



1150 Connecticut Ave., NW | Suite 300 | Washington, DC 20036
P 202-785-7900 | F 202-785-7950 | www.heart.org

330 N. Wabash Ave. | Suite 39300 | Chicago, IL 60611-5885
P 312-464-5000 | F 312-464-4184 | www.ama-assn.org

May 18, 2018

Tamara Syrek-Jensen, J.D.
Director, Evidence and Analysis Group, Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd., C1-14-15
Baltimore, MD 21244

Via email: Tamara.Syrek-Jensen@cms.hhs.gov

Formal National Coverage Determination Request for Reconsideration of an Existing National Coverage Determination: Ambulatory Blood Pressure Monitoring

Dear Ms. Syrek-Jensen:

On behalf of the American Heart Association and the American Medical Association, we are pleased to co-submit the attached documents which represent a request for NCD Reconsideration for coverage of ambulatory blood pressure monitoring (ABPM) to diagnose hypertension in Medicare beneficiaries. This change would align Medicare coverage policy with the 2016 recommendation of the U.S. Preventive Services Task Force (USPSTF).

Improving the diagnosis and control of high blood pressure is an organizational priority for both of our organizations. Launched in 2016, Target: BP™ is a national collaboration between the American Heart Association and the American Medical Association, to reduce the number of Americans who have heart attacks and strokes by urging medical practices, health service organizations and patients to prioritize blood pressure control. Target: BP aims to increase awareness, engagement and action of health care providers and patients by educating them on steps they can take to help improve blood pressure control and, in turn, prevent the progression to serious or sometimes deadly co-morbid conditions, with a shared commitment to increase the national blood pressure control rate to 70 percent or higher. Together our collective efforts will galvanize more physician practices and health care organizations across the country to prioritize blood pressure control within the patient populations they serve.

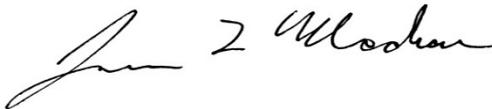
Our organizations have also identified it as a priority to improve coverage of the evidence-based practices that support better diagnosis and control of high blood pressure. To this end, enclosed is a formal request for reconsideration, which includes a summary of new evidence in support of ABPM since CMS last considered an NCD. We have also enclosed a detailed evidence review describing the USPSTF recommendation, current professional society guidelines, and recent peer-reviewed literature related to ABPM to serve as a comprehensive evidence base that supports an expansion of the current NCD.

The American Heart Association and the American Medical Association are grateful for the guidance CMS has provided in informing this NCD request to date. Please do not hesitate to contact Madeleine Konig at madeleine.konig@heart.org or 202-785-7930 should you require any additional information.

Sincerely,



John Warner, MD, FAHA
President
American Heart Association



James L. Madara, MD
Executive Vice President, CEO
American Medical Association

**Formal Request for Reconsideration of an Existing National Coverage Determination:
Ambulatory Blood Pressure Monitoring (20.19)
May 2018**

Request for NCD Reconsideration

Accurate diagnosis of hypertension is crucial. Formal diagnosis of hypertension, as defined by the American Heart Association (AHA) and American College of Cardiology (ACC), occurs when individuals have an office systolic blood pressure ≥ 130 mm Hg or diastolic blood pressure ≥ 80 mm Hg (newly revised from an earlier 140/90 mm Hg standard).^{i,ii} Of the more than 55.5 million Medicare beneficiaries in the United States,ⁱⁱⁱ 55 percent have hypertension, including nearly 40 percent of disabled Medicare beneficiaries and over 58 percent of aged Medicare beneficiaries, according to 2015 administrative claims data from the Centers for Medicare and Medicaid Services (CMS);^{iv} rates under the new definition of hypertension will likely be higher. Further, there are significant racial disparities in hypertension prevalence: while approximately 55 percent of non-Hispanic white Medicare beneficiaries have hypertension, the prevalence rate among black Medicare beneficiaries is 62.5 percent.^v

Cardiovascular disease (CVD) has been the leading cause of death in the United States for almost a century^{vi,vii} and, of CVD attributable deaths, more than nine percent are because of high blood pressure.^{viii} Fortunately, blood pressure management, along with not smoking, eating a healthy diet, engaging in physical activity, maintaining a healthy weight, and controlling diabetes and elevated lipid levels can prevent approximately 80 percent of CVDs.^{ix} CMS itself has called hypertension “the most important modifiable risk factor for coronary heart disease... stroke... congestive heart failure, and end-stage renal disease.”^x

CVD is also enormously costly. Direct medical costs for CVD are some of the most expensive in the healthcare industry, exceeding expenditures for other costly diseases like Alzheimer’s and diabetes.^{xi} In 2016, CVD cost the United States \$555 billion including \$318 billion in direct medical costs and another \$237 billion in indirect costs (e.g. lost work productivity).^{xii} By 2035, CVD will cost an estimated \$1.1 trillion (\$749 billion direct, \$368 billion indirect).^{xiii} High blood pressure accounts for the second largest expenditure among CVD; in 2016, the United States spent \$68 billion for high blood pressure and will spend an estimated \$154 billion in 2035.^{xiv} This projected increase in expenditure will be driven by the aging US population particularly as Baby Boomers become eligible for Medicare.^{xv} Estimates suggest Baby Boomers ages 80 and older will be the largest driver of CVD expenditure increase by 2035.^{xvi} A more accurate diagnosis of hypertension can prevent hospitalizations, overtreatment, and other costly CVD-related outcomes, both direct and indirect, ultimately saving important resources for Medicare.

New Evidence Supports a Reconsideration

A large body of evidence amassed since CMS last reviewed this benefit supports ambulatory blood pressure monitoring (ABPM) as an effective diagnostic tool to correctly diagnose HBP/hypertension.^{xvii,xviii,xix,xx,xxi,xxii,xxiii,xxiv}

Currently, ABPM is covered only in cases of suspected white coat hypertension (WCH). Suspected WCH, as currently defined by CMS, occurs when patients have an “office blood pressure $>140/90$ mm Hg on at least three clinic/office visits with two separate measurements made at each visit.”^{xxv} CMS further defines WCH to include “at least two blood pressure measurements taken outside the office which are $<140/90$ mm Hg...[along with] no evidence of end-organ damage.”^{xxvi}

CMS’s decision to cover ABPM for cases of suspected white-coat hypertension was made in 2001; minor modifications specifying that a physician must review the ABPM data were made in 2003.^{xxvii} In

the fifteen years since, researchers have devoted considerable research to ascertaining the diagnostic value of ABPM and found it to be an effective, evidence-based tool in circumstances beyond suspected WCH (see evidence review included in submission). In the most recent guidelines that AHA released with the American College of Cardiology (ACC), along with the American Academy of Physician Assistants (AAPA), Association of Black Cardiologists (ABC), American College of Preventive Medicine (ACPM), American Geriatrics Society (AGS), American Pharmacists Association (APhA), American Society of Hypertension (ASH), American Society for Preventive Cardiology (ASPC), National Medical Association (NMA), and Preventive Cardiovascular Nurses Association (PCNA),^{xxviii} we recommend ABPM for a broader set of indications.

This National Coverage Determination Reconsideration request seeks to expand Medicare coverage for ABPM. While considerable evidence also supports the use of ABPM in the context of treatment and blood pressure management, this request focuses on diagnosis.

In support of this request, we have provided information from recent peer reviewed literature that demonstrates the evidence and the benefits of ABPM as a diagnostic test for a range of patients both with and without elevated office blood pressure. The evidence in support of such a determination is summarized below. Further detail on this evidence is available in the accompanying evidence review.

Benefit category

The proposed benefit would fall under the following benefit category:

- Diagnostic Tests (other)

Submitted by

- American Heart Association (AHA)
- American Medical Association (AMA)

Description of Service

There are currently four current procedural terminology (CPT) codes related to ambulatory blood pressure monitoring:

- 93784: Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; including recording, scanning analysis, interpretation and report
- 93786: recording only
- 93788: scanning analysis with report
- 93790: review with interpretation and report

CMS defines ABPM as involving “the use of a non-invasive device, which is used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted at the physician’s office. ABPM must be performed for at least 24 hours to meet coverage criteria.”^{xxix}

Since April 1, 2002, coverage for ABPM has been limited to beneficiaries with suspected “white coat hypertension.” CMS currently defines suspected “white coat hypertension” as:

- Office blood pressure >140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit;
- At least two documented separate blood pressure measurements taken outside the office which are < 140/90 mm Hg; and
- No evidence of end-organ damage.

ABPM is not presently covered for any other uses. This NCD Reconsideration request seeks to expand coverage for ABPM in accordance with the indications listed below.

Description of Proposed Use of Service for Identified Medical Conditions in Target Medicare Population and Medical Conditions for Which It Can Be Used

In 2017, AHA/ACC released a set of guidelines for the prevention, detection, evaluation, and management of high blood pressure in adults.^{xxx} These guidelines included recommended applications of ABPM. Broadly, AHA/ACC recommends out-of-office BP measurements to confirm the diagnosis of hypertension. Specific recommendations are:

1. In adults with an untreated systolic blood pressure (SBP) greater than 130 mm Hg but less than 160 mm Hg or diastolic blood pressure (DBP) greater than 80 mm Hg but less than 100 mm Hg, it is reasonable to screen for the presence of white coat hypertension by using either daytime ABPM or HBPM before diagnosis of hypertension [moderate recommendation, is reasonable].
2. In adults with white coat hypertension, periodic monitoring with either ABPM or HBPM is reasonable to detect transition to sustained hypertension [moderate recommendation].
3. In adults being treated for hypertension with office BP readings not at goal and HBPM readings suggestive of a significant white coat effect, confirmation by ABPM can be useful [moderate recommendation, is reasonable].
4. In adults with untreated office BPs that are consistently between 120 mm Hg and 129 mm Hg for SBP or between 75 mm Hg and 79 mm Hg for DBP, screening for masked hypertension with HBPM (or ABPM) is reasonable [moderate recommendation].
5. In adults on multiple-drug therapies for hypertension and office BPs within 10 mm Hg above goal, it may be reasonable to screen for white coat effect with HBPM or ABPM [weak recommendation, may be reasonable].
6. In adults being treated for hypertension with elevated HBPM readings suggestive of masked uncontrolled hypertension, confirmation of the diagnosis by ABPM might be reasonable before intensification of antihypertensive drug treatment [weak recommendation may be reasonable].

Indications

Based on the guidelines noted above, we request coverage of ABPM for the diagnosis of hypertension.

Recommendation for a Clinically-Beneficial Application of Ambulatory Blood Pressure Monitoring for the Target Medicare Population

Compilation of Supporting Medical and Scientific Evidence for Medical Benefit

The United States Preventive Services Task Force commissioned an evidence review by the Kaiser Permanente Research Affiliates Evidence-based Practice Center and released a recommendation in 2015 in support of screening for adults for high blood pressure and “obtaining measurements outside the clinical setting for diagnostic confirmation before treatment.”^{xxxii} USPSTF made the following conclusion regarding the evidence on ABPM:

The USPSTF found convincing evidence that ABPM is the best method for diagnosing hypertension. Although the criteria for establishing hypertension varied across studies, there was significant discordance between the office diagnosis of hypertension and 12- and 24-hour average blood pressures using ABPM, with significantly fewer patients requiring treatment based on ABPM (Figure 1).³⁰ Elevated ambulatory systolic blood pressure was consistently and significantly associated with increased risk for fatal and nonfatal stroke and cardiovascular events, independent of office blood pressure (Figure 2).³⁰ **For these reasons, the USPSTF recommends ABPM as the reference standard for confirming the diagnosis of hypertension.**^{xxxii} (emphasis added)

The AHA evidence review submitted with this NCD request outlines the relevant peer-reviewed literature on ABPM published since that time. Specifically, this review focuses on the most recent

evidence on ABPM's efficacy as a diagnostic tool, its ability to prevent overtreatment, its predictive capabilities, and how ABPM is currently used in the physician office setting. The evidence review contains detailed descriptions of relevant studies, their results, and full references for CMS's consideration. The following section briefly summarizes this evidence.

ABPM as a diagnostic tool

Research demonstrates that ABPM is a superior diagnostic tool compared to office based blood pressure monitoring (OBPM).^{xxxiii,xxxiv,xxxv,xxxvi} ABPM has superior specificity and sensitivity compared to OBPM, and best practices suggest it is clinically important for confirmation of hypertension diagnosis.^{xxxvii} ABPM measurements are generally lower than those obtained by OBPM in the same patients^{xxxviii} which suggests a white-coat effect CMS has already deemed worthy of Medicare coverage.

ABPM is also useful for diagnosing a number of other conditions beyond suspected WCH, including masked hypertension^{xxxix,xi} and elevated BP during sleep.^{xli} These conditions are no less significant public health issue than WCH which is currently covered by Medicare; an estimated 12.3 percent of US adults ages 21 and older have masked hypertension, including 28 percent of adults over the age of 65.^{xlii} Further, elderly individuals, those with type 2 diabetes, chronic kidney disease and treatment resistant hypertension are at increased risk for elevated nighttime BP.^{xliii,xliv}

ABPM as a means to prevent overtreatment

Because of its superior effectiveness, ABPM can help prevent overtreatment stemming from misdiagnosis of hypertension. This is especially important among older adults. In one study, ABPM revealed around one third of elderly patients receiving hypertension treatment were at risk for hypotension, and more than half of patients were actually hypotensive.^{xlv} Falls due to low blood pressure among the elderly can restrict mobility, either from physical injury or fear of subsequent falls,^{xlvi} making it especially important that clinicians not subject their elderly patients to antihypertensive treatment that is unnecessary at best, and potentially harmful at worst.

A systemic review conducted on behalf of the United States Preventive Services Task Force found between 35 and 95 percent of individuals with hypertension based on OBPM measurements were still categorized as hypertensive after ABPM,^{xlvii} indicating that OBPM has an inconsistent predictive value and warrants confirmation through ABPM. From the population perspective, reclassifying individuals from hypertension to normotension (because of WCH) and normotension to hypertension (because of masked hypertension) may have little net effect on proportions of the two classifications.^{xlviii} Nevertheless, from the individual perspective, ABPM can reduce misclassification to facilitate treatment tailored to an individual patient's accurate blood pressure patterns and thus can reduce overtreatment and the associated risks.^{xlix}

Predictive and preventive capabilities of ABPM

Ambulatory blood pressure is an important predictor of a number of health outcomes and, as such, ABPM presents an effective preventive tool for clinicians and patients. Target organ damage (TOD) due to hypertension can affect the heart, kidneys, and brain and increase risk of negative health outcomes including heart failure and myocardial infarction, renal failure, and stroke.^l^{li} ABPM is a better predictor of TOD than OBPM,^{lii} including, but not limited to cardiovascular events.^{liii} When analyzed with biomarkers like amino-terminal pro-B-type natriuretic peptide (NT-proBNP), ABPM has potential to better predict atherosclerotic cardiovascular disease.^{liv}

ABPM is well suited to identify hidden forms of hypertension, such as non-dipping or reverse-dipping (i.e. blood pressure that does not decrease during sleep or actually increases during sleep), that are prevalent among chronic kidney disease (CKD) patients, along with sustained or masked

hypertension.^{lv, lvi} ABPM may also assist in controlling ambulatory blood pressure to prevent cognitive decline, depression, decreases in physical mobility,^{lvii} increases in white matter hyperintensity volume,^{lviii} and enlarged perivascular spaces in the brain.^{lix} This is especially important among the aged Medicare population where cognitive and physical decline may lead to transition from the home and/or community to long-term care facilities.

ABPM in clinical practice

Assessing the usage and effectiveness of ABPM under typical clinical conditions is an integral step in understanding the potential benefit expanding coverage of ABPM under Medicare could have.

For the purposes of clinical practice, ABPM provides several distinct advantages^{lx}:

- Ambulatory blood pressure monitoring allows multiple blood pressure readings to be taken across a 24-hour period compared to OBPM which only allows for the measurement of blood pressure at a clinic visit.
- US and international guidelines strongly recommend the use of ambulatory blood pressure monitoring in clinical practice.
- Using ambulatory blood pressure monitoring to rule out white-coat hypertension prevents patients from being prescribed unnecessary antihypertensive medications.
- Using ambulatory blood pressure monitoring to identify masked hypertension identifies patients who do not have high office blood pressure but are at high cardiovascular disease risk.
- Ambulatory blood pressure monitoring also allows measurement of nocturnal blood pressure, an increasingly important prognostic parameter for cardiovascular disease risk.

However, in surveys, many clinics and clinicians report a lack of access to ABPM^{lxi, lxii} and, perhaps because of this, many physicians report *not* having used ABPM to confirm hypertension diagnosis.^{lxiii} Providers reported difficulty accessing testing centers and the cost of ABPM as the primary barriers for implementing ABPM.^{lxiv}

Reasoning for How Coverage of ABPM Will Help Improve Medical Benefit to the Target Population

The evidence outlined in this document and the supporting evidence review reinforces the case for ABPM as a diagnostic tool for patients with and without elevated OBPM, yet Medicare only covers for ABPM for patients with elevated OBPM when WCH is suspected. Medicare beneficiaries would benefit considerably from an expansion of coverage for ABPM, particularly elderly Medicare beneficiaries. ABPM has been shown to be effective at diagnosing a number of blood pressure patterns and comorbid conditions prevalent in the Medicare population which can help ensure Medicare beneficiaries receive appropriate treatment tailored to their individual health needs.

ABPM is also an effective diagnostic tool to preventing overtreatment, a particularly problematic phenomenon among aged Medicare beneficiaries who may experience physical and psychological harm from overly-aggressive antihypertensive treatment that could lead to dangerous drops in blood pressure and subsequent falls. ABPM is well suited to predict and prevent disease, as ambulatory blood pressure is associated with a number of negative health outcomes and blood pressure control is associated with reduced risk of these outcomes.

-
- ⁱ Benjamin, E. J., Blaha, M. J., Chiuve, S. E., Cushman, M., Das, S. R., Deo, R., ... & Jiménez, M. C. (2017). Heart disease and stroke statistics-2017 update: a report from the American Heart Association. *Circulation*, *135*(10), e146-e603.
- ⁱⁱ Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., ... & MacLaughlin, E. J. (2017). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*, *24430*.
- ⁱⁱⁱ Centers for Medicare and Medicaid Services. Medicare Enrollment Dashboard. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/Dashboard.html>
- ^{iv} Centers for Medicare and Medicaid Services. Chronic Conditions. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main.html
- ^v *Id.*
- ^{vi} National Center for Health Statistics. (2014). Mortality multiple cause micro-data files. public-use data file and documentation: NHLBI tabulations. http://www.cdc.gov/nchs/data_access/Vitalstatsonline.htm#Mortality_Multiple.
- ^{vii} Ford ES, Ajani UA, Croft JB, Critchley JA, Labarthe DR, Kottke TE, Giles WH, Capewell S. (2007). Explaining the decrease in U.S. deaths from coronary disease, 1980-2000. *New England Journal of Medicine*. *356*:2388–2398. doi: 10.1056/NEJMsa053935.
- ^{viii} Benjamin, E. J., Blaha, M. J., Chiuve, S. E., Cushman, M., Das, S. R., Deo, R., ... & Jiménez, M. C. (2017). Heart disease and stroke statistics-2017 update: a report from the American Heart Association. *Circulation*, *135*(10), e146-e603.
- ^{ix} *Id.*
- ^x Centers for Medicare and Medicaid Services. (2015). Hypertension. https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Dwnld-DataSnapshot-Hypertension.pdf
- ^{xi} American Heart Association, & American Stroke Association. (2017). Cardiovascular disease: a costly burden for America. Projections through 2035.
- ^{xii} *Id.*
- ^{xiii} *Id.*
- ^{xiv} *Id.*
- ^{xv} *Id.*
- ^{xvi} *Id.*
- ^{xvii} Grezzana, Guilherme, et al. Impact of Different Normality Thresholds for 24-hour ABPM at the Primary Health Care Level. *Sociedade Brasileira De Cardiologica*. 2016. Available Online. DOI: 10.5935/abc.20160204
- ^{xviii} Hao, Zirui, et al. Relationship and associated mechanisms between ambulatory blood pressure and clinic blood pressure with prevalent cardiovascular disease in diabetic hypertensive patients. *Medicine*. 2017 April; *96*(16): doi: 10.1097/MD.00000000000006756.
- ^{xix} Wang, Y Claire, et al. Prevalence of Masked Hypertension Among US Adults With Nonelevated Clinic Blood Pressure. *American Journal of Epidemiology*. 2017; *185*(3). [EPub ahead of print; Full access pending]
- ^{xx} Gijón-Conde, T., Graciani, A., López-García, E., Guallar-Castillón, P., García-Esquinas, E., Rodríguez-Artalejo, F., & Banegas, J. R. (2017). Short-term variability and nocturnal decline in ambulatory blood pressure in normotension, white-coat hypertension, masked hypertension and sustained hypertension: a population-based study of older individuals in Spain. *Hypertension Research*. *40*(6), 613.
- ^{xxi} O'Brien E, Parati G, Stergiou G, et al. European Society of Hypertension position paper on ambulatory blood pressure monitoring. *J Hypertens*. 2013;**31**:1731–1768.
- ^{xxii} Zhang, S., et al. The relationship between AASI and arterial atherosclerosis in ESRD patients. *Renal Failure*. 2015 Fe; *37*(1): 22-28.
- ^{xxiii} Maricoto, Tiago, et al. The OXIMAPA Study: Hypertension Control by ABPM and Association with Sleep Apnea Syndrome by Pulse Oximetry. *Acta Médica Portuguesa*. 2017; *30*(2): 93-99.
- ^{xxiv} Vichayanrat, E., et al. Twenty-four-hour ambulatory blood pressure and heart rate profiles in diagnosing orthostatic hypotension in Parkinson's disease and multiple system atrophy. *European Journal of Neurology*. 2017; *24*: 90-97.
- ^{xxv} Centers. for Medicare & Medicaid Services. (2001, Oct, 17). Decision Memo for Ambulatory Blood Pressure Monitoring. <https://www.cms.gov/medicare-coverage-database/details/nca-decision->

memo.aspx?NCAId=5&NcaName=Ambulatory+Blood+Pressure+Monitoring&ver=9&from=%252527lmpstate%252527&contractor=22&name=CIGNA+Government+Services+(05535)+
+Carrier&letter_range=4&bc=gCAAAAAAIAAA

xxvi *Id.*

xxvii Centers for Medicare & Medicaid Services. (2003, Jan, 16). Decision Memo for Ambulatory Blood Pressure Monitoring <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=6&NCDId=254&ncdver=2&ver=6&TAId=27&IsPopup=y&bc=AAAAAAAACAAAAA%3d%3d&>

xxviii Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., ... & MacLaughlin, E. J. (2017). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*, 24430.

xxix Centers for Medicare and Medicaid Services. (2001, Dec. 18). Coverage and Billing of Ambulatory Blood Pressure Monitoring (ABPM). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/AB01188.pdf>

xxx Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., ... & MacLaughlin, E. J. (2017). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*, 24430.

xxxi U.S. Preventive Services Task Force. (2017). Final Recommendation Statement: High Blood Pressure in Adults: Screening. <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/high-blood-pressure-in-adults-screening>

xxxii *Id.*

xxxiii Morrin, Niamh M., Stone, Mark R. and Keiran J. Henderson. Reproducibility of 24-h ambulatory blood pressure and measures of autonomic function. *Blood Pressure Monitoring*. 2017 June; 22(3): 169-172.

xxxiv Banegas, José R., et al. Clinic Versus Daytime Ambulatory Blood Pressure Difference in Hypertensive Patients The Impact of Age and Clinic Blood Pressure. *Hypertension*. 2017 February; 69:211-219.

xxxv Grezzana, Guilherme, et al. Impact of Different Normality Thresholds for 24-hour ABPM at the Primary Health Care Level. *Sociedade Brasileira De Cardiologica*. 2016. Available Online. DOI: 10.5935/abc.20160204

xxxvi Jegatheswaran, Januvi, et al. Are Automated Blood Pressure Monitors Comparable to Ambulatory Blood Pressure Monitors? A Systematic Review and Meta-analysis. *Canadian Journal of Cardiology*. 2017 May; 33(5): 644-652.

xxxvii Reino-González, Sergio, et al. Validity of clinic blood pressure compared to ambulatory monitoring in hypertensive patients in a primary care setting. *Blood Pressure*. 2015 April; 24(2): 111-118.

xxxviii *Id.*

xxxix Franklin, SS, O'Brien, E and JA Staessen. Masked hypertension: understanding its complexity. *European Heart Journal*. 2017 April; 38(15): 1112-1118.

xl Wang, Y Claire, et al. Prevalence of Masked Hypertension Among US Adults With Nonelevated Clinic Blood Pressure. *American Journal of Epidemiology*. 2017; 185(3). [EPub ahead of print; Full access pending].

xli Hermida, Ramón C., et al. Sleep-time blood pressure: Unique sensitive prognostic marker of vascular risk and therapeutic target for prevention. *Sleep Medicine Reviews*. 2017 June;33:17-27

xlii Wang, Y Claire, et al. Prevalence of Masked Hypertension Among US Adults With Nonelevated Clinic Blood Pressure. *American Journal of Epidemiology*. 2017; 185(3). [EPub ahead of print; Full access pending].

xliiii Hermida RC, Moya A, Ayala DE. Ambulatory blood pressure monitoring in diabetes for the assessment and control of vascular risk. *Endocrinología y Nutrición*. 2015 Oct; 62(8);400-410

xliiv Hermida, Ramón C., et al. Sleep-time blood pressure: Unique sensitive prognostic marker of vascular risk and therapeutic target for prevention. *Sleep Medicine Reviews*. 2017 June;33:17-27

xlv Divisón-Garrote, Juan A, et al. Magnitude of Hypotension Based on Office and Ambulatory Blood Pressure Monitoring: Results From a Cohort of 5066 Treated Hypertensive Patients Aged 80 Years and Older. *J Am Med Dir Assoc*. 2017 May; 18(5):452.e1-452.e6

xlvi Prudham, D., & Evans, J. G. (1981). Factors associated with falls in the elderly: a community study. *Age and ageing*, 10(3), 141-146.

-
- xlvii Piper, Margaret A., et al. Diagnostic and Predictive Accuracy of Blood Pressure Screening Methods With Consideration of Rescreening Intervals: A Systematic Review for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*. 2015 Feb; 162(3):192-204
- xlviii O'Flynn AM, Curtin RJ, Perry IJ, Kearney PM. Hypertension prevalence, awareness, treatment, and control: Should 24-hour ambulatory blood pressure monitoring be the tool of choice? *The Journal of Clinical Hypertension*. 2016 Nov; 18(7):697-702.
- xlix *Id.*
- ⁱ Mensah, G. A., Croft, J. B., & Giles, W. H. (2002). The heart, kidney, and brain as target organs in hypertension. *Cardiology clinics*, 20(2), 225-247.
- ⁱⁱ Nadar, S. K., Tayebjee, M. H., Messerli, F., & Lip, G. Y. (2006). Target organ damage in hypertension: pathophysiology and implications for drug therapy. *Current pharmaceutical design*, 12(13), 1581-1592.
- ⁱⁱⁱ Yang, Y, et al. Ambulatory versus clinic blood pressure in predicting overall subclinical target organ damage progression in essential hypertensive patients: a 3-year follow-up study. *Blood Pressure Monitoring*. 2016 Dec; 21(6): 319-326.
- ⁱⁱⁱⁱ Conen, D., & Bamberg, F. (2008). Noninvasive 24-h ambulatory blood pressure and cardiovascular disease: a systematic review and meta-analysis.
- ^{lv} Skoglund, Per H., et al. Amino-Terminal Pro-B-Type Natriuretic Peptide Improves Discrimination for Incident Atherosclerotic Cardiovascular Disease Beyond Ambulatory Blood Pressure in Elderly Men. *Hypertension*. 2015; 66: 681-686.
- ^{lv} Oh, YK, et al. Discrepancies in Clinic and Ambulatory Blood Pressure in Korean Chronic Kidney Disease Patients. *Journal of Korean Medical Sciences*. 2017 May; 32(5): 772-781
- ^{lvi} Cunha, Catia, et al. 24-hour ambulatory blood pressure monitoring in chronic kidney disease and its influence on treatment. *Portuguese Journal of Nephrology and Hypertension*. 2017 March; 31(1): 31-36. Advanced Access Copy Retrieved from: http://www.bbg01.com/cdn/rsc/spnefro/advaccess/61/n1_2017_pjnh_07.pdf
- ^{lvii} Wolfson, Leslie, et al. Rapid Buildup of Brain White Matter Hyperintensities Over 4 Years Linked to Ambulatory Blood Pressure, Mobility, Cognition, and Depression in Old Persons. *Journals of Gerontology: Medical Sciences*. Nov 2013; 68(11): 1387-1394
- ^{lviii} White, W. B., Wolfson, L., Wakefield, D. B., Hall, C. B., Campbell, P., Moscufo, N., ... & Guttmann, C. R. (2011). Average Daily Blood Pressure, Not Office Blood Pressure, Is Associated With Progression of Cerebrovascular Disease and Cognitive Decline in Older People Clinical Perspective. *Circulation*, 124(21), 2312-2319.
- ^{lix} Yang, S, et al. Higher ambulatory systolic blood pressure independently associated with enlarged perivascular spaces in basal ganglia. *Neurological Research*. 2017 May: 1-8. [EPub ahead of print; Full access pending].
- ^{lx} Turner JR, Viera AJ, Shimbo D. Ambulatory blood pressure monitoring in clinical practice: A review. *American Journal of Medicine*. 2015 Jan;128(1):14-20.
- ^{lxi} Woolsey, Sarah, et al. Diagnosing Hypertension in Primary Care Clinics According to Current Guidelines. *Journal of the American Board of Family Medicine*. 2017 March/April: 30(2): 170-177.
- ^{lxii} Carter BU, Kaylor MB. The use of ambulatory blood pressure monitoring to confirm a diagnosis of high blood pressure by primary-care physicians in Oregon. *Blood Pressure Monitoring*. 2016 Apr;21(2):95-102.
- ^{lxiii} *Id.*
- ^{lxiv} Kronish, I. M., Kent, S., Moise, N., Shimbo, D., Safford, M. M., Kynerd, R. E., ... & Muntner, P. (2017). Barriers to conducting ambulatory and home blood pressure monitoring during hypertension screening in the United States. *Journal of the American Society of Hypertension*, 11(9), 573-580.

Evidence Review in Support of a National Coverage Determination

Ambulatory Blood Pressure Monitoring

May 2018

A growing body of evidence supports a national coverage determination (NCD) for ambulatory blood pressure monitoring (ABPM) to better diagnose hypertension, a significant risk factor for cardiovascular disease (CVD). CMS's decision to cover ABPM for cases of suspected white-coat hypertension was made in 2001; minor modifications specifying that a physician must review the ABPM data were made in 2003. In the nearly 15 years since, researchers have devoted considerable research to ascertaining the diagnostic value of ABPM and found it to be an effective, evidence-based tool in circumstances beyond suspected WCH as defined in the current NCD.

The United States Preventive Services Task Force commissioned an evidence review by the Kaiser Permanente Research Affiliates Evidence-based Practice Center and released a recommendation in 2015 in support of screening for adults for high blood pressure and “obtaining measurements outside the clinical setting for diagnostic confirmation before treatment” – namely, as discussed further below, ABPM.¹

Additionally, in 2017, the American Heart Association (AHA) and American College of Cardiology (ACC) released an update to the guidelines for high blood pressure in adults.² These updated guidelines no longer classify individuals as having prehypertension; instead, blood pressure is divided into five categories:

- Normal: less than 120/80 mmHg,
- Elevated: Systolic blood pressure (SBP) between 120-129 mmHg and diastolic blood pressure (DBP) less than 80,
- Stage 1: SBP between 130-139 mmHg or DBP between 80-89 mmHg,
- Stage 2: SBP greater than or equal to 140 mmHg or DBP greater than or equal to 90 mmHg,
- Hypertensive crisis: SBP greater than 180 mmHg and/or DBP greater than 120 mmHg.

In light of evidence surrounding the public health burden caused by hypertension, AHA/ACC recommended adjusting the threshold for hypertension diagnosis so that more patients are offered essential treatment. These new guidelines also recommended wider application of out-of-office BP measurement to confirm hypertension diagnoses: out-of-office BP measurements for confirming the diagnosis of hypertension were a Class I Recommendation (Level of Evidence

¹ U.S. Preventive Services Task Force. (2017). Final Recommendation Statement: High Blood Pressure in Adults: Screening. <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/high-blood-pressure-in-adults-screening>

² Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., ... & MacLaughlin, E. J. (2017). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*.

A). Many hypertension guidelines including from the ACC/AHA consider ABPM to be the superior means to obtain out-of-office blood pressure.

This document provides an updated review of the evidence base on ABPM since CMS' last consideration of an NCD, with emphasis on research published since USPSTF's own systematic review of the literature in 2014. Additionally, this document summarizes guideline recommendations from stakeholder organizations and subject area experts related to ABPM. The remainder of the evidence review is organized into four sections:

- a. ABPM as a diagnostic tool
- b. ABPM diagnostic use as a means of preventing overtreatment
- c. Predictive and preventive capabilities of ABPM
- d. ABPM in clinical practice

I. Professional Recommendations

Many organizations have issued recommendations supporting the use of ABPM as a diagnostic tool. The most notable recent recommendation was issued by the United States Preventive Services Task Force (USPSTF) in 2015. The USPSTF “recommends screening for high blood pressure in adults aged 18 years or older” and “obtaining measurements outside of the clinical setting for diagnostic confirmation before starting treatment.”³ USPSTF made the following conclusion regarding the evidence on ABPM:

The USPSTF found convincing evidence that ABPM is the best method for diagnosing hypertension. Although the criteria for establishing hypertension varied across studies, there was significant discordance between the office diagnosis of hypertension and 12- and 24-hour average blood pressures using ABPM, with significantly fewer patients requiring treatment based on ABPM (Figure 1).³⁰ Elevated ambulatory systolic blood pressure was consistently and significantly associated with increased risk for fatal and nonfatal stroke and cardiovascular events, independent of office blood pressure (Figure 2).³⁰ **For these reasons, the USPSTF recommends ABPM as the reference standard for confirming the diagnosis of hypertension.**⁴ (emphasis added)

The Task Force's conclusion was based on a commissioned systematic review of the evidence surrounding blood pressure monitoring, including ABPM, by the Kaiser Permanente Research Affiliates Evidence-based Practice Center (KPRC EPC). The KPRC EPC reviewed 19,309 abstracts and 1,171 full-text articles published between January 1, 1966 and February 24, 2014 seeking to answer 5 key questions:⁵

³ U.S. Preventive Services Task Force. (2017). Final Recommendation Statement: High Blood Pressure in Adults. <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/high-blood-pressure-in-adults-screening>

⁴ *Id.*

⁵ Piper, M. A., Evans, C. V., Burda, B. U., Margolis, K. L., O'Connor, E., Smith, N., ... & Whitlock, E. P. (2014). Screening for high blood pressure in adults.

1. Does screening for high BP reduce CVD and mortality in adults age 18 years or older?
2. What is the best way to screen for high BP in adults in the primary care setting?
[...]
3. What is the best way to confirm hypertension in adults who initially screen positive for high BP?
 - a. How well do ABPM and home blood pressure monitoring (HBPM) methods predict cardiovascular (CV) events compared with clinic-based methods?
 - b. How accurate are other noninvasive BP measurement methods in establishing or confirming the diagnosis of hypertension compared with these best methods and associated protocols? Does diagnostic accuracy vary by protocol characteristics (i.e., number of visits)?
 - c. Does changing the measurement method from that used during the initial screening improve diagnostic accuracy for some specific patient subgroups (e.g., those with suspected white coat hypertension)?
4. What is the clinically appropriate rescreening interval for patients who have previously been screened and found to have normal BP?
[...]
5. What are the adverse effects of screening for high BP in adults?

For the purposes of this evidence review, key question 3 is of distinct interest.

Eleven studies included in the USPSTF-commissioned systematic review found ABPM can predict stroke and other cardiovascular events, both fatal and non-fatal, independently of office blood pressure monitoring (OBPM).⁶ Using ABPM to confirm a diagnosis of hypertension based originally on office measurements revealed normotensive blood pressure levels in 5 to 65 percent of study participants depending on the study.⁷ False positives for hypertension diagnosis (also known as isolated clinic hypertension,⁸ or white-coat hypertension⁹) are of legitimate clinical concern as such diagnoses can lead to overtreatment, a phenomenon with a robust evidence base discussed later in this document.

Several studies included in the Task Force's systematic review sought to assess development of hypertension in participants by measuring blood pressure at regular intervals (between one and five years depending on the study). For participants with at least one risk factor, hypertension risk reached or exceeded 20 percent at three to five years of follow-up in most studies.¹⁰ These data helped inform USPSTF's recommendation on intervals for blood pressure screening and use of ambulatory blood pressure monitoring. The Task Force recommends annual blood pressure

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ Pickering, T. G., James, G. D., Boddie, C., Harshfield, G. A., Blank, S., & Laragh, J. H. (1988). How common is white coat hypertension?. *Jama*, 259(2), 225-228.

¹⁰ U.S. Preventive Services Task Force. (2017). Final Recommendation Statement: High Blood Pressure in Adults. <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/high-blood-pressure-in-adults-screening>

screening in high-risk patients and every three to five years in lower risk patients (i.e. individuals between the ages of 18 and 39 with no CVD risk factors).¹¹ Where blood pressure is elevated, USPSTF also recommends confirmatory testing with ABPM.

Four studies in the USPSTF-commissioned review dealt with the potential harms associated with ABPM. Reviewers found no evidence of major or long-term negative outcomes from the usage of this diagnostic test.¹² While some patients that used an ABPM device reported minor adverse events such as sleep disturbances, arm discomfort, and restriction of daily activities, these effects did not persist upon completion of the ambulatory blood pressure monitoring period.¹³ Nevertheless, the Task Force acknowledges there may be instances in which ABPM is not possible for an individual. In these cases, USPSTF suggests using home blood pressure monitoring (HBPM).

Ultimately, researchers concluded, “ABPM...is a better predictor of long-term [cardiovascular] outcomes than OBPM...*and should be considered the reference standard for evaluating noninvasive BP measurements*”¹⁴ (emphasis added). The USPSTF recommendation for ABPM is in accordance with this evidence.

In 2017, the new AHA/ACC hypertension guidelines support out-of-office BP measurements to confirm the diagnosis of hypertension and a set of specific recommendations regarding indications for ABPM (see Table 1).

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ Piper, M. A., Evans, C. V., Burda, B. U., Margolis, K. L., O'Connor, E., Smith, N., ... & Whitlock, E. P. (2014). Screening for high blood pressure in adults.

Table 1: ACC/AHA Guideline Recommendations on Out-of-clinic BP Monitoring including ABPM and HBPM¹⁵

COR	LOE	Recommendation
IIa [moderate recommendation]	B-NR [moderate quality, nonrandomized evidence]	In adults with an untreated SBP greater than 130 mm Hg but less than 160 mm Hg or DBP greater than 80 mm Hg but less than 100 mm Hg, it is reasonable to screen for the presence of white coat hypertension by using daytime ABPM or HBPM before diagnosis of hypertension.
IIa [moderate recommendation]	C-LD [limited data]	In adults with white coat hypertension*, periodic monitoring with either ABPM or HBPM is reasonable to detect transition to sustained hypertension.
IIa [moderate recommendation]	C-LD [limited data]	In adults being treated for hypertension with office BP readings not at goal and HBPM readings suggestive of a significant white coat effect, confirmation by ABPM can be useful.
IIa [moderate recommendation]	B-NR [moderate quality, nonrandomized evidence]	In adults with untreated office BPs that are consistently between 120 mm Hg and 129 mm Hg for SBP or between 75 mm Hg and 79 mm Hg for DBP, screening for masked hypertension with ABPM or HBPM is reasonable.
IIb [weak recommendation]	C-LD [limited evidence]	In adults on multiple-drug therapies for hypertension and office BPs within 10 mm Hg above goal, it may be reasonable to screen for white coat effect with HBPM or ABPM
IIb [weak recommendation]	C-EO [consensus expert opinion]	In adults being treated for hypertension with elevated HBPM readings suggestive of masked uncontrolled hypertension, confirmation of the diagnosis by ABPM might be reasonable before intensification of antihypertensive drug treatment

COR: Class of recommendation

LOE: Level of evidence

*Among those not taking antihypertensive medication.

AHA/ACC guideline recommendations are, in part, consistent with USPSTF recommendations. Namely, both recommend ABPM for confirming the diagnosis of hypertension and to rule out white coat hypertension among those with elevated office BP and not taking antihypertensive medication. Additionally, the ACC/AHA guidelines further recommended ABPM for with non-elevated office BP to rule out masked hypertension among those not taking antihypertensive medication. In short, AHA/ACC guidelines assert ABPM is useful for confirming the diagnosis

¹⁵ Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., ... & MacLaughlin, E. J. (2017). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*, 24430.

of hypertension not only for those with elevated office BP but also for some patients with non-elevated office BP.

The National Institute for Health and Care Excellence (NICE) in the United Kingdom has also issued guidelines that support the use of ABPM for providing definitive evidence for the diagnosis of hypertension for those with elevated office blood pressure. Specifically, for individuals with two elevated office blood pressure measurements ($\geq 140/90$ mmHg), NICE recommends confirming this diagnosis with ABPM.¹⁶ At least two measurements should be taken per hour during the individual's normal waking hours and averaged to confirm a hypertension diagnosis.¹⁷

In its own set of guidelines on ABPM, the European Society of Hypertension (ESH) sought to address three questions commonly raised:¹⁸

1. Which patients should have ABPM?
2. How should providers apply and interpret ABPM in daily practice?
3. How should providers introduce an ABPM service in routine clinical practice?

ESH found compelling indications for the following patient groups:¹⁹

Identifying white-coat hypertension phenomena

- White-coat hypertension in untreated individuals with elevated office BP
- White-coat effect in treated or untreated individuals
- False resistant hypertension due to white-coat effect in treated individuals whose BP remains elevated despite taking three antihypertensive drugs at maximal or maximally tolerated doses

Identifying masked hypertension phenomena

- Masked hypertension in untreated individuals without elevated office BP
- Masked uncontrolled hypertension in treated individuals without elevated office BP

Identifying abnormal 24-h BP patterns

- Daytime hypertension
- Siesta dipping/post-prandial hypotension
- Nocturnal hypertension
- Dipping status/isolated nocturnal hypertension

¹⁶ National, C. G. C. U. (2011). Hypertension: The Clinical Management of Primary Hypertension in Adults: Update of Clinical Guidelines 18 and 34.

¹⁷ *Id.*

¹⁸ Parati, G., Stergiou, G., O'Brien, E., Asmar, R., Beilin, L., Bilo, G., ... & Fagard, R. (2014). European Society of Hypertension practice guidelines for ambulatory blood pressure monitoring. *Journal of hypertension*, 32(7), 1359-1366.

¹⁹ *Id.*

Assessment of treatment

- Assessing 24-h BP control
- Identifying true resistant hypertension

ESH found additional indications for; screening and follow up of obstructive sleep apnea; assessing increased BP variability; assessing hypertension in children and adolescents, pregnancy, the elderly, and high-risk patients; identifying ambulatory hypotension, identifying blood pressure patterns in Parkinson's disease, and assessing endocrine hypertension.²⁰ ESH recommended that National Healthcare Systems in European countries should expand ABPM services in accordance with these indications where they have not done so already.²¹

Finally, the Canadian Hypertension Education Program (CHEP) conducted a review of the evidence surrounding ABPM as a tool to diagnose and assess hypertension. Upon completing its review the CHEP Recommendations Task Force outlined four new recommendations related to blood pressure monitoring:²²

- Routine office BP measurement (OBPM) should be performed using an electronic oscillometric device.
- If a patient has elevated BP readings in the office, a series of standardized out-of-office BP measurements should be performed in order to rule out white-coat hypertension ...and identify those patients who truly have hypertension.
- The out-of-office assessment should preferably be done using 24-hour...ABPM. A series of measurements with ...HBPM can be done if ABPM is not available or not tolerated by the patient.
- If the average of the out-of-office readings is normal, a diagnosis of [white-coat hypertension] is made. Patients with [white-coat hypertension] should have their BP assessed annually and should not be treated pharmacologically, although a healthy lifestyle should be encouraged and supported at all times.

While the various professional guidelines and recommendations may slightly vary in specifics, these reputable professional organizations broadly agree ABPM is an effective diagnostic tool that warrants clinical utilization.

II. Literature Review

a. ABPM as a diagnostic tool

²⁰ Parati, G., Stergiou, G., O'Brien, E., Asmar, R., Beilin, L., Bilo, G., ... & Fagard, R. (2014). European Society of Hypertension practice guidelines for ambulatory blood pressure monitoring. *Journal of hypertension*, 32(7), 1359-1366.

²¹ *Id.*

²² Gelfer, M., Dawes, M., Kaczorowski, J., Padwal, R., & Cloutier, L. (2015). Diagnosing hypertension: Evidence supporting the 2015 recommendations of the Canadian Hypertension Education Program. *Canadian Family Physician*, 61(11), 957-961.

As early as 2001, the evidence base in support of ABPM as a mechanism to rule out white-coat hypertension was compelling. CMS initiated coverage for these indications.²³ The evidence supporting such an expansion was largely based on ABPM and its value in “determining the appropriate management of the patient” particularly by preventing overtreatment. In the nearly two decades since CMS made this original coverage determination, the evidence base on ABPM and over-treatment of hypertension has expanded.

In the decades since the last consideration of ABPM by CMS, researchers have devoted considerable attention to ascertaining the diagnostic value of ABPM. Evidence suggests ABPM is superior to OBPM at diagnosing hypertension in a number of circumstances and among a number of different patient populations. Broadly, researchers have found blood pressure measurements obtained via ABPM are lower than those obtained by OBPM for the same patients.²⁴ Further, OBPM lacks the specificity and sensitivity to be the only diagnostic tool clinicians rely on in hypertension diagnosis.²⁵ In the vast majority of the studies, ABPM demonstrated its superiority to OBPM. ABPM has superior reproducibility compared to resting OBPM.²⁶ Banegas, et al. found that physicians often underestimate the number of patients with uncontrolled hypertension and simultaneously overestimate those with controlled hypertension because of unrepresentative OBPM readings.²⁷ Grezzana, et al. found that ABPM, which can be more than twice as accurate as OBPM, can lead to different medical decisions by the physician.²⁸ ABPM is particularly superior among diabetic hypertensive patients—particularly those with CVD, who have significantly higher systolic blood pressure that may not be detected by OBPM.²⁹

However, extended OBPM, which utilizes automated BPM for 10 to 30 minutes, may offer physicians information comparable to daytime values derived by ABPM. In one comparative study, extended OPBM lowered hypertensive medication prescription or intensification from 79 to 25 percent, especially for patients over 70 years old.³⁰ Similarly, Nunan, et al. found value in self-monitoring in the clinic over five consecutive days, which produced more accurate readings

²³ Centers for Medicare and Medicaid Services. (2001, Dec. 18). Medicare Coverage Issues Manual. *Department of Health and Human Services*. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R149CIM.pdf>

²⁴ Reino-González, Sergio, et al. Validity of clinic blood pressure compared to ambulatory monitoring in hypertensive patients in a primary care setting. *Blood Pressure*. 2015 April; 24(2): 111-118.

²⁵ *Id.*

²⁶ Morrin, Niamh M., Stone, Mark R. and Keiran J. Henderson. Reproducibility of 24-h ambulatory blood pressure and measures of autonomic function. *Blood Pressure Monitoring*. 2017 June; 22(3): 169-172.

²⁷ Banegas, José R., et al. Clinic Versus Daytime Ambulatory Blood Pressure Difference in Hypertensive Patients The Impact of Age and Clinic Blood Pressure. *Hypertension*. 2017 February; 69:211-219.

²⁸ Grezzana, Guilherme, et al. Impact of Different Normality Thresholds for 24-hour ABPM at the Primary Health Care Level. *Sociedade Brasileira De Cardiologica*. 2016. Available Online. DOI: 10.5935/abc.20160204

²⁹ Hao, Zirui, et al. Relationship and associated mechanisms between ambulatory blood pressure and clinic blood pressure with prevalent cardiovascular disease in diabetic hypertensive patients. *Medicine*. 2017 April; 96(16).

³⁰ Bos, Miciel J. and Sylvia Buis. Thirty-Minute Office Blood Pressure Monitoring in Primary Care. *Annals of Family Medicine*. 2017 March/April; 15(2): 120-123.

than those taken by a physician or outside of the clinic.³¹ Nevertheless, the authors did acknowledge serious questions of feasibility in implementing such a rigorous measurement procedure in clinical practice,³² suggesting the utility of ABPM is still superior to clinic self-monitoring. A systematic literature review on extended OBPM compared to ABPM by Jegatheswaran, et al. concluded that, due to significant heterogeneity in the OBPM results, ABPM should still be considered the reference standard for predicting cardiovascular events, and confirming hypertension diagnoses.³³

Piper et al.'s 2015 review found that across studies, ABPM measurements were associated with long-term cardiovascular outcomes independent of OBPM measurements.³⁴ In a recent review of the evidence on the utility of ABPM by Campbell and White, reviewers note ABPM is “uniquely capable of identifying patients with white-coat hypertension..., masked hypertension and abnormal nocturnal BP profiles.”³⁵

Diagnosis in the presence of specific conditions

There are a number of specific clinical conditions which ABPM is well suited to diagnose:

Masked Hypertension

It is important that clinicians effectively diagnose masked effects, both white-coat hypertension and masked hypertension, in their patients to determine the most appropriate treatment. ABPM has repeatedly demonstrated its diagnostic capabilities to diagnose *both* white-coat hypertension and masked hypertension. The diagnostic utility of ABPM in identifying white-coat hypertension and preventing overtreatment is well established (see section IIb). As a result, CMS covers ABPM for Medicare beneficiaries with suspected white-coat hypertension.³⁶

However, the current lack of coverage for ABPM in suspected cases of masked hypertension is problematic considering masked hypertension is a no less significant public health issue than white-coat hypertension. Pooling data from the Masked Hypertension Study and the National Health and Nutrition Examination Survey (NHANES) between 2005 and 2010, Wang, et al. estimated 12.3 percent of U.S. adults ages 21 years and older (17.1 million people) had masked hypertension, including 28

³¹ Nunan, David, et al. Accuracy of self-monitored blood pressure for diagnosing hypertension in primary care. *Journal of Hypertension*. 2015 April; 33(4): 755-762.

³² *Id.*

³³ Jegatheswaran, Januvi, et al. Are Automated Blood Pressure Monitors Comparable to Ambulatory Blood Pressure Monitors? A Systematic Review and Meta-analysis. *Canadian Journal of Cardiology*. 2017 May; 33(5): 644-652.

³⁴ Piper, Margaret A., et al. Diagnostic and Predictive Accuracy of Blood Pressure Screening Methods With Consideration of Rescreening Intervals: A Systematic Review for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*. 2015 Feb; 162(3):192-204

³⁵ Campbell, Patrick T. and William B. White. Utility of ambulatory blood pressure monitoring for the management of hypertension. *Current Opinion in Cardiology*. 2017 March; 32(0); 1-8.

³⁶ Centers for Medicare and Medicaid Services. (2001, Dec. 18). Medicare Coverage Issues Manual. *Department of Health and Human Services*. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R149CIM.pdf>

percent of adults over the age of 65.³⁷ Age, male sex, prehypertension, and diabetes were all positively associated with diagnosis of masked hypertension via ABPM. Overall, authors estimate as many as 1 in 8 U.S. adults may be misclassified as normotensive based on OBPM when ABPM would classify them as hypertensive.³⁸

ABPM offers an effective solution for diagnosing these patients. Clinical experts have called ABPM “the gold standard for diagnosing masked hypertension.”³⁹ Nearly one out of three treated patients with masked hypertension never achieve blood pressure control; therefore, “it becomes important...to use ABPM...for the effective diagnosis and control of hypertension.”⁴⁰

Elevated BP during sleep

While OBPM has historically been the standard for diagnosis of hypertension, there are some blood pressure readings OBPM cannot obtain due to the limitations of the diagnostic test itself. OBPM cannot measure blood pressure during sleep, yet evidence indicates elevated blood pressure during sleep is more common than conventional wisdom suggests, especially among elderly individuals and individuals with type 2 diabetes,⁴¹ chronic kidney disease, or treatment resistant hypertension.⁴² Among different ABPM measurement periods (awake, sleep, 24-hour mean), sleep ABPM measurements are the best predictor of CVD risk.⁴³ It is not possible to diagnose and manage elevated sleep blood pressure without ABPM.

Broader studies like one conducted by Gijón-Conde⁴⁴ have demonstrated the diagnostic effectiveness of ABPM for both types of blood pressure patterns. In their cohort of 1,047 community-dwelling Spaniards ages 60 and older, 21.7 percent had white-coat hypertension, 7 percent had masked hypertension, 21.4 percent had sustained hypertension, and 49.9 percent were normotensive.⁴⁴ Those with white-coat hypertension had the highest blood pressure variability while masked hypertensives had less decline in night-time blood pressures. The

³⁷ Wang, Y Claire, et al. Prevalence of Masked Hypertension Among US Adults With Nonelevated Clinic Blood Pressure. *American Journal of Epidemiology*. 2017; 185(3).

³⁸ *Id.*

³⁹ Franklin, SS, O'Brien, E and JA Staessen. Masked hypertension: understanding its complexity. *European Heart Journal*. 2017 April; 38(15): 1112-1118.

⁴⁰ *Id.*

⁴¹ Hermida RC, Moya A, Ayala DE. Ambulatory blood pressure monitoring in diabetes for the assessment and control of vascular risk. *Endocrinología y Nutrición*. 2015 Oct; 62(8);400-410.

⁴² Hermida, Ramón C., et al. Sleep-time blood pressure: Unique sensitive prognostic marker of vascular risk and therapeutic target for prevention. *Sleep Medicine Reviews*. 2017 June;33:17-27

⁴³ *Id.*

⁴⁴ Gijón-Conde, T., Graciani, A., López-García, E., Guallar-Castillón, P., García-Esquinas, E., Rodríguez-Artalejo, F., & Banegas, J. R. (2017). Short-term variability and nocturnal decline in ambulatory blood pressure in normotension, white-coat hypertension, masked hypertension and sustained hypertension: a population-based study of older individuals in Spain. *Hypertension Research*. 40(6), 613.

authors posit these differences may explain why individuals with both white-coat and masked hypertension have higher cardiovascular risk and warrant further utilization of ABPM.⁴⁵

b. ABPM as a means of preventing overtreatment

Because of its superior diagnostic effectiveness, ABPM helps prevent overtreatment stemming from misdiagnosed hypertension. This is especially important among older adults who may be at risk of hypotension. Divisón-Garrote, et al. investigated the potential for overtreatment in their study of 5,066 patients, ages 80 and older, undergoing hypertension treatment. Researchers found approximately one-third of very elderly hypertensive patients receiving treatment for hypertension were, in fact, at risk for hypotension and more than half of patients could not be identified as hypotensive with OBPM alone.⁴⁶ Banegas, et al, explored a similar phenomenon among individuals ages 60 and older. Their 1,047 study participants received three clinic BP measurements (i.e. OBPM) and one 24-hour ABPM study. While 54.1 percent of patients with treatment-eligible hypertension met blood pressure goals based on ABPM, only 37.4 percent of patients met BP goals based on OBPM.⁴⁷ Broadly, ABPM reduced the proportion of older patients indicated for hypertension treatment and increased the proportion of those who had their hypertension under control when compared to OBPM.⁴⁸

Researchers have also studied whether ABPM can prevent misclassification and overtreatment altogether. A 2015 systematic review by Piper, et al. conducted on behalf of the USPSTF served as a follow up to the USPSTF 2014 review and focused on the diagnostic and predictive accuracy of blood pressure screening methods.⁴⁹ The 2015 review analyzed the same 1,171 full-text articles published between January 1, 1966 and February 24, 2014 identified in the USPSTF 2014 systematic review.⁵⁰ Between 35 and 95 percent of individuals with hypertension based on OBPM measurements were still categorized as hypertensive after ABPM, indicating that OBPM has an inconsistent predictive value for detecting hypertension⁵¹ However, individuals with white-coat hypertension confirmed by ABPM had similar cardiovascular outcomes to individuals

⁴⁵ Gijón-Conde, T., Graciani, A., López-García, E., Guallar-Castillón, P., García-Esquinas, E., Rodríguez-Artalejo, F., & Banegas, J. R. (2017). Short-term variability and nocturnal decline in ambulatory blood pressure in normotension, white-coat hypertension, masked hypertension and sustained hypertension: a population-based study of older individuals in Spain. *Hypertension Research*.

⁴⁶ Divisón-Garrote, Juan A, et al. Magnitude of Hypotension Based on Office and Ambulatory Blood Pressure Monitoring: Results From a Cohort of 5066 Treated Hypertensive Patients Aged 80 Years and Older. *J Am Med Dir Assoc*. 2017 May; 18(5):452.e1-452.e6

⁴⁷ Banegas JR, de la Cruz JJ, Graciani A, Lopez-Garcia E, Gijon-Conde T, Ruilope LM, Rodriguez-Artalejo F. Impact of ambulatory blood pressure monitoring on reclassifications of hypertension prevalence and control in older people in Spain. *Journal of Clinical Hypertension*. 2015 Jun; 17(6): 453-461.

⁴⁸ Banegas JR, de la Cruz JJ, Graciani A, Lopez-Garcia E, Gijon-Conde T, Ruilope LM, Rodriguez-Artalejo F. Impact of ambulatory blood pressure monitoring on reclassifications of hypertension prevalence and control in older people in Spain. *Journal of Clinical Hypertension*. 2015 Jun; 17(6): 453-461.

⁴⁹ Piper, Margaret A., et al. Diagnostic and Predictive Accuracy of Blood Pressure Screening Methods With Consideration of Rescreening Intervals: A Systematic Review for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*. 2015 Feb; 162(3):192-204

⁵⁰ *Id.*

⁵¹ *Id.*

whose OBPM initially categorized them as normotensive.⁵² Accordingly, it is important these individuals are not treated as if they have hypertension. The authors concluded that “[e]vidence supports ABPM as the reference standard for confirming elevated office BP screening results to avoid misdiagnosis and overtreatment of persons with isolated clinic hypertension.”

In a 2016 study by O’Flynn, et al.,⁵³ researchers attempted to collect OBPM measurements, their own study blood pressure measurements, and ABPM measurements to see how patient categorization compared based on the method of measurement utilized. Forty-five percent of study participants (931 individuals) had all three types of measurements. Thirteen and a half percent of participants were reclassified from normotensive to hypertensive based on ABPM while 14.5 percent of participants went from a diagnosis of hypertension to normotension.⁵⁴ From the population perspective, these reciprocal reclassifications amounted to very little net effect on the proportions characterized as having hypertension or normotension, but at the individual level, the authors conclude that diagnostic ABPM “reduced incorrect classification and facilitates more appropriate management” including preventing overtreatment.⁵⁵

c. Predictive and preventive value of ABPM

Ambulatory blood pressure is an important predictor of a number of health outcomes and, as such, ABPM presents an effective preventive tool for clinicians and patients. Hypertension-related death may be due to a variety of factors. Foremost, individuals with hypertension may suffer from target organ damage (TOD), that is, damage to the heart, kidney, and brain that will lead to an increased risk of negative health outcomes including heart failure and myocardial infarction, renal failure, and stroke.^{56,57} Several studies have explored the specific, predictive relationship between ABPM and TOD.

A team of researchers led by Yang compared the predictive capabilities of ABPM and OBPM on target organ damage as a whole⁵⁸ They collected OBPM and ABPM for 280 participants and followed up with 199 for an average of 39 months to assess for TOD. Night-time SBP was strongly associated with TOD, although both daytime and clinic SBP were associated with TOD to a lesser extent. Twenty-four-hour pulse pressure was a better predictor of TOD than clinic pulse pressure, and night-time pulse pressure was a better predictor of TOD than daytime pulse

⁵² *Id.*

⁵³ O’Flynn AM, Curtin RJ, Perry IJ, Kearney PM. Hypertension prevalence, awareness, treatment, and control: Should 24-hour ambulatory blood pressure monitoring be the tool of choice? *The Journal of Clinical Hypertension*. 2016 Nov; 18(7):697-702.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Mensah, G. A., Croft, J. B., & Giles, W. H. (2002). The heart, kidney, and brain as target organs in hypertension. *Cardiology clinics*, 20(2), 225-247.

⁵⁷ Nadar, S. K., Tayebjee, M. H., Messerli, F., & Lip, G. Y. (2006). Target organ damage in hypertension: pathophysiology and implications for drug therapy. *Current pharmaceutical design*, 12(13), 1581-1592.

⁵⁸ Yang, Y, et al. Ambulatory versus clinic blood pressure in predicting overall subclinical target organ damage progression in essential hypertensive patients: a 3-year follow-up study. *Blood Pressure Monitoring*. 2016 Dec; 21(6): 319-326.

pressure.⁵⁹ This suggests ABPM is superior at predicting TOD than OBPM and warrants further application.

Among TOD, ABPM predicts CVD risk and organ failure more accurately than other BP measures. For example, Skoglund, et al. aimed to determine methods to improve risk prediction for atherosclerotic cardiovascular disease (ASCVD). Their study followed 70-year-old men with no additional baseline disease for incident ASCVD—defined as nonfatal or fatal myocardial infarction or stroke—for a median period of 10 years. They utilized a model containing traditional risk factors as well as ambulatory blood pressure (ABP) and the biomarkers amino-terminal pro-B-type natriuretic peptide (NT-proBNP), high-sensitivity c-reactive protein, (hs-CRP), and cystatin C. Prior literature had found a positive correlation between ABP and all three biomarkers. The researchers aimed to determine whether the predictive value of ABP could be explained by variations in the three biomarkers; they determined that NT-proBNP added predictive value to both an ABP model and traditional BP model using 24-hour systolic blood pressure. While the results suggest that the use of NT-proBNP and ABP could improve risk prediction in elderly men, the researchers call for further research into cost-effectiveness and effectiveness for other populations before these methods are recommended for clinical practice.⁶⁰

A systematic review and meta-analysis by Conen, et al.⁶¹ of the association between systolic blood pressure, collected by ABPM, and cardiovascular events revealed ABPM's predictive effectiveness across a broad range of studies. Upon identifying and analyzing 15 studies, the authors found 24-hour, awake and sleep BP were each strongly associated with an increased risk of cardiovascular events. These ABPM measures predicted cardiovascular events over and above that of OBPM.

Overall, ABPM is considered a more accurate diagnostic tool than clinic BP monitoring.⁶² Measuring blood pressure over time uncovers variability and abnormality that might otherwise be overlooked during a single set of office blood pressure determinations. Parati and Schumacher assert “the ability of ABPM to provide a quantification of blood pressure throughout the 24-h period during an individual's normal daily routine” is invaluable to treatments that effectively maintain smooth blood pressure over 24 hours and subsequently may improve cardiovascular risk, cardiovascular outcomes, and decrease organ damage. ABPM may also be used with echocardiographic criteria to predict left ventricular hypertrophy (LVH) as there is a significant association between 24-hour blood pressure parameter and LVH.⁶³ Gomez-Marcos, et al. conclude that monitoring and controlling BP according to 24-hour parameters may be an

⁵⁹ *Id.*

⁶⁰ Skoglund, Per H., et al. Amino-Terminal Pro-B-Type Natriuretic Peptide Improves Discrimination for Incident Atherosclerotic Cardiovascular Disease Beyond Ambulatory Blood Pressure in Elderly Men. *Hypertension*. 2015; 66: 681-686.

⁶¹ Conen, D., & Bamberg, F. (2008). Noninvasive 24-h ambulatory blood pressure and cardiovascular disease: a systematic review and meta-analysis.

⁶² Turner JR, Viera AJ, Shimbo D. Ambulatory blood pressure monitoring in clinical practice: A review. *American Journal of Medicine*. 2015 Jan;128(1):14-20.

⁶³ Gómez-Marcos, Manuel A., et al. Electrocardiographic left ventricular hypertrophy criteria and ambulatory blood pressure monitoring parameters in adults. *American Journal of Hypertension*. 2014 March; 27(3): 355-362

important addition to the standard treatment for patients with LVH. With recognition of the importance of out-of-office blood pressure monitoring as a predictor of CVD risk, Ahmad and Oparil encourage providers to incorporate ABPM to diagnose and monitor blood pressure.⁶⁴ Finally, Lazaridis, et al. note both the diagnostic capabilities of ABPM to identify pseudoresistant hypertension (i.e. patients who are, in fact, responding to treatment, but have elevated clinical blood pressure levels) and the predictive capabilities of ABPM to identify CVD risk among individuals with legitimate resistant hypertension.⁶⁵

In addition to those at risk of CVD morbidity and mortality, blood pressure control is also considered crucial for preventing chronic kidney disease (CKD) progression and associated cardiovascular complications. Namely, hidden forms of hypertension, such as non- or reverse-dipping (i.e. blood pressure that does not decrease during sleep or actually increases during sleep) and sustained or masked hypertension may be prevalent among CKD patients.⁶⁶ Misclassification is particularly hazardous for CKD patients, as these conditions can cause or aggravate one another.⁶⁷ For these reasons, ABPM is considered a highly clinically relevant tool to correctly identify hypertension in patients with kidney disease.^{68,69}

White, et al. explored blood pressure's effect on the progression of small vessel disease of the brain, a condition associated with functional decline in mobility and cognition in the elderly. Researchers followed a cohort of elderly participants for two years collecting neurological and cognitive data, blood pressure readings, physical data in the form of gait assessment, and MRI data. Increases in ambulatory systolic blood pressure were associated with increases in white matter hyperintensity (WMH) volume over the 2-year study period, in addition to related cognitive decline. Twenty-four-hour blood pressure, awake blood pressure, and sleep blood pressure exhibited comparable associations. In contrast, researchers observed no such relationship between systolic OBPM and WMH/cognitive function.⁷⁰

Similarly, Wolfson, et al. aimed to determine whether 24-hour ambulatory systolic blood pressure played a role in preserving mobility, cognition, and preventing depressive symptoms.

⁶⁴ Ahmad, Amier and Suzanne Oparil. Hypertension in Women: Recent Advances and Lingering Questions. *Hypertension*. 2017 June; 69(6): DOI: 10.1161/HYPERTENSIONAHA.117.08317.

⁶⁵ Lazaridis AA, Sarafidis PA, Ruilope LM. Ambulatory blood pressure monitoring in the diagnosis, prognosis, and management of resistant hypertension: Still a matter of our resistance? *Current Hypertension Reports*. 2015 Oct;17(10):78.

⁶⁶ Oh, YK, et al. Discrepancies in Clinic and Ambulatory Blood Pressure in Korean Chronic Kidney Disease Patients. *Journal of Korean Medical Sciences*. 2017 May; 32(5): 772-781.

⁶⁷ Choudhary, Lekharaj, et al. 24 hour ambulatory blood pressure monitoring and left ventricular ejection fraction-prognostic markers in chronic kidney disease. *International Journal of Advances in Medicine*. 2016 May; 3(2): 402-408

⁶⁸ Oh, YK, et al. Discrepancies in Clinic and Ambulatory Blood Pressure in Korean Chronic Kidney Disease Patients. *Journal of Korean Medical Sciences*. 2017 May; 32(5): 772-781

⁶⁹ Cunha, Catia, et al. 24-hour ambulatory blood pressure monitoring in chronic kidney disease and its influence on treatment. *Portuguese Journal of Nephrology and Hypertension*. 2017 March; 31(1): 31-36. Advanced Access Copy Retrieved from: http://www.bbg01.com/cdn/rsc/spnefro/advaccess/61/n1_2017_pjnh_07.pdf

⁷⁰ White, W. B., Wolfson, L., Wakefield, D. B., Hall, C. B., Campbell, P., Moscufo, N., ... & Guttmann, C. R. (2011). Average Daily Blood Pressure, Not Office Blood Pressure, Is Associated With Progression of Cerebrovascular Disease and Cognitive Decline in Older People. *Circulation*, 124(21), 2312-2319.

Their study followed women and men ages 75 and older for a period of four years for WMH accrual, ABP and clinical blood pressure, and symptoms of functional decline. Notably, 69% of the cohort were on antihypertensive medication, and 21% had coronary artery disease. Clinical BP was assessed as the average of three seated measurements taken five minutes apart but were not found to be associated with WMH. Ambulatory blood pressure was taken every 15 minutes during the day, every 30 minutes at night, and summarized as 24-hour, awake, and sleep BP measurements. Increases in ABP were associated with greater WMH accrual in the first two years, and ABP was related to WMH after four years; increased WMH was directly associated with reduced mobility. Those with 24-hour BP above 130 mm Hg were most affected. The findings suggest that controlling ambulatory blood pressure, even in those without symptoms, and setting lower target BP values than are typical, may be critical to preserving function.⁷¹ Another team of researchers lead by Shuna Yang investigated ABP levels and their association with enlarged perivascular spaces (EPVS), a specific form of brain damage. Enlarged perivascular spaces are a marker of cerebral small vessel disease⁷² and are associated with vascular risk factors and cognitive and motor impairment.⁷³ In some cases, they may even lead to dementia or Parkinson's disease.⁷⁴ In their study of 573 participants, 24-hour, day and night systolic blood pressure, all collected via ABPM, were significantly predictive of EPVS found in the basal ganglia. While ABPM readings could not predict EPVS in the smaller centrum semiovale nuclei after adjusting for confounders,⁷⁵ ABPM was still considered an effective diagnostic test to predict this specific type of hypertension-related brain damage.

d. ABPM in clinical practice

While it is important to examine the effectiveness of ABPM in controlled settings, researchers have also acknowledged the importance of applying this evidence base to every day clinical practice. Assessing the usage and effectiveness of ABPM under typical clinical conditions is an integral step in understanding the potential benefit expanding coverage of ABPM under Medicare could have.

Turner, et al. outline four key advantages for ABPM that are consistent with the evidence presented in this document:⁷⁶

- ABPM allows blood pressure readings to be taken across a 24-hour period.

⁷¹ Wolfson, Leslie, et al. Rapid Buildup of Brain White Matter Hyperintensities Over 4 Years Linked to Ambulatory Blood Pressure, Mobility, Cognition, and Depression in Old Persons. *Journals of Gerontology: Medical Sciences*. Nov 2013; 68(11): 1387-1394.

⁷² Yang, S, et al. Higher ambulatory systolic blood pressure independently associated with enlarged perivascular spaces in basal ganglia. *Neurological Research*. 2017 May: 1-8. [EPub ahead of print; Full access pending].

⁷³ van Norden, A. G., de Laat, K. F., Gons, R. A., van Uden, I. W., van Dijk, E. J., van Oudheusden, L. J., ... & Tendolkar, I. (2011). Causes and consequences of cerebral small vessel disease. The RUN DMC study: a prospective cohort study. Study rationale and protocol. *BMC neurology*, 11(1), 29.

⁷⁴ *Id.*

⁷⁵ Yang, S, et al. Higher ambulatory systolic blood pressure independently associated with enlarged perivascular spaces in basal ganglia. *Neurological Research*. 2017 May: 1-8. [EPub ahead of print; Full access pending].

⁷⁶ Turner JR, Viera AJ, Shimbo D. Ambulatory blood pressure monitoring in clinical practice: A review. *American Journal of Medicine*. 2015 Jan;128(1):14-20.

- Several guidelines [discussed earlier in this document] exist for the use of ambulatory blood pressure monitoring in clinical practice.
- Using ABPM to rule out white-coat hypertension prevents patients from being prescribed unnecessary antihypertensive medications [i.e. overtreatment, discussed earlier in this document].
- ABPM also allows measurement of nocturnal blood pressure, an increasingly important prognostic parameter for cardiovascular disease risk.

A related review by Angeli, et al. additionally notes that ABPM is principally useful in clinical practice when utilized in the outpatient setting with its ability to perform much greater numbers of readings compared to traditional OBPM.⁷⁷ Notably, both groups of authors are careful to avoid suggesting that ABPM should replace OBPM entirely. Given its broad application including to predict cardiovascular events, identify white-coat hypertension, identify masked hypertension, and inform decision-making in whether to initiate or modify hypertensive treatment, both groups of clinical researchers promote the clinical value of ABPM.

Woolsey, et al.⁷⁸ and Carter, et al.⁷⁹ surveyed clinics to assess their ability to effectively implement ABPM under current policies in the United States. The former surveyed primary care clinics comparing current clinical blood pressure measurement practices with USPSTF blood pressure measurement recommendations. Many clinics currently lacked the resources to follow USPSTF guidelines on blood pressure. For instance, only 25.2 percent of clinics had access to ABPM.⁸⁰ The latter conducted a survey of primary-care physicians in Oregon on their usage of and preparedness for ABPM. Nineteen percent of physicians said they order ABPM to confirm hypertension diagnosis based on OBPM, but more than half of surveyed physicians had never done so. A similarly small percentage of practices (20.3 percent) had ABPM devices.⁸¹ The effectiveness of any potential expansion of ABPM coverage relies, in part, on the clinic's ability to adapt their current practices to align with newer guidelines⁸² and, in particular, the support they receive to develop complementary services.⁸³

Such survey results are not surprising considering clinical practitioners in the United States have faced a number of barriers to effective ABPM utilization. In 2017, Kronish, et al. surveyed

⁷⁷ Angeli, F., Reboldi, G., Poltronieri, C., Bartolini, C., D'Ambrosio, C., De Filippo, V., & Verdecchia, P. (2014). Clinical utility of ambulatory blood pressure monitoring in the management of hypertension. *Expert review of cardiovascular therapy*, 12(5), 623-634.

⁷⁸ Woolsey, Sarah, et al. Diagnosing Hypertension in Primary Care Clinics According to Current Guidelines. *Journal of the American Board of Family Medicine*. 2017 March/April: 30(2): 170-177.

⁷⁹ Carter BU, Kaylor MB. The use of ambulatory blood pressure monitoring to confirm a diagnosis of high blood pressure by primary-care physicians in Oregon. *Blood Pressure Monitoring*. 2016 Apr;21(2):95-102.

⁸⁰ Woolsey, Sarah, et al. Diagnosing Hypertension in Primary Care Clinics According to Current Guidelines. *Journal of the American Board of Family Medicine*. 2017 March/April: 30(2): 170-177.

⁸¹ Carter BU, Kaylor MB. The use of ambulatory blood pressure monitoring to confirm a diagnosis of high blood pressure by primary-care physicians in Oregon. *Blood Pressure Monitoring*. 2016 Apr;21(2):95-102.

⁸² *Id.*

⁸³ Mengen, Thomas, et al. Blood pressure control and cardiovascular risk in hypertensive patients with type 2 diabetes: The German T2Target registry. *The Journal of Clinical Hypertension*. 2017 May: 1-7.

primary care providers to identify major barriers to ABPM.⁸⁴ Providers reported difficulty accessing testing centers and the cost of ABPM (amount of reimbursement, cost of equipment, staff and physician time) as the primary barriers to implementing ABPM.⁸⁵ Increasing accessibility to ABPM, including through insurance coverage, is a major way to mitigate these primary barriers.

National Coverage Determination Request

Based on the strength of the evidence that has emerged in recent decades supporting ABPM as a preferred confirmatory diagnostic test for hypertension, AHA and AMA seek a National Coverage Determination expanding reimbursement to all Medicare beneficiaries for the diagnosis of hypertension. We recommend this change based on the existence of out-of-office blood pressure patterns that ABPM is well-equipped to diagnose, the predictive and clinical value of ABPM as a whole, and recommendations by multiple professional societies.

⁸⁴ Kronish, I. M., Kent, S., Moise, N., Shimbo, D., Safford, M. M., Kynerd, R. E., ... & Muntner, P. (2017). Barriers to conducting ambulatory and home blood pressure monitoring during hypertension screening in the United States. *Journal of the American Society of Hypertension*, 11(9), 573-580.

⁸⁵ *Id.*