



1150 Connecticut Ave., NW | Suite 300 | Washington, DC 20036  
P 202-785-7900 | F 202-785-7950 | [www.heart.org](http://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](http://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](mailto: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.

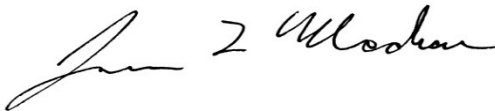
Our organizations have also identified it as a priority to improve coverage of the evidence-based practices that support better diagnosis and control of high blood pressure. To this end, enclosed is a formal request for reconsideration, which includes a summary of new evidence in support of ABPM since 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](mailto: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  $\geq 130$  mm Hg or diastolic blood pressure  $\geq 80$  mm Hg (newly revised from an earlier 140/90 mm Hg standard).<sup>i,ii</sup> Of the more than 55.5 million Medicare beneficiaries in the United States,<sup>iii</sup> 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);<sup>iv</sup> 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.<sup>v</sup>

Cardiovascular disease (CVD) has been the leading cause of death in the United States for almost a century<sup>vi,vii</sup> and, of CVD attributable deaths, more than nine percent are because of high blood pressure.<sup>viii</sup> 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.<sup>ix</sup> CMS itself has called hypertension “the most important modifiable risk factor for coronary heart disease... stroke... congestive heart failure, and end-stage renal disease.”<sup>x</sup>

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.<sup>xi</sup> 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).<sup>xii</sup> By 2035, CVD will cost an estimated \$1.1 trillion (\$749 billion direct, \$368 billion indirect).<sup>xiii</sup> 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.<sup>xiv</sup> This projected increase in expenditure will be driven by the aging US population particularly as Baby Boomers become eligible for Medicare.<sup>xv</sup> Estimates suggest Baby Boomers ages 80 and older will be the largest driver of CVD expenditure increase by 2035.<sup>xvi</sup> 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.<sup>xvii,xviii,xix,xx,xxi,xxii,xxiii,xxiv</sup>

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.”<sup>xxv</sup> 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.”<sup>xxvi</sup>

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.<sup>xxvii</sup> 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),<sup>xxviii</sup> 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.”<sup>xxix</sup>

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.<sup>xxx</sup> 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.”<sup>xxxii</sup> 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).<sup>30</sup> 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).<sup>30</sup> **For these reasons, the USPSTF recommends ABPM as the reference standard for confirming the diagnosis of hypertension.**<sup>xxxii</sup> (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).<sup>xxxiii,xxxiv,xxxv,xxxvi</sup> ABPM has superior specificity and sensitivity compared to OBPM, and best practices suggest it is clinically important for confirmation of hypertension diagnosis.<sup>xxxvii</sup> ABPM measurements are generally lower than those obtained by OBPM in the same patients<sup>xxxviii</sup> 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<sup>xxxix,xi</sup> and elevated BP during sleep.<sup>xli</sup> 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.<sup>xlii</sup> Further, elderly individuals, those with type 2 diabetes, chronic kidney disease and treatment resistant hypertension are at increased risk for elevated nighttime BP.<sup>xliii,xliv</sup>

#### 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.<sup>xlv</sup> Falls due to low blood pressure among the elderly can restrict mobility, either from physical injury or fear of subsequent falls,<sup>xlvi</sup> 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,<sup>xlvii</sup> 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.<sup>xlviii</sup> 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.<sup>xlix</sup>

#### 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.<sup>l</sup><sup>li</sup> ABPM is a better predictor of TOD than OBPM,<sup>lii</sup> including, but not limited to cardiovascular events.<sup>liii</sup> When analyzed with biomarkers like amino-terminal pro-B-type natriuretic peptide (NT-proBNP), ABPM has potential to better predict atherosclerotic cardiovascular disease.<sup>liv</sup>

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.<sup>lv, lvi</sup> ABPM may also assist in controlling ambulatory blood pressure to prevent cognitive decline, depression, decreases in physical mobility,<sup>lvii</sup> increases in white matter hyperintensity volume,<sup>lviii</sup> and enlarged perivascular spaces in the brain.<sup>lix</sup> 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<sup>lx</sup>:

- 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<sup>lxi, lxii</sup> and, perhaps because of this, many physicians report *not* having used ABPM to confirm hypertension diagnosis.<sup>lxiii</sup> Providers reported difficulty accessing testing centers and the cost of ABPM as the primary barriers for implementing ABPM.<sup>lxiv</sup>

### *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.

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- <sup>xvii</sup> 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
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