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

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 preprogrammed intervals. Ambulatory blood pressure monitoring (ABPM) has the potential to improve the accuracy of diagnosing hypertension and thus improve the appropriateness of medication treatment.

Background
Ambulatory blood pressure monitoring (ABPM), typically done over a 24-hour period with a fully automated monitor, provides more detailed blood pressure information than typically obtained during office visits. The greater number of readings with ABPM ameliorates the variability of single blood pressure measurements, and is more representative of the circadian rhythm of BP compared to the limited number obtained during office measurement.

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

In evaluating patients having elevated office BP, ABPM is often intended to identify patients 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 WCH are not at increased risk for cardiovascular events and would not benefit from antihypertensive treatment.

This policy does not directly address other uses of ABPM, including the use of ABPM 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. Other potential 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 nighttime BP; examining diurnal patterns of BP; and/or other potential uses.

**Regulatory Status**

Many ambulatory blood pressure monitors have received clearance to market through the FDA 510(k) marketing clearance process. As an example of an FDA indication for use, the Welch Allyn ABPM 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. The system is only for measurement, recording, and display. It makes no diagnosis.” (1)

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Automated ambulatory blood pressure monitoring over a 24 hour period may be considered **medically necessary** for patients with elevated office BP, when performed one time to differentiate between “white coat hypertension” and true hypertension, and when the following conditions are met (See Policy Guidelines for considerations in pediatric patients):

- Office BP elevation is in the mild to moderate range (<180/110), not requiring immediate treatment with medications.
- There is an absence of hypertensive end-organ damage on physical examination and laboratory testing.

All other uses of ambulatory blood pressure monitoring for patients with elevated office BP, including but not limited to repeated testing in patients with persistently elevated office BP, and monitoring of treatment effectiveness is considered **not medically necessary**.

**Policy Guidelines**

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 device should be selected that is appropriate for use in pediatric patients, including use of a cuff size appropriate to the child’s size.
- 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.
- Recommendations from AHA guidelines concerning classification of hypertension in pediatric patients using clinic and ambulatory BP are given in PGTable 1

PGTable 1. American Heart Association Classification of Ambulatory BP Levels in Children (Flynn et al, 2014)
### Classification

<table>
<thead>
<tr>
<th>Classification</th>
<th>Clinic BP</th>
<th>Mean Ambulatory SBP</th>
<th>SBP Load a</th>
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</thead>
<tbody>
<tr>
<td>Normal BP</td>
<td>&lt;95th percentile</td>
<td>&lt;95th percentile</td>
<td>&lt;25%</td>
</tr>
<tr>
<td>WC HTN</td>
<td>&gt;95th percentile</td>
<td>&lt;95th percentile</td>
<td>&lt;25%</td>
</tr>
<tr>
<td>Masked HTN</td>
<td>&lt;95th percentile</td>
<td>&gt;95th percentile</td>
<td>&gt;25</td>
</tr>
<tr>
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<td>&gt;95th percentile</td>
<td>&lt;95th percentile</td>
<td>25-50%</td>
</tr>
<tr>
<td>Ambulatory HTN</td>
<td>&gt;95th percentile</td>
<td>&gt;95th percentile</td>
<td>25-50%</td>
</tr>
<tr>
<td>Severe Ambulatory HTN</td>
<td>&gt;95th percentile</td>
<td>&gt;95th percentile</td>
<td>&gt;50%</td>
</tr>
</tbody>
</table>

BP: blood pressure; HTN: hypertension; SBP: systolic blood pressure; WC: white coat

*a Percent of SBP readings that are above 95th percentile for gender and height

### Rationale

The evidence base for this review originates from a 1999 TEC Assessment and subsequent 2001 reanalysis of this report conducted for the Centers for Medicare and Medicaid Services. The focus 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.

Evidence on whether ABPM improves health outcomes for patients with elevated office BP will be summarized in 3 general areas of research:

1. Reference values for ABPM
2. Impact of ABPM on outcomes
   a) Clinical trials
   b) Prospective cohort studies
3. Accuracy of ABPM as a diagnostic test for hypertension
   a. Prospective cohort studies
   b. Cross-sectional studies

### Reference values for ABPM monitoring

One important area addresses the question of reference values for ABPM to provide guidelines for “normal” and “abnormal” ABPM readings. Studies that have compared ABPM measurements to office measurement consistently reveal lower values for ABPM. Therefore, it is not possible to use reference values for office blood pressure 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 blood pressure (BP) of 140/90, 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 for an office BP of 140/90. 6,7

Although specific recommendations vary slightly, current thresholds for defining a normal ABPM are 24-hour average BP of 130/80 and daytime average BP of 135/85. An ABPM Consensus Conference task force on ABPM considered data on the statistical distribution of ABPM, the correlation with office BP, and correlation with cardiovascular outcomes in deriving recommendations for reference values for ABPM. 8 Their recommendations are summarized in Table 1. Subsequent studies have identified racial and ethnic variation in ABPM results, 9 but impacts of these differences on clinical management may be minimal. 10

<table>
<thead>
<tr>
<th>ABPM Measure</th>
<th>95th Percentile</th>
<th>Normotension</th>
<th>Hypertension</th>
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<tbody>
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<td>24-hour average</td>
<td>132/82</td>
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<tr>
<td>Daytime average</td>
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<tr>
<td>Nighttime average</td>
<td>123/74</td>
<td>≤120/70</td>
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ABPM: ambulatory blood pressure monitoring.

Section Summary: Reference Values for ABPM Monitoring
Reference values for normal and abnormal ABPM results have been derived from epidemiologic research. These reference values vary slightly among different sources but are available for clinical use.

Impact of ABPM on outcomes

Clinical Trials: Direct evidence of the efficacy of ABPM improving outcomes in this setting would be obtained from randomized controlled trials (RCTs) comparing outcomes of: 1) patients diagnosed and treated based on conventional blood pressure 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 National High Blood Pressure Education Program Working Group on Ambulatory Blood Pressure Monitoring 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.” 11 RCTs using ABPM for monitoring treatment response but not to diagnose hypertension have been conducted. However, a substudy of the Systolic Hypertension in Europe (Syst-Eur) trial did address this question indirectly. 12

The Syst-Eur trial, a large, multicenter RCT, enrolled patients 60 years of age or older with isolated systolic hypertension and randomized them to antihypertensive treatment or placebo. 12 A substudy 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 blood pressure was defined from the mean of 6 baseline clinic BPs (2 readings obtained with the patient seated at 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. The reduction in
cardiovascular events was compared between active and placebo groups among patients in each of the 3 categories. For patients with nonsustained hypertension, there was a numerically lower rate of adverse outcomes in the treated group for stroke (0 vs. 2, p=0.16) and cardiovascular events (2 vs. 6, p=0.17), ie, differences not reaching statistical significance. 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 [SBP]: 160–219 mm Hg, diastolic BP [DBP]: <95 mm Hg). 13 BPs also were measured by ABPM; average SBP and DBP were higher with conventional measurements (by 21.9 and 1.9 mm Hg, respectively). ABPM was significantly associated with cardiovascular endpoints, even when conventional BP was taken into account.

Prospective Cohort Studies

Well-designed, prospective cohort studies could provide indirect evidence on the potential benefit of treatment for patients with WCH. Ideally, prospective studies would compare outcomes of untreated patients with WCH with normotensive and sustained hypertensive patients (the latter being treated). Studies should control for important potential confounders such as adequacy of BP control, age, sex, smoking, lipid levels, and diabetes. Well-designed and conducted prospective cohort studies finding untreated WCH patients having a cardiovascular event risk similar to 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.

A systematic review by Piper et al was performed for the U.S. Preventive Services Task Force (USPSTF) and identified 11 cohort studies that compared ABPM with alternate measurement methods for predicting cardiovascular events. 14 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 SBP, the hazard ratio (HR) for fatal and nonfatal cardiovascular events ranged from 1.11 to 1.42, and the HR for stroke ranged from 1.28 to 1.40.

Numerous large cohort studies have used ABPM to identify patients with WCH and compared future cardiovascular outcomes in WCH patients, normotensive patients, and sustained hypertensive patients. 15-22 These studies have been generally consistent in reporting that the cardiovascular risk for patients with WCH is intermediate, between that of hypertensive patients and normotensive patients. For example, a 2014 meta-analysis found that mean left ventricular mass index and mean left atrial diameter in patients with WCH was intermediate, between that of hypertensive patients and normotensive individuals. 23 A 2013 review found that in patients with WCH, prevalence of cardiovascular risk factors, such as glucose dysregulation, diabetes, increased left ventricular mass index, and sustained hypertension, was increased compared with normotensive individuals, but the risk of cardiovascular events was not. 24 The authors attributed the latter finding to the frequent use of antihypertensive treatment in WCH.
At least 3 meta-analyses have been published that summarize the results of the available cohort studies. Fagard and Cornelissen (2007) summarized data from 7 cohort studies that compared outcomes in 4 groups of patients: normotensive patients, WCH patients, “masked” hypertensive patients, and sustained hypertensive patients (total N=11,502). Average follow-up in these studies was 8.0 years. Using normotensive patients as the reference standard, the risk for patients with WCH was not significantly higher (hazard ratio [HR] = 1.12; 95% confidence interval [CI], 0.84 to 1.50). There was an increased risk for patients with “masked” hypertension (HR = 2.00; 95% CI, 1.58 to 2.52) and patients with sustained hypertension (HR = 2.28; 95% CI, 1.87 to 2.78).

Hansen et al (2007) used patient-level data from 4 previous cohorts of patients to construct an international database on ambulatory BP monitoring. This database included 7069 patients from 4 cohorts in Europe and Japan that represented population-level patient samples. In this analysis, there was a trend toward increased cardiovascular events in patients with WCH that did not reach statistical significance (HR= 1.22; 95% CI, 0.96 to 1.53, p=0.09). Statistically increased risks were found in patients with “masked” hypertension (HR = 1.62; 95% CI, 1.35 to 1.96, p<0.001) or sustained hypertension (HR= 1.80; 95% CI, 1.59 to 2.03, p<0.001).

A third pooled analysis by Verdecchia et al (2005) included studies conducted in the United States, Italy, and Japan. This analysis compared short- and long-term stroke risk among 4406 individuals with essential hypertension and 1549 normotensive controls; none treated at baseline. WCH was present in 9% of the hypertensive group. During the first 6 years, follow-up stroke incidence appeared similar among WCH and normotensive groups. However, by 9 years, stroke incidence among WCH patients reached that of the hypertensive group (measured by ABPM). At the last telephone contact or clinic visit, similar proportions of those initially classified as WCH and normotensive were receiving antihypertensive medications from 5 different drug classes. This result suggests WCH may not be entirely benign.

Section Summary: Impact of ABPM on Outcomes
Data from large prospective cohort studies have established that ABPM correlates more strongly with cardiovascular outcomes compared with 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.

Accuracy of ABPM as a diagnostic test for hypertension

Studies of the accuracy of ABPM as a diagnostic test for hypertension are of two types. First, prospective cohort studies, that correlate the results of ABPM with future cardiovascular events, and compare this correlation to office BP measurements, provides indirect evidence on ABPM accuracy by assuming that the more accurate test will have a higher correlation with hypertension-related outcomes. Second, cross-sectional studies can directly compare the accuracy of ABPM compared with office BP, using a criterion standard for diagnosis. For these types of studies, ABPM is often considered to be the criterion standard, and the accuracy of other methods of measuring BP is compared against ABPM.
Prospective Cohort Studies
Many prospective cohort studies have compared ABPM with office BP in predicting cardiovascular events. Although the results of these studies are not entirely consistent, the majority report that ABPM has greater predictive ability for cardiovascular events compared with office BP measurement. 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 four populations in Belgium, Denmark, Japan, and Sweden (total N= 7030). Predictive value of ABPM and clinic BP for fatal and non-fatal cardiovascular events was 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 et al (2008) conducted a meta-analysis on 20 cohort studies that evaluated the correlation between ABPM and outcomes and controlled for office BP in the analysis. These authors reported that ABPM was a strong predictor of cardiovascular outcomes and that controlling for office BP had little effect on the risk estimates. These results support the hypothesis that the risk information obtained from ABPM is independent of that from office BP.

Cross-Sectional Diagnostic Accuracy Studies
In the systematic review published by Piper for USPSTF, 7 studies of diagnostic accuracy were identified. 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 clearly defined thresholds to determine the accuracy of diagnosis of hypertension. 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, clinic BP measurements had a sensitivity of 75% (95% 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 not considered adequate for use as a single diagnostic test for hypertension, and it was hypothesized that the use of office and/or home measurements may lead to substantial over diagnosis 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. Sixteen studies were included in this analysis. Sensitivity of home BP measurement, compared with ABPM, ranged from 36% to 100% (median, 74%). Specificity ranged from 44% to 96% (median, 84%). This study also reported the diagnostic agreement between the 2 methods of BP measurement, as measured by the $\kappa$ statistic. Kappa could be calculated in 11 studies; the range of scores was 0.37 to 0.73 (median, 0.46). This $\kappa$ level indicates moderate agreement between ABPM and home monitoring in the diagnosis of hypertension.
Lovibond et al (2011) performed a cost-effectiveness study comparing ABPM with office BP measurement and home measurements. For most patient indications, ABPM resulted in the greatest amount of quality-adjusted life years (QALYs) gained, and, in individuals older than age 50 years, ABPM was consistently associated with the largest incremental gain in QALYs. ABPM was cost-saving in all patient groups compared with alternatives and remained the most cost-effective alternative under the majority of sensitivity analyses. As a result of these findings, the authors recommended that ABPM be performed for most patients before the decision to start antihypertensive medications is made.

Other Studies

A number of trials have evaluated ABPM for the management of established hypertension, comparing the effect of ABPM use on BP control and medication use with usual care based on office measurements. Some studies have compared home self-monitoring to ABPM and office measurement for management of medication treatment. Others have attempted to determine predictors of WCH based on clinical factors and office BP readings. However, these areas of research do not provide specific evidence on the use of ABPM for diagnosing and treating patients with elevated office BP and thus are not included in the final evidence base for this review.

Section Summary: Accuracy of ABPM as a Diagnostic Test for Hypertension

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.

ABPM in children and adolescents

ABPM 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 of ABPM in children and adolescents is of similar type for adults but of a smaller quantity. A representative sample of studies identified follows.

Normative values for pediatric patients have been established by large population-based studies of children and adolescents. Elevated readings are defined as values greater than the 95th percentile for sex, age, and height. These studies also have 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 in 2008 (see Policy Guidelines section for specific recommendations).

In a study from Europe, 139 children and adolescents between the ages of 4 to 19 years of age with elevated office BP were evaluated by ABPM monitoring. Thirty-two (23%) 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 from the U.S., 67 otherwise healthy children underwent ABPM, 51 of who had an elevated office BP. Using 3 definitions of WCH of varying BP cutoffs, WCH was identified in 22% to 53% of children with elevated office BP. In a study from Japan, 206 children and adolescents between the ages of 6 to 25 years underwent ABPM, 70 of whom had elevated office BP. 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: ABPM in Children and Adolescents
Reference values for normal and abnormal ABPM results in children and adolescents have been derived from epidemiologic research and have been used to differentiate WCH from true hypertension in pediatric patients.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>Ongoing</td>
<td>Comparative Effectiveness of Ambulatory Blood Pressure Monitoring vs Usual Care for Diagnosing and Managing Hypertension: A Pilot Study</td>
<td>30</td>
<td>Jun 2016 (ongoing)</td>
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</tbody>
</table>

NCT: national clinical trial.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence
The UK’s National Institute for Health and Clinical Excellence (NICE) issued updated hypertension guidelines in 2011. For diagnosing hypertension, NICE made the following recommendations concerning ABPM:

- If the clinic BP is 140/90 mm Hg or higher, offer ABPM 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.
Canadian Hypertension Education Program (CHEP):
Guidelines for BP measurement, diagnosis, and risk assessment have been published annually by CHEP. Strength of evidence underlying recommendations is graded ranging from “A” (studies with high internal validity, statistical precision, and generalizability) to “D” (expert opinion).

The 2015 recommendations\(^{47}\) include:
- Ambulatory BP readings can be used in the diagnosis of hypertension (Grade C).
- ABPM should be considered when an office-induced increase in BP is suspected in treated patients with:
  - BP that is not below target despite receiving appropriate chronic antihypertensive therapy (Grade C);
  - symptoms suggestive of hypotension (grade C); or
  - fluctuating office BP readings (grade D).
- Ambulatory monitoring upper arm devices that have been validated independently using established protocols must be used (grade D).
- Therapy adjustment should be considered in patients with a 24-hour ambulatory SBP (systolic blood pressure) of ≥130 mm Hg or DBP (diastolic blood pressure) of ≥80 mm Hg or an awake SBP of ≥135 mm Hg or DBP of ≥85 mm Hg (grade D).
- The magnitude of changes in nocturnal BP should be taken into account in any decision to prescribe or withhold drug therapy based upon ambulatory BP (grade C) because a decrease in nocturnal BP of less than 10% is associated with increased risk of CV events.

American Heart Association (AHA) Recommendations for ABPM in Children and Adolescents:

The AHA published consensus recommendations in 2008 developed by their Atherosclerosis, Hypertension, and Obesity in Youth Committee of the Council on Cardiovascular Disease in the Young and the Council for High Blood Pressure Research.\(^{42}\) These recommendations were updated in 2014.\(^{48}\) Consensus recommendations for routine ABPM include the following:
- To confirm the diagnosis of hypertension in a patient with hypertension according to casual BP measurements
  - Determine whether sustained hypertension or white coat hypertension exists.
- To evaluate for the presence of 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, 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
  o Confirm BP control in treated patients, especially those with secondary forms of hypertension.
  o Evaluate for apparent drug-resistant hypertension.
  o Determine whether symptoms can be attributed to drug-related hypotension.

**European Society of Hypertension and European Society of Cardiology European**

In 2013, the European Society of Cardiology and the European Society of Hypertension published joint evidence-based guidelines for the management of arterial hypertension. 49 These guidelines recommend ABPM or home BP monitoring for out-of-office BP measurements depending on indication, availability, ease, cost of use, and patient preference (class 2b recommendation [usefulness/efficacy is less well established; use may be considered] based on level C evidence [consensus expert opinion and/or small studies, retrospective studies, or registries]). Guideline authors stated, “Whether subjects with WCH can be equalled to true normotensive individuals is an issue still under debate because, in some studies, the long-term cardiovascular risk of this condition was found to be intermediate between sustained hypertension and true normotension, whereas in meta-analyses it was not significantly different from true normotension when adjusted for age, gender, and other covariates.” 49

**European Society of Hypertension:**
Since 2003, the European Society of Hypertension has published consensus-based guidelines on ABPM. 50, 51 The most recent update in 2013 identified white-coat phenomena, masked hypertension, and nocturnal hypertension as indications for ABPM. 52, 53

**British Hypertension Society (BHS):**
The British Hypertension Society issued a 2011 guideline on hypertension which was produced in collaboration with the National Institute for Health and Care Excellence (NICE). Refer to the NICE Clinical Guideline (CG) 127 previously referenced. 46 This guideline is scheduled for update in September 2015.

**National High Blood Pressure Education Program**
The fourth report on the diagnosis, evaluation, and treatment of high BP in children and adolescents was published in 2004. 54 This report made the following statements concerning the use of ABPM in children and adolescents:

• ABPM is especially helpful in the evaluation of WCH, as well as the risk for hypertensive organ injury, apparent drug resistance, and hypotensive symptoms with antihypertensive drugs.
• ABPM is also useful for evaluating patients for whom more information on BP patterns is needed, such as those with episodic hypertension, chronic kidney disease, diabetes, and autonomic dysfunction.
• Conducting ABPM requires specific equipment and trained staff. Therefore, ABPM in children and adolescents should be used by experts in the field of pediatric hypertension who are experienced in its use and interpretation.
Joint National Committee VII:
The seventh report of the Joint National Committee on the prevention, detection, evaluation, and treatment of high BP, released in 2003, includes a brief section on the use of ABPM. The report stated that “[a]mbulatory blood pressure monitoring is warranted for the evaluation of (white-coat) hypertension in the absence of target organ damage. It is also helpful to assess patients with apparent drug resistance, hypotensive symptoms with antihypertensive medications, episodic hypertension, and autonomic dysfunction.”

U.S. Preventive Services Task Force

The U.S. Preventive Services Task Force (USPSTF) published a recommendation in 2015 that individuals 18 years and older be screened for hypertension. 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, with the following statement about 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. 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. For these reasons, the USPSTF recommends ABPM as the reference standard for confirming the diagnosis of hypertension.”

Summary of Evidence

For individuals with elevated office blood pressure (BP) who receive 24-hour automated ambulatory blood pressure monitoring (ABPM), the evidence includes randomized controlled trials, 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. When compared directly to 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 (white coat hypertension). Prospective cohort studies have reported that patients with white coat hypertension 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 for overdiagnosis and overtreatment based on office BP measurements alone. Use of 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

Medicare National Coverage Determination

Medicare considers ABPM eligible for coverage as follows:

“At this point in time, ABPM will be covered for those patients with suspected WCH. Suspected WCH will be defined as office blood pressure >140/90 mm Hg on at least 3 separate clinic/office visits with 2 separate measurements made at each visit. In addition, there should be at least 2 blood pressure measurements taken outside the office that are <140/90 mm Hg. There should be no evidence of end-organ damage. The information obtained by ABPM is necessary in order to determine the appropriate management of the patient.”

References

2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). 24-hour ambulatory blood pressure monitoring for the evaluation of patients with elevated office blood pressure. TEC Assessments 1999: Volume 14, Tab 8.

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<td>references 9, 10, 11, 12, 31, 33 were added. URL changed in</td>
</tr>
<tr>
<td></td>
<td></td>
<td>reference 34.</td>
</tr>
<tr>
<td>June 2012</td>
<td>Update Policy</td>
<td>Policy updated with literature review and name change. References</td>
</tr>
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<td>renumbered and 26-29, 37 added. Addition to policy statement</td>
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### Keywords

Ambulatory Blood Pressure Monitor  
Blood Pressure Monitoring, Ambulatory  
Monitor, Blood Pressure, Ambulatory  
Sphygmomanometry, Ambulatory

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 2, 2016 and is effective January 15, 2017.