



Australian Government

Department of Health

Application Form

**Diagnosis of hypertension using ambulatory blood pressure
monitoring in patients with clinic blood pressure $\geq 140/90$ mmHg
and $\leq 180/110$ mmHg**

November 2018

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant): REDACTED

Corporation name: REDACTED

ABN: REDACTED

Business trading name: REDACTED

Primary contact name: REDACTED

Primary contact numbers

Business: REDACTED

Mobile: REDACTED

Email: REDACTED

Alternative contact name: REDACTED

Alternative contact numbers

Business: REDACTED

Mobile: REDACTED

Email: REDACTED

2. (a) Are you a lobbyist acting on behalf of an Applicant?

Yes

No

(b) If yes, are you listed on the Register of Lobbyists?

Yes

No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Diagnosis of hypertension using ambulatory blood pressure monitoring in patients with clinic blood pressure $\geq 140/90\text{mmHg}$ and $\leq 180/110\text{mmHg}$

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

High blood pressure currently is defined as a BP reading $\geq 140/90\text{mmHg}$ usually taken using a sphygmomanometer as part of a standard consultation with either a General Practitioner or a Specialist in hypertension.

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

The actual proposed service is conducted after the patient has worn an ambulatory blood pressure monitor for a specified period, generally ≥ 24 hours. The proposed service involves the doctor downloading, analysing and reviewing the reading from the ambulatory blood pressure monitor, making a diagnosis and determining the appropriate therapeutic management of the hypertension.

Prior to the proposed service

Ambulatory blood pressure monitoring (ABPM) involves the patient wearing a portable blood pressure (BP) measuring device for a specified period (usually ≥ 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. The resulting series of BP readings, taken throughout the person's normal daytime activities and during sleep, provides a robust assessment of the impact of BP on the person's cardiovascular system (BP load).

6. (a) Is this a request for MBS funding?

- Yes
 No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

- Amendment to existing MBS item(s)
 New MBS item(s)

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

Insert relevant MBS item numbers here

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

- i. An amendment to the way the service is clinically delivered under the existing item(s)
- ii. An amendment to the patient population under the existing item(s)
- iii. An amendment to the schedule fee of the existing item(s)
- iv. An amendment to the time and complexity of an existing item(s)
- v. Access to an existing item(s) by a different health practitioner group
- vi. Minor amendments to the item descriptor that does not affect how the service is delivered
- vii. An amendment to an existing specific single consultation item
- viii. An amendment to an existing global consultation item(s)
- ix. Other (please describe below):

Insert description of 'other' amendment here

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

- i. A new item which also seeks to allow access to the MBS for a specific health practitioner group
- ii. A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
- iii. A new item for a specific single consultation item
- iv. A new item for a global consultation item(s)

(f) Is the proposed service seeking public funding other than the MBS?

- Yes
- No

(g) If yes, please advise:

Insert description of other public funding mechanism here

7. What is the type of service:

- Therapeutic medical service
- Investigative medical service
- Single consultation medical service
- Global consultation medical service
- Allied health service
- Co-dependent technology
- Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):

- i. To be used as a screening tool in asymptomatic populations
- ii. Assists in establishing a diagnosis in symptomatic patients
- iii. Provides information about prognosis
- iv. Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- v. Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

- Pharmaceutical / Biological
- Prosthesis or device
- No

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

- Yes
- No

(b) If yes, please list the relevant PBS item code(s):

Insert PBS item code(s) here

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

- Yes (please provide PBAC submission item number below)
- No

Insert PBAC submission item number here

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

Trade name: Insert trade name here

Generic name: Insert generic name here

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

- Yes
 No

(b) If yes, please provide the following information (where relevant):

Billing code(s): Insert billing code(s) here

Trade name of prostheses: Insert trade name here

Clinical name of prostheses: Insert clinical name here

Other device components delivered as part of the service: Insert description of device components here

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

- Yes
 No

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

- Yes
 No

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

Sponsor	Manufacturer
HealthStats Australia	HealthSTATS International Pte Ltd
Atcor Medical Pty Ltd	SunTech Medical Inc
Australian Sales and Trade Services (ASTS)	Andon Health Co Ltd
Core Diagnostics Pty Ltd	DM Systems (Beijing) Co Limited
Ecomed Pty Ltd	Spacelabs Healthcare Inc
Cellmed Pty Ltd	SunTech Medical Inc
A & D Australasia Pty Ltd	A & D Co Ltd
Welch Allyn Australia Pty Limited	IEM GmbH Industrielle Entwicklung Medizintechnik und Vertriebsgesellschaft mbH
Cardioscan Services Pty Ltd	IEM GmbH Industrielle Entwicklung Medizintechnik und Vertriebsgesellschaft mbH
GE Healthcare Australia Pty Ltd	GE Medical Systems Information Technologies
InMed Healthcare Pty Ltd	Meditech KFT

12. Please identify any single and / or multi-use consumables delivered as part of the service?

Single use consumables: N/A

Multi-use consumables: The Ambulatory Blood pressure monitor consists of the device, and a number of different sized arm cuffs/sensors, and an air hose that connects the cuff/sensor and the device. Whilst the device has a useful life of 5 years, the arm cuffs/sensors and the hose are reused on subsequent patients, but as over time these components perish and wear out, they are considered multi-use consumables.

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

Type of therapeutic good: HealthSTATS BPro Ambulatory Blood Pressure Monitoring System - Patient data recorder, long-term, sphygmomanometer

Manufacturer's name: HealthSTATS International Pte Ltd

Sponsor's name: HealthSTATS Australia

Type of therapeutic good: Patient data recorder, long-term, sphygmomanometer

Manufacturer's name: SunTech Medical Inc

Sponsor's name: SunTech Medical Inc

Type of therapeutic good: Blood pressure monitor - Sphygmomanometer, electronic, automatic-inflation, portable, arm/wrist

Manufacturer's name: Andon Health Co Ltd

Sponsor's name: Australian Sales and Trade Services (ASTS)

Type of therapeutic good: Automatic Blood Pressure Monitoring System - Automatic-inflation electronic sphygmomanometer, portable, arm/wrist

Manufacturer's name: DM Systems (Beijing) Co Limited

Sponsor's name: Core Diagnostics Pty Ltd

Type of therapeutic good: Patient data recorder, long-term, sphygmomanometer

Manufacturer's name: Spacelabs Healthcare Ltd

Sponsor's name: Ecomed Pty Ltd

Type of therapeutic good: Patient monitoring system module, blood pressure, non-invasive

Manufacturer's name: SunTech Medical Inc

Sponsor's name: Cellmed Pty Ltd

Type of therapeutic good: Patient monitor module, multifunction

Manufacturer's name: A & D Co Ltd

Sponsor's name: A & D Australasia Pty Ltd

Type of therapeutic good: Patient data recorder, long-term, sphygmomanometer

Manufacturer's name: IEM GmbH Industrielle Entwicklung Medizintechnik und Vertriebsgesellschaft mbH

Sponsor's name: Welch Allyn Australia Pty Limited

Type of therapeutic good: Sphygmomanometer, electronic, automatic

Manufacturer's name: IEM GmbH Industrielle Entwicklung Medizintechnik und Vertriebsgesellschaft mbH

Sponsor's name: Cardioscan Services Pty Ltd

Type of therapeutic good: Patient monitor, blood pressure, noninvasive

Manufacturer's name: GE Medical Systems Information Technologies

Sponsor's name: GE Healthcare Australia Pty Ltd

Type of therapeutic good: Patient data recorder, long-term, sphygmomanometer

Manufacturer's name: Meditech KFT

Sponsor's name: InMed Healthcare Pty Ltd Pty Ltd

(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

- Class III
- AIMD
- N/A

14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

- Yes (If yes, please provide supporting documentation as an attachment to this application form)
- No

(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

- Yes (if yes, please provide details below)
- No

ARTG listing, registration or inclusion number: **HealthStats 221446, Atcor 234635, Australian Sales and Trade Services (ASTS) 217021, Ecomed Pty Ltd 237321, Cellmed Pty Ltd 310020, Core Diagnostics Pty Ltd 285458, A & D Australasia Pty Ltd 137370, Welch Allyn Australia Pty Limited 295312, Cardioscan Services Pty Ltd 228227, GE Healthcare Australia Pty Ltd 93116, InMed Healthcare Pty Ltd 147014**

TGA approved indication(s), if applicable: N/A

TGA approved purpose(s), if applicable: N/A

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

- Yes (please provide details below)
- No

Date of submission to TGA: Insert date of submission here

Estimated date by which TGA approval can be expected: Insert estimated date here

TGA Application ID: Insert TGA Application ID here

TGA approved indication(s), if applicable: If applicable, insert description of TGA approved indication(s) here

TGA approved purpose(s), if applicable: If applicable, insert description of TGA approved purpose(s) here

16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

- Yes (please provide details below)
- No

Estimated date of submission to TGA: Insert date of submission here

Proposed indication(s), if applicable: If applicable, insert description of proposed indication(s)

Proposed purpose(s), if applicable: If applicable, insert description of proposed purpose(s) here

PART 4 – SUMMARY OF EVIDENCE

17. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
	ABPM vs. Clinic BP measurement.				
1.		Banegas et al. Relationship between Clinic and Ambulatory Blood-Pressure Measurements and Mortality. N Engl J Med. 2018 Apr 19;378(16):1509-1520.	Ambulatory blood-pressure measurements were a stronger predictor of all-cause and cardiovascular mortality than clinic blood-pressure measurements.	https://www.ncbi.nlm.nih.gov/pubmed/29669232	2018
2.	Observational	Bjorklund K et.al. Prognostic significance of 24-h ambulatory blood pressure characteristics for cardiovascular morbidity in a population of elderly men. <i>Journal of Hypertension.</i> 2004; 22(9):1691-1697	Compared ABPM and clinic Blood Pressure for detection of CV morbidity in 872 patients followed for an average 6.6 years. Found HR for ABPM (24h): 1.23 (1.07, 1.42) p<0.05, ABPM (daytime): 1.23 (1.07, 1.42) p<0.05 Clinic: 1.21 (1.04, 1.41) p<0.05 per 1 SD rise in SBP. “Daytime ambulatory PP predicted CV morbidity independently of office PP and other established CV risk factors.”	https://www.ncbi.nlm.nih.gov/pubmed/15311096	2004

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
3.	Prospective, Multicentre Observational	Dawes MG, et.al. Daytime ambulatory systolic blood pressure is more effective at predicting mortality than clinic blood pressure. <i>Blood Pressure Monitoring.</i> 2006; 11(3):111-118.	Compared ABPM and clinic Blood Pressure for detection of mortality in 10,129 patients followed for 10 years. Found HR ABPM (daytime): 1.51 (1.25, 1.83); p<0.001 vs Clinic: 1.02 (0.84, 1.24); p=0.90 for the highest quartile of SBP compared to lowest. "Ambulatory blood pressure was also a better predictor of all-cause mortality both in patients taking medication and those not taking medication at the time of monitoring."	https://www.ncbi.nlm.nih.gov/pubmed/16702819	2006
4.	Observational	Dolan et.al Superiority of ambulatory over clinic blood pressure measurement in predicting mortality: the Dublin outcome study. <i>Hypertension.</i> 2005; 46(1):156-161.	Compared ABPM and clinic Blood Pressure for detection of CV mortality in 5292 patients for an average of 7.9 years. Found HR for ABPM (24h): 1.19 (1.14, 1.26) p<0.001 ABPM (night-time): 1.21 (1.16, 1.27) p<0.001 vs. Clinic: 1.06 (1.02, 1.10) p<0.01 per 10mmHg rise in SBP. "Ambulatory measurement of blood pressure is superior to clinic measurement in predicting cardiovascular mortality"	https://www.ncbi.nlm.nih.gov/pubmed/15939805	2005

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
5.	Meta-Analysis.	Fagard et.al. Prognostic significance of ambulatory blood pressure in hypertensive patients with history of cardiovascular disease. <i>Blood Pressure Monitoring.</i> 2008; 13(6):325-332	Compared ABPM and clinic Blood Pressure for detection of CV mortality, mortality and CV events in 302 patients (3 studies) for an average of 6.8 years. Found HR for ABPM (24h): 1.20 (0.91-1.58) NS ABPM (daytime): 1.03 (0.77-1.36) NS ABPM (night-time): 1.34 (1.06-1.69) p<0.01 per 1SD rise in SBP. "Night-time BP is the better predictor of death and recurrent CV events in hypertensive patients with a history of CV disease"	https://www.ncbi.nlm.nih.gov/pubmed/18756173	2008
6.	Observational	Hansen TW, et.al Ambulatory blood pressure and mortality: a population-based study. <i>Hypertension.</i> 2005; 45(4):499-504.	Compared ABPM and clinic Blood Pressure for detection of CV mortality, mortality and CV events in 1700 patients for an average of 9.5 years. Found HR for ABPM (24h): 1.51 (1.28, 1.77) p<0.0001, ABPM (daytime):1.50 (1.27, 1.76) p<0.0001 vs. Clinic: 1.25 (1.10, 1.42) p<0.001 per 10mmHg rise in SBP. "Ambulatory blood pressure provided prognostic information on mortality above and beyond that of office blood pressure".	https://www.ncbi.nlm.nih.gov/pubmed/15753229	2005

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
7.	Meta-analysis	Hansen TW, et.al Prognostic superiority of daytime ambulatory over conventional blood pressure in four populations: a meta-analysis of 7,030 individuals. <i>Journal of Hypertension.</i> 2007; 25(8):1554-1564.	Compared ABPM and clinic Blood Pressure for detection of CV death, cardiac events, stroke and CHD in 7030 patients with an average of 9.5 years follow-up. Found HR for Cardiac events ABPM (daytime): 1.13 (1.04, 1.23) p<0.0001 vs. Cardiac events Clinic: 1.06 (0.99, 1.13) p>0.05 per 10mmHg rise in SBP. "ABP is superior to CBP in predicting cardiovascular events, but not total and non-cardiovascular mortality".	https://www.ncbi.nlm.nih.gov/pubmed/17620947	2007
8.	Observational	Ingelsson E, et.al Diurnal blood pressure pattern and risk of congestive heart failure. <i>JAMA.</i> 2006; 295(24):2859-2866.	Compared ABPM and clinic Blood Pressure for detection of CHF in 951 patients with an average of 9.1 years follow-up. Found HR for ABPM (24h): 1.13 (0.91, 1.40) p>0.05, ABPM (night-time): 1.21 (0.98, 1.49) p>0.05 vs Clinic: 1.25 (0.98, 1.59) p>0.05 per 1 SD rise in SBP	https://www.ncbi.nlm.nih.gov/pubmed/16804152	2006

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
9.	Observational, prospective.	Kikuya M, et.al International Database on Ambulatory Blood Pressure Monitoring in relation to Cardiovascular Outcomes Investigators. Diagnostic thresholds for ambulatory blood pressure monitoring based on 10-year cardiovascular risk. <i>Circulation.</i> 2007; 115(16):2145-2152.	Compared ABPM and clinic Blood Pressure for detection of CV death, cardiac events, stroke and CHD in 5682 patients with an average of 9.5 years follow-up. Found no difference between ABPM and clinic BP.	https://www.ncbi.nlm.nih.gov/pubmed/17420350	2007
10.	Observational, prospective.	Mesquita-Bastos J, et.al Cardiovascular prognostic value of ambulatory blood pressure monitoring in a Portuguese hypertensive population followed up for 8.2 years. <i>Blood Pressure Monitoring.</i> 2010; 15(5):240-246	Compared ABPM and clinic Blood Pressure for detection of cardiac events and stroke in 1200 patients with an average of 8.2 years follow-up. Found ABPM (24h): 1.41 (1.20-1.65) <0.001, ABPM (daytime): 1.33 (1.10-1.60) <0.01 and ABPM (night-time): 1.57 (1.32-1.86) p<0.001 per 1 SD rise in SBP. "In predicting CV events and stroke, ABP is superior to office BP"	https://www.ncbi.nlm.nih.gov/pubmed/20616705	2010
	Home vs. clinic BP				

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
11.	Observational	Bobrie G, et.al. Cardiovascular prognosis of "masked hypertension" detected by blood pressure self-measurement in elderly treated hypertensive patients. <i>JAMA.</i> 2004; 291(11):1342-1349	Compared Home and clinic BP for detection of CV events in 4939 patients with 3.2 years average follow up. Found HR for Home: 1.02 (1.01, 1.02) p<0.001 and Clinic: 1.01 (1.00, 1.01) p=0.09 per 1mmHg rise in SBP, so home superior.	https://www.ncbi.nlm.nih.gov/pubmed/15026401	2004
12.	Observational	Niiranen TJ, et.al. Home-measured blood pressure is a stronger predictor of cardiovascular risk than office blood pressure: the Finn-Home study. <i>Hypertension.</i> 2010; 55(6):1346-1351.	Compared Home and clinic BP for detection of mortality and CV events in 2081 patients followed up for an average 6.8 years. Found HR for Home: 1.22 (1.09, 1.37) p<0.001 and HR for Clinic: 1.01 (0.92, 1.12) p=0.80 per 10mmHg rise in SBP, so home superior	https://www.ncbi.nlm.nih.gov/pubmed/20385970	2010
13.	Observational	Stergiou GS, et.al Cardiovascular risk prediction based on home blood pressure measurement: the Didima study. <i>Journal of Hypertension.</i> 2007; 25(8):1590-1596	Compared home and clinic BP for detection of CV events in 665 patients with an average follow up of 8.2 years. Found NS difference between the 2 methods.	https://www.ncbi.nlm.nih.gov/pubmed/17620954	2007
	Home vs. ABPM vs. Clinic Blood pressure				

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
14.	Observational	Fagard RH, et.al Prognostic significance of blood pressure measured in the office, at home and during ambulatory monitoring in older patients in general practice. <i>Journal of Human Hypertension.</i> 2005; 19(10):801-807.	Compared ABPM, home and clinic Blood Pressure for detection of cardiac events and stroke in 391 patients with an average of 10.9 years follow-up. Found Home: 1.32 (1.06, 1.64) p=0.01, ABPM (daytime): 1.33 (1.07, 1.64) p<0.01, ABPM (night-time): 1.42 (1.16, 1.74) p<0.001 vs Clinic: 1.13 (0.88, 1.45) p=0.34 Per 1mmHg rise in SBP. "the prognostic value of home BP is better than that of office BP in older patients in primary care, and is at least equal to that of daytime ambulatory BP"	https://www.ncbi.nlm.nih.gov/pubmed/15959536	2005
15.	Observational	Sega R, et.al. Prognostic value of ambulatory and home blood pressures compared with office blood pressure in the general population: follow-up results from the Pressioni Arteriose Monitorate e Loro Associazioni (PAMELA) study. <i>Circulation.</i> 2005; 111(14):1777-1783	Compared ABPM, home and clinic Blood Pressure for mortality in 2051 patients with an average of 10.9 years follow-up. Results were that "In the PAMELA population, risk of death increased more with a given increase in home or ambulatory than in office BP. The overall ability to predict death, however, was not greater for home and ambulatory than for office BP"	https://www.ncbi.nlm.nih.gov/pubmed/15809377	2005

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
	Sensitivity and specificity of clinic, home and ambulatory measurements				
16.	Systematic Review/ Meta-analysis	Hodgkinson J, ed. al Relative effectiveness of clinic and home blood pressure monitoring compared with ambulatory blood pressure monitoring in diagnosis of hypertension: systematic review. <i>BMJ.</i> 2011; 342:d3621	Meta-analysis of 20 studies and 5863 patients to determine the relative accuracy of clinic and home BP vs ABPM in determining the diagnosis of Hypertension “Neither clinic nor home measurement had sufficient sensitivity or specificity to be recommended as a single diagnostic test. If ambulatory monitoring is taken as the reference standard, then treatment decisions based on clinic or home blood pressure alone might result in substantial over diagnosis. Ambulatory monitoring before the start of lifelong drug treatment might lead to more appropriate targeting of treatment, particularly around the diagnostic threshold.”	https://www.ncbi.nlm.nih.gov/pubmed/21705406	2011

* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

**Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.

*** If the publication is a follow-up to an initial publication, please advise.

	Type of study design* GUIDELINES	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1.	Guidelines	Nerenberg et al. Hypertension Canada's 2018 Guidelines for Diagnosis, Risk Assessment, Prevention, and Treatment of Hypertension in Adults and Children	Canadian Guidelines	https://guidelines.hypertension.ca/	2018
2.	Guidelines	Gabb et al. Guideline for the diagnosis and management of hypertension in adults	Australian Guidelines	https://www.mja.com.au/journal/2016/205/2/guideline-diagnosis-and-management-hypertension-adults-2016	2016
3.	Guidelines	NICE Management of hypertension	UK Guidelines	http://pathways.nice.org.uk/pathways/hypertension	2018 updated

	Type of study design* ECONOMICS	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1.	Australian cost analysis based on a model	Ewald et al. Cost analysis of ambulatory blood pressure monitoring in initiating antihypertensive drug treatment in Australian general practice. Med J Aust. 2002 Jun 17;176(12):580-3.	Australian costing - compare the cost of ambulatory blood pressure monitoring (ABPM) with the putative savings made through treatment avoided by identification and nontreatment of those with "white coat" hypertension.	https://www.ncbi.nlm.nih.gov/pubmed/12064956	2002

	Type of study design* ECONOMICS	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
2.		Costa et al. Cost-effectiveness of ambulatory blood pressure monitoring in the management of hypertension. Rev Port Cardiol. 2017 Feb;36(2):129-139.	The evidence shows that ABPM is cost-effective, avoiding iatrogenic effects and reducing expenditure on treatment (grade of recommendation B). The included studies provide a solid basis, but further evidence of reproducibility is needed in research that is not based mainly on analytical models.	https://www.ncbi.nlm.nih.gov/pubmed/28159431	2017
3.		Pessanha et al. Diagnostic value and cost-benefit analysis of 24 hours ambulatory blood pressure monitoring in primary care in Portugal. BMC Cardioasc Disord. 2013 Aug 12;13:57.	In PC, the widespread use of ABPM in newly diagnosed HTs increases diagnostic accuracy of hypertension, improves cardiovascular risk stratification, reduces health expenses showing a highly favourable benefit-cost ratio vs a strategy without ABPM.	https://www.ncbi.nlm.nih.gov/pubmed/23937261	2013

	Type of study design* ECONOMICS	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
4.	Evidence-Based Analysis	Health Quality Ontario. Twenty-Four-Hour Ambulatory Blood Pressure Monitoring in Hypertension - An Evidence-Based Analysis. Ont Health Technol Assess Ser. 2012; 12(15): 1–65.	A 2-fold increased risk for CBPM was shown for total combined cardiovascular events (RR, 1.79; 95% CI, 1.03–3.02) over 5 years. Patients using ABPM were more likely to have control of blood pressure (RR, 1.72; 95% CI, 1.18–2.52) and to discontinue drug therapy (RR, 3.61; 95% CI, 2.11–6.18) in short-term studies. Ambulatory blood pressure monitoring would save the health system \$19 million (Cdn) over 5 years, with a borderline dominant effect (ICER: \$30 per QALY). The quality of evidence was heterogeneous.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3377518/	2012

18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.	For yet to be published research that may have results relevant to your application, insert the type of study design in this column and columns below	For yet to be published research that may have results relevant to your application, insert the title of research (including any trial identifier if relevant) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a short description of research (max 50 words) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a website link to this research (if available) in this column and columns below	For yet to be published research that may have results relevant to your application, insert date in this column and columns below
2.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
3.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
4.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
5.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
6.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
7.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
8.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
9.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
10.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
11.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
12.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
13.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
14.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
15.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

**Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.

***Date of when results will be made available (to the best of your knowledge).

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

19. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):

Cardiac Society of Australia and New Zealand (CSANZ)

Royal Australian College of General Practitioners (RACGP)

20. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):

Cardiac Society of Australia and New Zealand (CSANZ)

Royal Australian College of General Practitioners (RACGP)

21. List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):

National Heart Foundation of Australia

22. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:

Sponsor	Manufacturer
HealthStats Australia	HealthSTATS International Pte Ltd
Atcor Medical Pty Ltd	SunTech Medical Inc
Australian Sales and Trade Services (ASTS)	Andon Health Co Ltd
Core Diagnostics Pty Ltd	DM Systems (Beijing) Co Limited
Ecomed Pty Ltd	Spacelabs Healthcare Inc
Cellmed Pty Ltd	SunTech Medical Inc
A & D Australasia Pty Ltd	A & D Co Ltd
Welch Allyn Australia Pty Limited	IEM GmbH Industrielle Entwicklung Medizintechnik und Vertriebsgesellschaft mbH
Cardioscan Services Pty Ltd	IEM GmbH Industrielle Entwicklung Medizintechnik und Vertriebsgesellschaft mbH
GE Healthcare Australia Pty Ltd	GE Medical Systems Information Technologies
InMed Healthcare Pty Ltd	Meditech KFT

23. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):

Name of expert 1: REDACTED

Telephone number(s): REDACTED

Email address: REDACTED

Justification of expertise: REDACTED

Name of expert 2: REDACTED

Telephone number(s): REDACTED

Email address: REDACTED

Justification of expertise: REDACTED

PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:

High blood pressure is defined by a measurement taken that $\geq 140/90$ mmHg. The measurement of BP is usually taken using a sphygmomanometer as part of a standard consultation. However, there are two groups of patients that are known to give misleading results.

- Masked hypertension refers to the situation in which clinic measurements are normal but ABP measurements are elevated, which occurs up to 10% of the general population.
- White-coat hypertension (isolated clinic hypertension) refers to the condition in which a person meets criteria for hypertension when measured in the clinic but shows normal BP levels when measured at home or by ABP monitoring. It occurs in approximately 10-20% of the general population.

In 2003, high blood pressure was the greatest attributor to the burden of Cardiovascular disease (CVD) accounting for 42.1% of CVD's total burden.

CVD accounts for 15 percent of the total burden of disease in Australia, second only to cancers at 19 percent of the total burden.

In 2012-13, \$5.0 billion was spent providing health care to admitted patients with CVD. This accounted for 11.1 percent of total admitted health expenditure – the largest share of health expenditure of any disease group.

25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

Patients who have a clinic BP measurement $\geq 140/90$ mmHg and $\leq 180/110$ mmHg.

26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

Currently, the management of hypertension is based on a clinic BP reading taken in the doctor's rooms or patient's home. This measurement is taken using a standard sphygmomanometer and is usually part of a standard consultation.

PART 6b – INFORMATION ABOUT THE INTERVENTION

27. Describe the key components and clinical steps involved in delivering the proposed medical service:

Standard consultation

Once it has been determined that the patient has a clinic blood pressure reading $\geq 140/90$ mmHg and $\leq 180/110$ mmHg, using the clinic sphygmomanometer the General Practitioner or Specialist in Hypertension has the patient fitted with an ambulatory blood pressure monitor (ABPM) including giving instructions to the patient about wearing the device for the next 24 hours.

Proposed service

The proposed diagnostic service starts when the patient returns to the clinic / doctors rooms after ≥ 24 hours and the monitor is removed. The General Practitioner or Specialist in Hypertension downloads the

data from the monitor, interprets and reviews the results, creates a report and puts together a patient management plan.

28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

Currently there are eleven different brands of ABPM available in Australia. *See answer to Question 22.*

29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

The use of ABPM is not new and has already been incorporated into Guidelines for the management for hypertension worldwide. However, funding of this diagnostic test via the MBS is not currently available.

30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

There are two proposed limitations on the provision of ABPM.

1. A clinic BP measurement $\geq 140/90$ mmHg and $\leq 180/110$ mmHg.
2. A maximum provision of the service twice in one year per patient.

31. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:

N/A

32. If applicable, advise which health professionals will primarily deliver the proposed service:

General Practitioners or Specialists in hypertension management.

33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

No. The downloading of the data from the monitor, interpretation and review of the results, creation of a report and putting together a patient management plan must be done by either a General Practitioner or Specialist in Hypertension management.

34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

Must be done by either a General Practitioner or Specialist in Hypertension management.

35. If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery:

No specific training required but the practitioner must follow the basic manufacturers' Instructions for Use. The European Society of Hypertension has also produced a position paper on ambulatory blood pressure monitoring that provides guideline for the effective use of ambulatory blood pressure monitors. (<https://www.ncbi.nlm.nih.gov/pubmed/24029863>)

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings):

- Inpatient private hospital
- Inpatient public hospital
- Outpatient clinic
- Emergency Department
- Consulting rooms
- Day surgery centre
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

Blood pressure measurements are usually carried out in either the doctor's room or during a home visit.

37. Is the proposed medical service intended to be entirely rendered in Australia?

- Yes
- No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

38. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

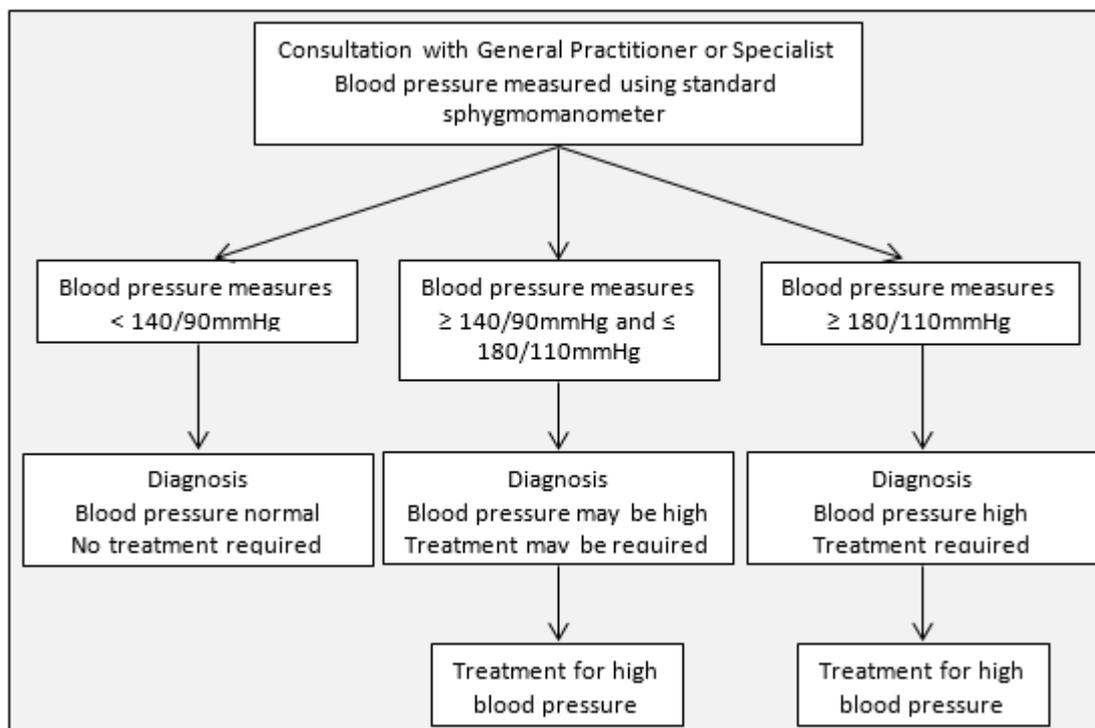
- Non-ambulatory blood pressure measurement carried out by a doctor in either the clinic or as part of a home visit; or
- Multiple non-ambulatory blood pressure measurements taken by the patient in their home.

39. Does the medical service that has been nominated as the comparator have an existing MBS item number(s)?

- Yes (please provide all relevant MBS item numbers below)
- No

Currently covered as part of a standard GP or Specialist consultation.

40. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources):



41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

- Yes

No

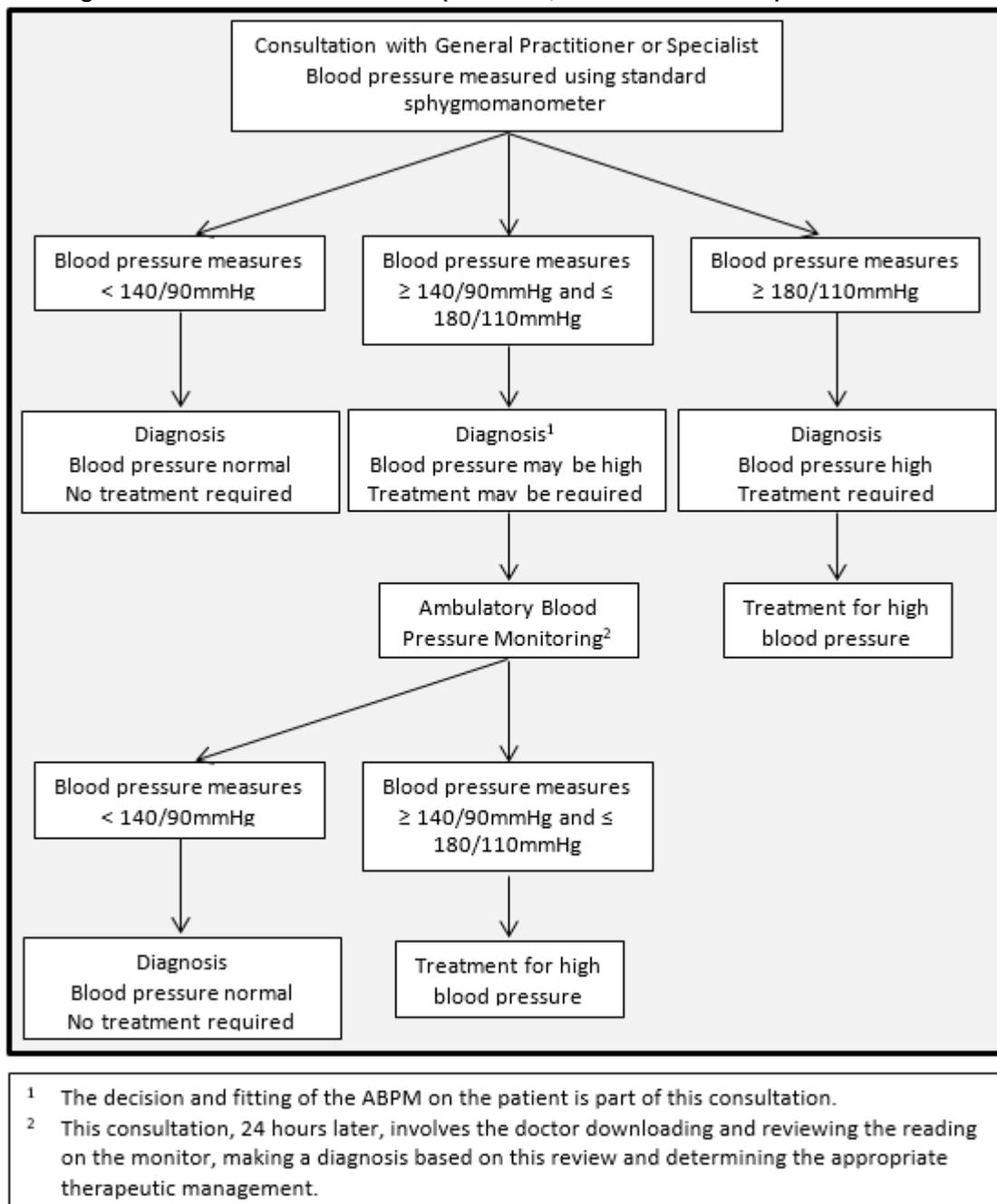
The first comparator, non-ambulatory blood pressure measured by a doctor in the clinic or patient's home, is used to determine if the patient qualifies for ambulatory blood pressure monitoring, that is, has a reading $\geq 140/90\text{mmHg}$ and $\leq 180/110\text{mmHg}$.

The second comparator, multiple non-ambulatory blood pressure measurements taken by the patient in their home, can be used as an alternative to ambulatory blood pressure monitoring.

(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted:

As per the NICE Guidelines, Ambulatory Blood Pressure Monitoring (ABPM) is preferred over patient administered home monitoring.

42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline):



PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

43. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

- A decrease in premature deaths due to Cardiovascular disease (CVD) as a consequence of better controlled blood pressure as a consequence of more accurate diagnosis.
- A reduction in the treating of patients who don't have high blood pressure but suffer from white coat hypertension.
- A reduction in the adverse events due to treating patient misdiagnosed with high blood pressure.

44. Please advise if the overall clinical claim is for:

- Superiority
 Non-inferiority

45. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety Outcomes:

- A reduction in the adverse events due to treating patient misdiagnosed with high blood pressure.

Clinical Effectiveness Outcomes:

More appropriate treatment of high blood pressure, resulting from the use of ambulatory blood pressure monitoring, will result in a reduction in the burden of Cardiovascular disease (CVD). CVD refers to all diseases and conditions involving the heart and blood vessels. The main types of CVD in Australia are coronary heart disease, stroke and heart failure/cardiomyopathy.

- In 2003, high blood pressure was the greatest attributor to the burden of Cardiovascular disease (CVD) accounting for 42.1% of CVD's total burden.
- CVD accounts for 15 percent of the total burden of disease in Australia, second only to cancers at 19 percent of the total burden.
- In 2012-13, \$5.0 billion was spent providing health care to admitted patients with CVD. This accounted for 11.1 percent of total admitted health expenditure – the largest share of health expenditure of any disease group.

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

46. Estimate the prevalence and/or incidence of the proposed population:

2011-12 - Measured high/very high blood pressure ($\geq 140/90$ mmHg to $\leq 180/110$ mmHg)*

% of population	Males	Females	Persons
Taking hypertension medication	6.9	7.0	7.0
Not taking hypertension medication	15.3	11.3	13.3
<i>Total high/very high measured blood pressure</i>	22.2	18.3	20.2

* Australian Health Survey: Health Service Usage and Health Related Actions, 2011–12

2014/15 - Prevalence of uncontrolled or unmanaged high blood pressure (includes $\geq 180/110$ mmHg)*

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%

* Australian Bureau of Statistics. Australian Health Survey 2014/15 (4364.0).

In 2014/15, the overall prevalence of uncontrolled or unmanaged high blood pressure was 23% (including $\geq 180/110$ mmHg).

47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

The proposed service would be funded up to a maximum of two services per year.

48. How many years would the proposed medical service(s) be required for the patient?

N/A

49. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

The potential patient population would be made up of two groups of patients. Firstly, patient with high blood pressure who are taking hypertension medication (7% of the population). Secondly, patients newly diagnosed with clinic blood pressure $\geq 140/90$ mmHg who the doctor suspects may have an elevated pressure due to white coat syndrome, for example (20% of newly diagnosed). Assuming a total of 10% of the total population is the potential patient population, that is, 250,000, the estimated projected patient population in the first year could be 10%, that is, 25,000.

50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

Predicted growth could be based on a doubling of the population each year. This would give 25,000 for the first year, 50,000 for the second year and 100,000 for the third. *(It's freely admitted that these estimates are closer to guesstimates!)*

PART 8 – COST INFORMATION

51. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

REDACTED

52. Specify how long the proposed medical service typically takes to perform:

REDACTED

53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Category 2 - DIAGNOSTIC PROCEDURES AND INVESTIGATIONS

Group D1 - Miscellaneous Diagnostic Procedures and Investigations

MBS Item 116XX

Continuous blood pressure recording of ambulatory patient for 24 or more hours (including resting blood pressure and the recording of parameters), not in association with ambulatory ECG monitoring, involving microprocessor based analysis equipment, interpretation and report of recordings by a general practitioner or specialist in hypertension.

For a patient who:

- Measures $\geq 140/90$ mmHg and $\leq 180/110$ mmHg using a sphygmomanometer
- Max two times per year

Fee: \$127.90 Benefit: 75% = \$95.95 85% = \$108.75

PART 9 – FEEDBACK

The Department is interested in your feedback.

54. How long did it take to complete the Application Form?

Insert approximate duration here

55. (a) Was the Application Form clear and easy to complete?

- Yes
- No

(b) If no, provide areas of concern:

Describe areas of concern here

56. (a) Are the associated Guidelines to the Application Form useful?

- Yes
- No

(b) If no, what areas did you find not to be useful?

Insert feedback here

57. (a) Is there any information that the Department should consider in the future relating to the questions within the Application Form that is not contained in the Application Form?

- Yes
- No

(b) If yes, please advise:

Insert feedback here