

Medical Policy



Title: Automated Ambulatory Blood Pressure Monitoring for the Diagnosis of Hypertension in Patients with Elevated Office Blood Pressure

Professional

Original Effective Date: February 2, 1995
Revision Date(s): July 1, 2000;
November 6, 2003; January 1, 2004;
September 18, 2009; December 7, 2012;
February 26, 2013; December 31, 2013;
March 18, 2015; September 15, 2016;
July 11, 2017; September 12, 2018;
August 16, 2019; January 1, 2020;
April 19, 2021; September 17, 2021
Current Effective Date: August 16, 2019

Institutional

Original Effective Date: July 1, 2005
Revision Date(s): October 19, 2009;
December 7, 2012; February 26, 2013;
December 31, 2013; March 18, 2015;
September 15, 2016; July 11, 2017;
September 12, 2018; August 16, 2019;
January 1, 2020; April 19, 2021;
September 17, 2021
Current Effective Date: August 16, 2019

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Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With elevated office blood pressure 	Interventions of interest are: <ul style="list-style-type: none"> • 24-hour automated ambulatory blood pressure monitoring 	Comparators of interest are: <ul style="list-style-type: none"> • Office blood pressure measurement • Home blood pressure measurement 	Relevant outcomes include: <ul style="list-style-type: none"> • Test accuracy • Other test performance measures • Morbid events • Medication use

DESCRIPTION

Ambulatory blood pressure (BP) monitors (24-hour sphygmomanometers) are portable devices that continually record BP while the patient is involved in daily activities. There are various types of ambulatory monitors; this evidence review addresses fully automated monitors, which inflate and record BP at pre-programmed intervals. Ambulatory blood pressure monitoring (ABPM) has the potential to improve the accuracy of diagnosing hypertension and thus improve the appropriateness of medication treatment.

Objective

The objective of this evidence review is to evaluate whether the use of automated ambulatory blood pressure monitoring for the diagnosis of hypertension improves the net health outcome in individuals with elevated office blood pressure.

Background

Typically done over a 24-hour period with a fully automated device, ambulatory blood pressure monitoring (ABPM) provides more detailed blood pressure (BP) information than readings typically obtained during office visits. The greater number of readings with ABPM ameliorates the variability of single BP measurements and is more representative of the circadian rhythm of BP. Various BP indexes can be derived from the detailed BP information provided by ABPM, including multiple measure times (e.g., 24 hours, daytime, nighttime) and dipping ratio (i.e., calculated by dividing nighttime by daytime systolic BP). Studies evaluating the comparative clinical utility of the various available ABPM BP indexes have suggested that higher 24-hour and nighttime BP indexes may marginally improve model predictions of greater risk of death and composite cardiovascular events.²

ABPM has a number of potential applications. One of the most common is evaluating suspected white coat hypertension, which is defined as an elevated office BP with normal BP readings outside the physician's office. The etiology of white coat hypertension is poorly understood but may be related to an "alerting" or anxiety reaction associated with visiting the physician's office.

In assessing patients with elevated office BP, ABPM is often intended to identify those with normal ambulatory readings who do not have sustained hypertension. Because this group of patients would otherwise be treated based on office BP readings alone, ABPM could improve outcomes by allowing these patients to avoid unnecessary treatment. However, this assumes patients with white coat hypertension are not at increased risk for cardiovascular events and would not benefit from antihypertensive treatment.

Other uses of ABPM include monitoring patients with established hypertension under treatment; evaluating refractory or resistant BP; evaluating whether symptoms such as lightheadedness

correspond with BP changes; evaluating night-time BP; examining diurnal patterns of BP; and other potential uses.

This evidence review does not directly address other uses of ABPM, including its use for the evaluation of "masked" hypertension. Masked hypertension refers to normal BP readings in the office and elevated BP readings outside of the office. This phenomenon has recently received greater attention, with estimates that up to 10% to 20% of individuals may exhibit this pattern.

REGULATORY STATUS

Many ambulatory blood pressure monitors have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. As an example of a Food and Drug Administration indication, the Welch Allyn Ambulatory Blood Pressure Monitoring 6100 is indicated "as an aid or adjunct to diagnosis and treatment when it is necessary to measure adult or pediatric patients' systolic and diastolic blood pressures over an extended period of time."³

FDA product code: DXN.

POLICY

- A. Automated ambulatory blood pressure monitoring (ABPM) performed one time over a 24 hour period with FDA approved devices may be considered **medically necessary** for the evaluation of individuals with any of the following:
1. Suspected “White Coat Hypertension” (WCH) defined as:
 - a. In-office BP >140/90 mmHg on at least three separate clinic/office visits with two separate measurements taken at each visit; and
 - b. At least two documented separate BP measurements taken outside the office setting which are <140/90 mmHg; and
 - c. No evidence of end-organ damage
 2. Resistant hypertension being treated with three or more antihypertensive medications at therapeutic doses.
 3. Hypertensive individuals with hypotensive symptoms and/or syncopal events thought to be related to antihypertensive medications or neurological syndromes, including autonomic dysfunction.
 4. Episodic hypertension suspected when office BP measurements are normal and associated symptoms (e.g., excessive sweating, palpitations, pallor) suggest episodic hypertension secondary to an existing condition.
 5. Suspected autonomic dysfunction.
- B. All other uses of ambulatory monitoring for patients with elevated office blood pressure are considered **experimental / investigational** including, but not limited to, repeated testing in patients with persistently elevated office blood pressure and monitoring of treatment effectiveness.

Policy Guidelines

1. For pediatric patients, the principles of ABPM use to confirm a diagnosis of hypertension are the same as in adults, but there are special considerations as follows (Flynn et al, 2014):
 - a. A device should be selected that is appropriate for use in pediatric patients, including use of a cuff size appropriate to the child’s size.
 - b. Threshold levels for the diagnosis of hypertension should be based on pediatric normative data, which use gender- and height-specific values derived from large pediatric populations.
 - c. Recommendations from the American Heart Association concerning classification of hypertension in pediatric patients using clinic and ambulatory BP are given in Table PG1:

Table PG1. Classification of Ambulatory BP Levels in Children

Classification	Clinic BP	Mean Ambulatory SBP	SBP Load ^a
Normal BP	<95 th percentile	<95 th percentile	<25%
White Coat HTN	>95 th percentile	<95 th percentile	<25%
Masked HTN	<95 th percentile	>95 th percentile	>25%
Pre-HTN	>95 th percentile	<95 th percentile	25-50%
Ambulatory HTN	>95 th percentile	>95 th percentile	25-50%
Severe Ambulatory HTN	>95 th percentile	>95 th percentile	>50%

Adapted from Flynn et al (2014). BP: blood pressure; HTN: hypertension; SBP: systolic blood pressure

^aPercent of SBP readings that are above 95th percentile for gender and height

RATIONALE

This evidence has been updated regularly with searches of the PubMed database. The most recent literature update was performed through May 7, 2021.

This review was informed by a TEC Assessment (1999)⁴, and a subsequent 2001 reanalysis of this report conducted by the Centers for Medicare & Medicaid Services.⁵

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

24-Hour Automated Ambulatory Blood Pressure Monitoring

The focus of the current review is on the use of ambulatory blood pressure monitoring (ABPM) in previously untreated patients with elevated office blood pressure (BP). In this situation, ABPM is primarily intended to evaluate white coat hypertension (WCH), or "isolated clinic hypertension." This entity is defined as an elevated office BP with normal BP readings outside the physician's office. It is diagnosed by obtaining multiple out-of-office BP measurements and comparing them with office readings.

Clinical Context and Test Purpose

The purpose of 24-hour automated ABPM in patients who have elevated office BP is to confirm a diagnosis of hypertension and to initiate an appropriate treatment regimen.

The question addressed in this evidence review is: Does the use of ABPM monitoring for the diagnosis of hypertension improve the net health outcome in individuals with elevated office BP?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with elevated office BP determined using guideline-based parameters. The appropriate setting for use, after initial setup, is the home or workplace.

Interventions

The test being considered is 24-hour automated ABPM.

Comparators

The following tests are currently being used: repeated BP measurement in office and/or home settings.

Outcomes

The general outcomes of interest are accurate BP readings to confirm a diagnosis of hypertension and to initiate appropriate treatment for those with elevated BP readings. Ruling out a diagnosis of hypertension avoids inappropriate treatment and adverse events of therapy. Twenty-four hour automated ABPM may be used when there is persistent unexplained variability in serial elevated BP measurements over a 1 to 3 month period.

Study Selection Criteria

For the evaluation of clinical validity of 24-hour automated ABPM, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology
- Included a suitable reference standard
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described.

Establishing reference values for ABPM is integral to providing guidelines for "normal" and "abnormal" ABPM readings.^{6,7} Studies that have compared ABPM measurements with office measurement have consistently revealed lower ABPM values. Therefore, it is not possible to use reference values for office BP to evaluate the results of ABPM.

Reference values for ABPM have been derived by several methods: (1) estimates of population-based ABPM results to define the range and distribution of ABPM values; (2) direct comparisons of average ABPM values and office BP to determine the level of ABPM that corresponds to an office BP of 140/90 mm Hg; and (3) correlations of ABPM results with cardiovascular outcomes to determine ABPM levels at which the risk for cardiovascular events increases, or is similar to the risk associated with an office BP of 140/90 mm Hg.^{8,9}

Although specific recommendations vary slightly, current thresholds for defining a normal ABPM are a 24-hour average BP of 130/80 mm Hg and daytime average BP of 135/85 mm Hg. An ABPM (1999) consensus conference task force considered data on the statistical distribution of ABPM, correlation with office BP, and correlation with cardiovascular outcomes in deriving recommendations for reference values for ABPM.¹⁰ Their recommendations are summarized in Table 1. Subsequent studies have identified racial and ethnic variations in ABPM results,¹¹ but the impact of these differences on clinical management may be minimal.¹²

Table 1. Adult ABPM Thresholds

ABPM Measure	95th Percentile	Normotension, mm Hg	Hypertension, mm Hg
24-hour average, mm Hg	132/82	≤130/80	>135/85
Daytime average, mm Hg	138/87	≤135/85	>140/90
Nighttime average, mm Hg	123/74	≤120/70	>125/75

Adapted from Staessen et al (1999).¹⁰

ABPM: ambulatory blood pressure monitoring.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

REVIEW OF EVIDENCE

Adults

Many prospective cohort studies have compared ABPM with office BP in predicting cardiovascular events. Although the results of these studies are not entirely consistent, most have reported that ABPM has greater predictive ability for cardiovascular events than office BP measurement.^{13,14} A summary of relevant systematic reviews and meta-analyses of these studies follows.

Hansen et al (2007) conducted a patient-level meta-analysis using data from 4 populations in Belgium, Denmark, Japan, and Sweden (N=7030 patients).¹⁵ The predictive values of ABPM and in-clinic BP for fatal and nonfatal cardiovascular events were reported. Both ABPM and office BP were predictors of outcomes in univariate and partially adjusted multivariate models. In the fully adjusted model, ABPM remained a significant predictor of outcomes while office BP did not.

Conen and Bamberg (2008) conducted a meta-analysis of 20 cohort studies that evaluated the correlation between ABPM and outcomes, controlling for office BP in the analysis.¹⁶ Reviewers reported that ABPM was a strong predictor of cardiovascular outcomes and that controlling for office BP had little effect on risk estimates. These results support the hypothesis that risk information obtained from ABPM is independent of that obtained from office BP.

A systematic review by Piper et al (2015), conducted for the U.S. Preventive Services Task Force, identified 7 studies of diagnostic accuracy.¹⁷ Four were rated high-quality and 3 moderate quality. Four studies directly compared ABPM with automated office BP readings. Using ABPM as the reference standard, the sensitivity of office BP measurement for the diagnosis of hypertension ranged from 51% to 91%, specificity ranged from 97% to 98%, and the positive predictive value ranged from 76% to 84%.

Numerous other studies have directly compared ABPM with office BP and/or home self-measured BP. Hodgkinson et al (2011) performed a systematic review of studies that compared ABPM with home or office BP and used defined thresholds to determine the accuracy of the diagnosis of hypertension.¹⁸ Of 10 studies identified, 7 compared ABPM with office BP measurements and 3 compared ABPM with home self-measurement. Using a 24-hour ABPM threshold of 135/85 mm Hg,

clinic BP measurements had a sensitivity of 75% (95% confidence interval [CI], 61% to 85%) and a specificity of 75% (95% CI, 48% to 90%). Home BP self-measurement had a sensitivity of 86% (95% CI, 78% to 91%) and a specificity of 62% (95% CI, 48% to 75%). The accuracy of office and home BP was considered inadequate for use as a single diagnostic test for hypertension, and it was hypothesized that the use of office and/or home measurements might lead to substantial overdiagnosis and overtreatment.

In a similar systematic review, Stergiou and Bliziotis (2011) compared the accuracy of ABPM with home BP measurement for the diagnosis of hypertension.¹⁹ Sixteen studies were selected. The sensitivity of home BP measurement, compared with ABPM, ranged from 36% to 100% (median, 74%). The specificity ranged from 44% to 96% (median, 84%). Reviewers also reported the diagnostic agreement between the 2 methods of BP measurement, as assessed using the κ statistic. Kappa could be calculated in 11 studies; the range of scores was 0.37 to 0.73 (median, 0.46). This κ level indicates moderate agreement between ABPM and home monitoring in the diagnosis of hypertension.

Children and Adolescents

Ambulatory blood pressure monitoring has been used in children and adolescents for similar purposes as in adults, including use in children and adolescents with elevated office BP to distinguish true hypertension from WCH. The evidence base for children and adolescents is smaller but generally consistent with the evidence in adults. A representative sample of studies follows.

Normative values for pediatric patients have been established by large population-based studies of children and adolescents.²⁰ Elevated readings are defined as values greater than the 95th percentile for sex, age, and height. These studies have also established that patterns of ambulatory BP in children differ from those in adults. In children, ambulatory BP is generally higher than the corresponding office BP, in contrast to adult ambulatory BP readings that are on average lower than office BP. This pattern is more pronounced in younger children, and the difference progressively declines with age. Guidelines for classification of hypertension in children and adolescents were published by the American Heart Association (2008).²¹

In a European study reported by Valent-Moric et al (2012), 139 children and adolescents between the ages of 4 and 19 years with elevated office BP were evaluated by ABPM.²² Thirty-two (23.0%) of 139 participants had WCH, as evidenced by a normal 24-hour ABPM result. Of patients with true hypertension, 21 (19.6%) of 107 had evidence of target organ damage, compared with none of the patients with WCH. In a similar study (2000) from the U.S., Sorof and Portman (2000) reported on 67 otherwise healthy children who underwent ABPM, 51 of whom had an elevated office BP.²³ Using 3 definitions of WCH at varying BP cutoffs, WCH was identified in 22% to 53% of children with elevated office BP. In a study from Japan, Matsuoka et al (2002) assessed 206 children and adolescents between the ages of 6 and 25 years who underwent ABPM, 70 of whom had elevated office BP.²⁴ Among the 70 patients with elevated office BP, 33 (47%) had WCH, as defined by a normal ABPM result. A "white coat" effect of 10 mm Hg or more was reported in 50% of patients with office hypertension and 25% of patients with normal office BP.

Section Summary: Clinically Valid

For adults, studies comparing home BP monitoring to office monitoring with ABPM as the criterion standard have reported that the sensitivity and specificity of alternative methods of diagnosing hypertension are suboptimal. For children and adolescents, reference values for normal and

abnormal ABPM results, derived from epidemiologic research, have been used to differentiate WCH from true hypertension.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

Direct evidence of the efficacy of ABPM for improving outcomes in this the outpatient setting would be obtained from RCTs comparing outcomes for (1) patients diagnosed and treated based on conventional BP measurements alone with (2) patients additionally undergoing ABPM used to guide therapy (eg, withholding or randomizing treatment among those with WCH). This notion parallels the statement from the U.S. National High Blood Pressure Education Program working group on ABPM in 1992: "Ideally, de novo longitudinal studies should be undertaken to determine which ambulatory profiles are associated with increased cardiovascular risk and what transformations of ambulatory profiles induced by antihypertensive therapy are associated with reductions in risk."²⁵ Randomized controlled trials using ABPM to monitor treatment response, but not to diagnose, hypertension have been conducted. However, a subgroup analysis of the Systolic Hypertension in Europe (Syst-Eur) trial (2000) addressed this question indirectly.²⁶

The Syst-Eur trial (2000), a large, multicenter RCT, enrolled patients 60 years of age or older with isolated systolic hypertension and randomized them to antihypertensive treatment or placebo.²⁶ A subgroup analysis evaluated 695 patients (from the total Syst-Eur sample of 4695 patients) who underwent 24-hour ABPM in addition to the usual study protocol. Conventional BP was defined from the mean of 6 baseline clinic BP readings (2 readings obtained with the patient seated at each of 3 baseline visits at least 1 month apart). Participants were classified into 3 groups based on ABPM readings: nonsustained hypertension (ie, WCH), mild-sustained hypertension, and moderate-sustained hypertension. Reduction in cardiovascular events was compared between active and placebo groups among patients in each category. For patients with nonsustained hypertension, there was a numerically lower rate of adverse outcomes in the treated group for stroke (0 vs 2, $p=.16$) and cardiovascular events (2 vs 6, $p=.17$) (ie, differences were not statistically significant). There was a significant reduction in events with treatment only among patients with moderate-sustained hypertension.

Staessen et al (1999) analyzed follow-up data (median follow-up, 4.4 years) from an apparently overlapping subset of 808 older individuals from the Syst-Eur trial who had isolated systolic hypertension measured conventionally (ie, systolic BP, 160-219 mm Hg; diastolic BP, <95 mm Hg) and BP by ABPM. Average systolic BP and diastolic BP were higher with conventional measurements (by 21.9 mm and 1.9 mm Hg, respectively). Ambulatory blood pressure monitoring was significantly associated with cardiovascular endpoints, even when conventional BP was taken into account.¹⁰

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Well-designed, prospective cohort studies could provide indirect evidence on the potential benefit of treating patients with WCH. Ideally, prospective studies would compare the outcomes of untreated patients with WCH to normotensive and sustained hypertensive patients (the latter being treated). Studies would have to control for important potential confounders such as adequacy of BP control, age, sex, smoking status, lipid levels, and diabetes. Well-designed and -conducted prospective cohort studies finding that untreated WCH patients have a cardiovascular event risk similar to that of normotensive patients would imply these patients accrue little treatment benefit. In contrast, if the cardiovascular risk for patients with WCH is increased, then there is a potential benefit to treatment.

The systematic review by Piper et al (2015), performed for the U.S. Preventive Services Task Force, identified 11 cohort studies that compared ABPM with alternative methods for predicting cardiovascular events.¹⁷ Six studies were rated good quality and 5 were rated fair quality. There was a significant correlation between ABPM measures and outcomes in most studies. For each 10-mm increase in the average 24-hour systolic BP, the hazard ratio for fatal and nonfatal cardiovascular events ranged from 1.11 to 1.42, and the hazard ratio for stroke ranged from 1.28 to 1.40.

Section Summary: Clinically Useful

Data from large prospective cohort studies have established that ABPM correlates more strongly with cardiovascular outcomes than other methods of BP measurement and that WCH, as defined by ABPM, is associated with an intermediate risk of cardiovascular outcomes compared with normotensive and hypertensive patients.

Summary of Evidence

For individuals with elevated office BP who receive 24-hour automated ABPM, the evidence includes RCTs, cohort studies, and studies of diagnostic accuracy. Relevant outcomes are test accuracy, other test performance measures, morbid events, and medication use. Data from large prospective cohort studies have established that ABPM correlates more strongly with cardiovascular outcomes than with other methods of BP measurement. Compared directly with other methods, ABPM performed over a 24-hour period has higher sensitivity, specificity, and predictive value for the diagnosis of hypertension than office or home BP measurements. Substantial percentages of patients with elevated office BP have normal BP on ABPM. Prospective cohort studies have reported that patients with WCH have an intermediate risk of cardiovascular outcomes compared with normotensive and hypertensive patients. The benefit of medication treatment in these patients is uncertain, and they are at risk of overdiagnosis and over treatment based on office BP measurements alone. Use of automated ABPM in these patients will improve outcomes by eliminating unnecessary pharmacologic treatment and avoiding adverse events in patients not expected to benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Pediatrics

In 2017, the American Academy of Pediatrics published clinical guidelines for the screening and management of high blood pressure (BP) in children and adolescents.²⁷ Table 2 lists recommendations made.

Table 2. Guidelines on Screening and Management of High Blood Pressure in Children and Adolescents

Recommendation	LOE	SOR
"ABPM should be performed for confirmation of HTN in children and adolescents with office BP measurements in the elevated BP category for 1 year or more or with stage 1 HTN over 3 clinic visits."	C	Moderate
"Routine performance of ABPM should be strongly considered in children and adolescents with high-risk conditions to assess HTN severity and determine if abnormal circadian BP patterns are present, which may indicate increased risk for target organ damage."	B	Moderate
"ABPM should be performed by using a standardized approach with monitors that have been validated in a pediatric population, and studies should be interpreted by using pediatric normative data."	C	Moderate
"Children and adolescents with suspected WCH should undergo ABPM."	B	Strong

ABPM: ambulatory blood pressure monitoring; BP: blood pressure; HTN: hypertension; LOE: level of evidence; SOR: strength of recommendation; WCH: white coat hypertension.

American College of Cardiology et al

In 2017, the American College of Cardiology, with 10 other medical specialty societies, published guidelines on the prevention, detection, evaluation, and management of high BP in adults.²⁸ Table 3 lists recommendations made.

Table 3. Guidelines on Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults

Recommendations	COR	LOE
"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 either daytime ABPM or HBPM before diagnosis of hypertension"	IIa	B-NR
"In adults with white coat hypertension, periodic monitoring with either ABPM or HBPM is reasonable to detect transition to sustained hypertension"	IIa	C-LD
"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	C-LD

Recommendations	COR	LOE
"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"	IIa	B-NR
"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	C-LD

ABPM: ambulatory blood pressure monitoring; COR: class of recommendation; DBP: diastolic blood pressure; HBPM: home blood pressure monitoring; LOE: level of evidence; SBP: systolic blood pressure.

American Heart Association

In 2014, the American Heart Association published updated recommendations on routine ambulatory blood pressure monitoring (ABPM) in children and adolescents, which included the following:¹:

- To confirm the diagnosis of hypertension in a patient with hypertension according to casual BP measurements
 - Determine whether sustained hypertension or WCH [white coat hypertension] exists.
- To evaluate for the presence of MH [masked hypertension] when there is a clinical suspicion of hypertension but normal or prehypertensive casual measurements
- To assess BP patterns in high-risk patients
 - Assess for abnormal circadian variation in BP, such as blunted dipping or isolated sleep hypertension in patients with diabetes mellitus, CKD [chronic kidney disease], solid organ transplants, and severe obesity with or without sleep-disordered breathing.
 - Assess the severity and persistence of BP elevation in patients at high-risk for hypertensive target-organ damage.
- To evaluate effectiveness of drug therapy for hypertension
 - Confirm BP control in treated patients, especially those with secondary forms of hypertension.
 - Evaluate for apparent drug-resistant hypertension.
 - Determine whether symptoms can be attributed to drug-related hypotension."

In 2019, the American Heart Association published a new scientific statement on blood pressure monitoring in humans that provides an overview of blood pressure measurement overall.²⁹ This scientific statement includes a summary of current knowledge about ABPM on topics such as medical staff or provider training; devices, cuffs and equipment; patient preparation and instruction; frequency and number of readings; duration of monitoring, and analysis of readings.

National Institute for Health and Care Excellence

In 2016 and 2019, the National Institute for Health and Care Excellence (NICE) updated its 2011 guidance on the diagnosis and management of hypertension in adults.³⁰ For diagnosing hypertension, the NICE made the following recommendations for ABPM:

- "If the clinic blood pressure is between 140/90 mmHg and 180/120 mmHg, offer ambulatory blood pressure monitoring (ABPM) to confirm the diagnosis of hypertension."
- "If ABPM is unsuitable or the person is unable to tolerate it, offer home blood pressure monitoring (HBPM) to confirm the diagnosis of hypertension."

- "When using ABPM to confirm a diagnosis of hypertension, ensure that at least 2 measurements per hour are taken during the person's usual waking hours. Use the average of at least 14 measurements taken during usual waking hours to confirm a diagnosis of hypertension."
- "Confirm diagnosis of hypertension in people with a clinic blood pressure of 140/90 mmHg or higher AND ABPM daytime average or HBPM average of 135/85 mmHg or higher."

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (USPSTF) (2021) commissioned a systematic review and reaffirmed its prior 2015 recommendations on screening for hypertension in adults.^{31,32,33} The following recommendation was given a grade A rating:

- "The USPSTF recommends screening for high blood pressure in adults aged 18 years or older. The USPSTF recommends obtaining measurements outside of the clinical setting for diagnostic confirmation before starting treatment."

The document further elaborated on the choice of office measurements, recommending ABPM as the reference standard for confirming the diagnosis of hypertension.³³

In 2021, the USPSTF issued updated recommendations for high BP screening in children and adolescents.³⁴ Based on a systematic review of 42 studies, the USPSTF concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening for high BP in this population.³⁵

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04826250	The Effect of Timing of Antihypertensive Medication on Diurnal Fluctuations in Blood Pressure Using a Wearable Sensor With Continuous Monitoring	150	Jan 2022 (recruiting)
NCT04726761	Frequent Cuff Inflations May Disrupt the Accuracy of 24-hour Ambulatory Blood Pressure Monitoring	154	Aug 2022 (recruiting)
<i>Unpublished</i>			
NCT03130257	Blood Pressure Checks for Diagnosing Hypertension (BP-CHECK)	510	Aug 2019 (completed)
NCT02121041	Comparative Effectiveness of Ambulatory Blood Pressure Monitoring vs Usual Care for Diagnosing and Managing Hypertension: A Pilot Study	28	Jun 2016 (completed)

NCT: national clinical trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS

- 99473 Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration
- 99474 Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient
- A4670 Automatic blood pressure monitor

ICD-10 Diagnoses

- I10 Essential (primary) hypertension
- I11.0 Hypertensive heart disease with heart failure
- I11.9 Hypertensive heart disease without heart failure
- R03.0 Elevated blood-pressure reading, without diagnosis of hypertension
- Z01.30 Encounter for examination of blood pressure without abnormal findings
- Z01.31 Encounter for examination of blood pressure with abnormal findings

REVISIONS

11-06-2003	Added #4 a and b – "One follow up test will be allowed at least three weeks after initial test for: a. patients diagnosed with white-coat hypertension or b. assessment of hypertension apparently resistant to appropriate therapy.
09-18-2009	In Description section: ▪ Updated wording In Policy section: ▪ Updated indications From: "Ambulatory blood pressure monitoring: will be allowed for patients with symptoms meeting the following criteria: 1. Failed home blood pressure monitoring 2. Office pressure greater than 180/95 but less than 105 diastolic. 3. Treatment resistant and taking multiple medications. 4. One follow up test will be allowed at least three weeks after initial test for: a. Patients diagnosed with white-coat hypertension or b. Assessment of hypertension apparently resistant to appropriate therapy."

	<p>To:</p> <p>"Automated ambulatory blood pressure monitoring (ABPM) includes multiple blood pressure (BP) measurements over a 24-hour period and is considered medically necessary, for up to 72 hours with FDA-approved devices, for the evaluation of individuals with any of the following:</p> <ol style="list-style-type: none"> 1. Suspected "White Coat Hypertension" (WCH) which is defined as: <ol style="list-style-type: none"> a. In-office BP >140/90 mmHg on at least three separate clinic/office visits with two separate measurements taken at each visit; and b. At least two documented separate BP measurements taken outside the office setting which are <140/90 mmHg; and c. No evidence of end-organ damage 2. Individuals with resistant hypertension who are being treated with three or more medications 3. Hypertensive individuals with hypotensive symptoms and/or syncopal events thought to be related to antihypertensive medications or neurological syndromes, including autonomic dysfunction. 4. Episodic hypertension suspected when office BP measurements are normal and associated symptoms (e.g., excessive sweating, palpitations, pallor) suggest episodic hypertension secondary to an existing condition. 5. Suspected autonomic dysfunction."
	Added Rationale section.
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added HCPCS code: A4670.
12-07-2012	Updated Description section.
	<p>In the Policy section:</p> <ul style="list-style-type: none"> ▪ In the policy statement, removed "includes multiple blood pressure (BP) measurements over a 24 hour period and is" and inserted "performed one time over a 24 hour period with FDA approved devices" to read "Automated ambulatory blood pressure monitoring (ABPM) performed one time over a 24 hour period with FDA approved devices may be considered medically necessary..." ▪ In the policy statement, removed "for up to 72 hours with FDA approved devices" to read "may be considered medically necessary, for the evaluation of individuals with any of the following:" ▪ In Item #1, removed "which is" to read "Suspected White Coat Hypertension defined as:" ▪ In Item #2, revised "Individuals with resistant hypertension who are being treated with three or more medications" to read "Resistant hypertension being treated with three or more antihypertensive medications at therapeutic doses."
	Updated Rationale section.
	Updated Reference section.
02-26-2013	Updated Rationale section.
	Updated Reference section.
12-31-2013	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added ICD-10 Diagnosis (<i>Effective October 1, 2013</i>)
03-18-2015	<p>Title of policy changed from "Ambulatory Blood Pressure Monitoring."</p> <p>Updated Description section.</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Added Policy Guidelines: <ol style="list-style-type: none"> "1. For pediatric patients, the principles of ABPM use to confirm a diagnosis of hypertension are the same as in adults, but there are special considerations as follows(1): <ol style="list-style-type: none"> a. A device should be selected that is appropriate for use in pediatric patients, including use of a cuff size appropriate to the child's size.

	<p>b. Threshold levels for the diagnosis of hypertension should be based on pediatric normative data, which use gender- and height-specific values derived from large pediatric populations.</p> <p>c. Recommendations from the American Heart Association concerning classification of hypertension in pediatric patients using clinic and ambulatory BP are given in Table 1:</p> <ul style="list-style-type: none"> ▪ Added Table 1.
	Updated Rationale section.
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added ICD-10 codes I11.0, I11.9, Z01.30, and Z01.31. ▪ Removed ICD-9 code 796.4. ▪ Removed ICD-10 code R68.89.
	Updated References section.
09-15-2016	Updated Description section.
	Updated Rationale section.
	Updated References section.
07-11-2017	Updated Description section.
	Updated Rationale section.
	Updated References section.
09-12-2018	Updated Description section.
	Updated Rationale section.
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Removed ICD-9 codes.
	Updated References section.
08-16-2019	Updated Description.
	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Added Item B, "All other uses of ambulatory monitoring for patients with elevated office blood pressure are considered experimental / investigational including, but not limited to, repeated testing in patients with persistently elevated office blood pressure and monitoring of treatment effectiveness."
	Updated Rationale section.
	Updated References section.
01-01-2020	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added CPT Codes: 99473, 99474 ▪ Removed CPT Codes: 93784, 93786, 93788, 93790
04-19-2021	Updated Description section.
	Updated Rationale section.
	Updated References section.
09-17-2021	Updated Rationale section.
	Updated References section.

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