-specific mortality
- Health-related quality of life

Diagnostic accuracy (eg. sensitivity, specificity, Area Under the Curve (AUC), False Positives (FP), False Negatives (FN), True Positives (TP), True Negatives (TN))

Safety

Adverse effects of using ABPM such as; skin irritation, haematoma, sleep quality.

Cost-effectiveness

- Cost of doctor consultation/s
- Cost of medication cost
- Cost of treating adverse events resulting from medication including hypotension related events.
- Cost per life year gained
- Cost per quality-adjusted life year (QALY) gained
- Cost of treating cardiac events/conditions
- Cost of treating cardiac events/conditions occuring in the 2-3 week period after confirmed diagnosis of Hypertension

Healthcare resources

- Cost of ABPM
- Cost of clinical consultation/s
- Cost associated with changes in clinical management

Total Australian Government Healthcare costs

- Total cost to the Medical Benefits Schedule (MBS)
- Total cost to the Pharmaceutical Benefits Scheme (PBS)

Total cost to other healthcare services

Rationale

CBPM, HBPM and ABPM all predict the risk of a cardiovascular event; however, HBPM and ABPM are stronger predictors of adverse cardiovascular outcomes, as out-of-clinic BP is considered a stronger predictor of outcome (Gabb 2016). However, it should be noted that the thresholds are different for diagnosis based on the measure used, as shown in Table 4.

Table 4: Criteria for diagnosis of hypertension using different methods

Method of measurement	Systolic (mmHg)		Diastolic (mmHg)
Clinic	≥ 140	and/or	≥ 90
ABPM daytime (awake)	≥ 135	and/or	≥ 85
ABPM night-time (asleep)	≥ 120	and/or	≥ 70
ABPM over 24 hours	≥ 130	and/or	≥ 80
HBPM	≥ 135	and/or	≥ 85

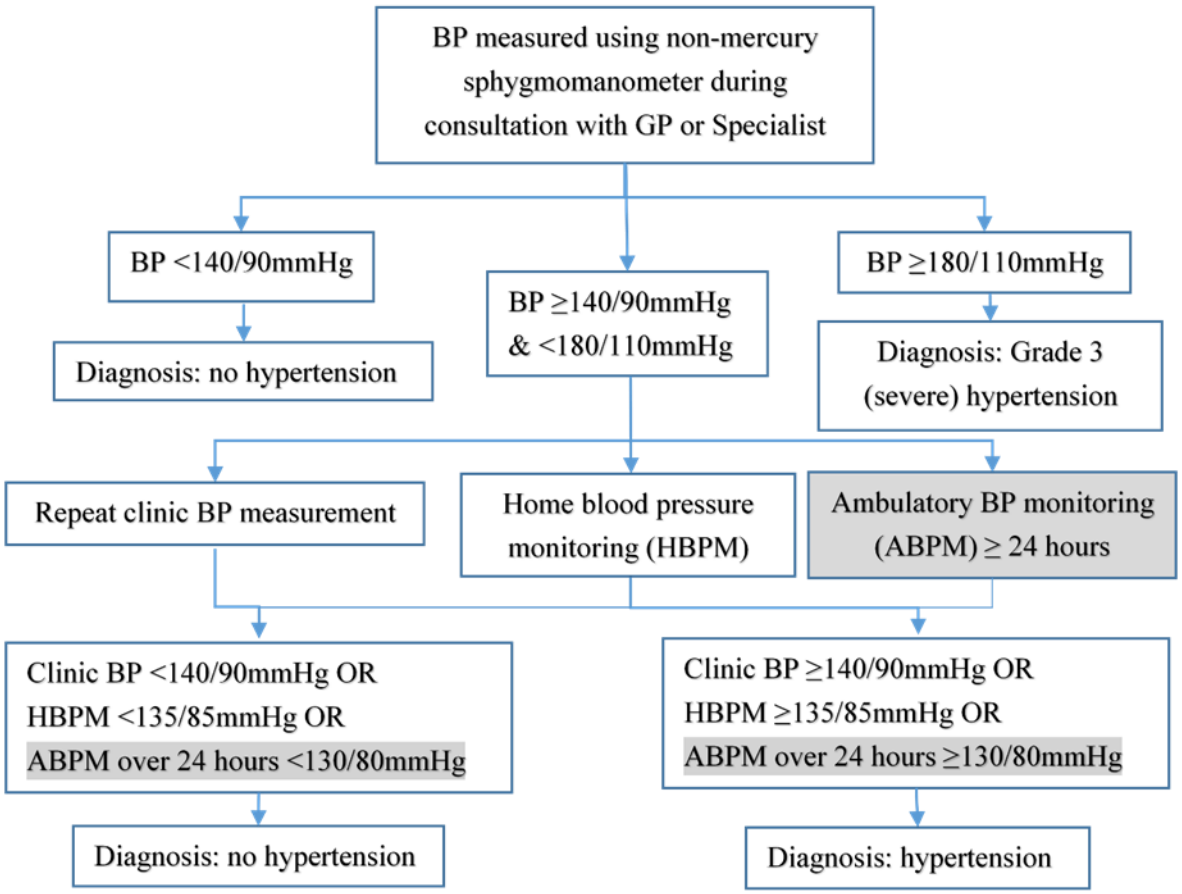
Source: Australian guideline for the diagnosis and management of hypertension in adults — 2016 (Gabb 2016).

Canadian guidelines also specify follow the same different thresholds as Australia for considering for therapy adjustments for ABPM over 24 hours and daytime (awake). The Canadian guidelines also highlight the importance of changes in BP at night-time (asleep) in therapy decisions (Nerenberg KA, Harris KC et al. 2018). Adverse effects of using ABPM have previously been reported such as; skin irritation, haematoma and sleep quality (Beltman, Heesen et al. 1996)

As per the Australian Guidelines (Gabb 2016, National Heart Foundation of Australia 2016), there are no specific contraindications to ABP monitoring; however, it is important that this test does not delay commencing drug therapy in patients with severe hypertension (CBPM grade 3; defined as systolic BP ≥180 mmHg and/or diastolic BP ≥110 mmHg).

Current and proposed (shaded) clinical management algorithm for identified population

The clinical management algorithm (below) in is in line with the Australian guidelines and thresholds for diagnosis show in Table 4 above. The treatments provided following diagnosis of grade 1 or grade 2 hypertension are a simplification of the treatment guidance, based on discussions at a teleconference with the department of health and the applicant.



Proposed economic evaluation

The clinical claim is that ABPM is non-inferior in safety and superior in clinical effectiveness to CBPM and HBPM. This is because HBPM and ABPM are stronger predictors of adverse cardiovascular outcomes, as out-of-clinic BP is considered a stronger predictor of outcome (Gabb 2016). Comparative prognostic and diagnostic evidence to this effect was provided in the application (Sega, Facchetti et al. 2005, Fagard, Thijs et al. 2008, Hodgkinson, Mant et al. 2011).

According to the *Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee: Investigative* the required economic analysis is therefore a cost-utility or a cost-effectiveness analysis. An Australian cost analysis study, based on a model, was provided in the application, however this study was conducted in 2002(Ewald and Pekarsky 2002). The 2011 NICE guideline conducted an original cost-utility analysis comparing CBPM, HBPM and ABPM that may be

useful to guide the modelling of this proposed assessment (NICE 2011). However, this analysis is UK-specific and provides recommendations for the NHS; therefore the results do not apply directly to the Australian context or MBS. The proposed economic model should include an examination of business and service delivery models (including proposed venue/location). The 2011 NICE guideline's original cost-utility analysis stated their conclusions as follows: "This analysis suggests that ABPM is the most cost-effective method of confirming a diagnosis of hypertension in a population suspected of having hypertension based a CBPM screening measurement >140/90 mmHg, compared with further CBPM or HBPM. This conclusion was consistent across a range of age/gender stratified subgroups. Uncertainties in the analysis were explored through extensive sensitive analysis which in most cases did not change conclusions."

The NICE guideline's original cost-utility analysis also stated that patients may be diagnosed faster with ABPM than a diagnosis with CBPM. A faster diagnosis could impact the number of doctor consultations, medications prescribed and need to treat adverse events resulting from medication including hypotension related events, which all have associated costs. Therefore, it would be useful for the current proposed assessment to investigate these as potential inputs in the model. Additionally, it may be worth investigating if there are any differences in cost of treating potential cardiac events/conditions that could occur in the 2-3 week period that the patient may be waiting for a confirmed diagnosis of hypertension.

If the evidence identified in the proposed assessment shows a difference in cardiovascular disease (CVD) as a consequence of a more accurate diagnosis and therefore a more targeted treatment plan (eg, timing of medication throughout the day), then this costs should be considered as part of the proposed economic analysis. It should be noted that the NICE cost-utility analysis reported a sensitivity analysis where cardiovascular risk reduction was applied to those correctly and incorrectly diagnosed, in which case CBPM was more cost-effective.

Proposed item descriptor

Category 2 DIAGNOSTIC PROCEDURES AND INVESTIGATIONS – Group D1 - Miscellaneous Diagnostic Procedures and Investigations
MBS Item 116XX 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 ≤110mmHg, using a sphygmomanometer, and who has not yet commenced anti-hypertensive therapy. Maximum one time per year MBS Fee: $106.10

Additional justifications by the applicant, as requested by PASC

Justification for use of ABPM once per year

ABPM will be used to confirm the diagnosis of hypertension in patients who have suspected hypertension, based on their clinic BP measurement of systolic blood pressure between ≥140 to ≤180 mmHg, and diastolic blood pressure between 90 to ≤110mmHg. 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, re-testing a patient with clinic-measured systolic blood pressure between ≥140 to ≤180 mmHg, and diastolic blood pressure between 90 to ≤110mmHg (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.

Justification for MBS benefit amount and clarification of the service provided

In order for a patient to be eligible for an ABPM measurement, they must have a demonstrated/recorded clinic BP measurement of systolic blood pressure between ≥140 to ≤180 mmHg, and diastolic blood pressure between 90 to ≤110mmHg, in a consultation with a medical practitioner, **that is billed as a separate service.**

For example, the patient may visit a medical practitioner for a consultation regarding influenza, where, as part of this consultation, the patient's clinic BP is measured. If the patient's measurements are within the prescribed (at risk) range, the patient is fitted with the ABPM monitor by the medical practitioner or nurse, and told to return in 24 hours. **No additional reimbursement for fitting the monitor to the patient is requested under this application – the medical practitioner will bill the entire pre-ABPM consultation service against a current MBS item (and fee) for a general consultation.**

When the patient returns with the monitor, the proposed service will commence. The medical practitioner will create a report (by downloading data from the ABPM monitor), review and interpret the report, and then develop a patient management plan, which could include lifestyle modifications and/or medication.

It is estimated by the applicant that the fee for the proposed service would be between:

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 = $72.80 MBS Benefit: 100% = $72.80 (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 = $84.80

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 = $115.40 Benefit: 75% = $86.55 (admitted patient) 100% = $115.40 (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 = $127.40

AVERAGE FEE = $106.10

As a comparator, if three standard GP consultations were required to confirm the diagnosis of high blood pressure using clinic blood pressure, the cost of these consultations would be 3 x $36.30 = $108.90.

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 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.

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 (hypertension is not terminal as can be reversed with lifestyle measures and medication) or refer to other diseases such as diabetes.
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 for patients with clinic systolic blood pressure between ≥140 to ≤180 mmHg, and diastolic blood pressure between 90 to ≤110mmHg, the MBS could be billed for long consultations for all patients regardless of their clinic BP.

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