Medical Policy



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Title: Ambulatory Blood Pressure Monitoring For Screening and Diagnosis of Hypertension

Description/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 indices 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 indices have suggested that higher 24-hour and nighttime BP indices may marginally improve model predictions of greater risk of death and composite cardiovascular events.¹.

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 individuals having elevated office BP, ABPM is often intended to identify individuals with normal ambulatory readings who do not have sustained hypertension. Because this group of individuals would otherwise be treated based on office BP readings alone, ABPM could improve outcomes by allowing these individuals to avoid unnecessary treatment. However, this assumes individuals 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 ABPMs 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 of time. The system is only for measurement, recording, and display. It makes no diagnosis."¹

FDA product code: DXN

Medical Policy Statement

Ambulatory blood pressure monitoring is established as safe and effective and is a useful option when performed for the screening, diagnosis and management of hypertension, when indicated.

Inclusionary and Exclusionary Guidelines

Ambulatory blood pressure monitoring is established in any of the following circumstances:

- To screen for the presence of hypertension in pediatric and adult individuals consistent with nationally accepted protocols (e.g., USPSTF).
- To confirm the diagnosis of hypertension before initiating pharmacotherapy, when the diagnosis is uncertain.
- When the information obtained by ambulatory blood pressure monitoring is necessary to determine the adequacy of antihypertensive management.

Ambulatory blood pressure monitoring should be used to support clinical decisionmaking. ABPM is not medically necessary if clinical decision-making can be accomplished with the use of traditional methods of blood pressure measurement alone. The medical record should reflect the need and rationale for use of ABPM.

For pediatric individuals, the principles of ABPM use to confirm a diagnosis of hypertension are the same as in adults, but there are special considerations as follows:

• 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 the American Heart Association concerning classification of hypertension in pediatric patients using clinic and ambulatory BP are given in Table PG1:

Classification	Clinic Systolic or Diastolic BP		Mean Ambulatory Systolic or Diastolic BP		
	·				
Category	<13 y of age	≥13 y of age	<13 y of age	≥13 y of age	
Normal BP	<95th percentile	<130/80 mm Hg		<125/75 mm Hg	
White coat hypertension	≥95th percentile	≥130/80	<95th percentile OR adolescent cut points ^a	over 24-h AND <130/80 mm Hg while awake AND <110/65 mm Hg while asleep	
Masked hypertension	<95th percentile	<130/80		≥125/75 mm Hg	
Ambulatory hypertension	≥95th percentile	≥130/80	≥95th percentile OR adolescent cut points ^a ≥130/ while ≥110/	over 24-h OR ≥130/80 mm Hg while awake OR ≥110/65 mm Hg while asleep	

Table PG1. Classification of Ambulatory Blood Pressure Levels in Children and Adolescents

Adapted from Flynn et al (2022).

BP: blood pressure.

^a Including 24 h, wake, and sleep blood pressure.

CPT/HCPCS Level II Codes (Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)

Established codes:93784937869378893790

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

The evidence base for this policy originates from a 1999 TEC Assessment³ and subsequent re-analysis of this report conducted for the Centers for Medicare and Medicaid Services in 2001.⁴ 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 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

Clinical Context and Test Purpose

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

The following **PICOs** were used to select literature to inform this review.

Populations

The relevant population of interest are individuals with elevated office blood pressure determined using guideline-based parameters.

Interventions

The test being considered is 24-hour automated ambulatory blood pressure monitoring.

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 blood pressure readings so 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. 24-hour automated ABPM may be used when there is persistent unexplained variability in serial elevated BP measurements over a 1-3 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.^{5,6} Studies that have compared ABPM measurements with office measurement consistently reveal lower values for ABPM. 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; 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.^{7,8}

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, correlation with office BP, and correlation with cardiovascular outcomes in deriving recommendations for reference values for ABPM.⁹ Their recommendations are summarized in Table 1. Subsequent studies have identified racial and ethnic variation in ABPM results,¹⁰ but impacts of these differences on clinical management may be minimal.¹¹

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).^{9.}

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.^{12,13} 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 (total n=7030 patients).¹⁴ 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.¹⁵ 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 were identified.¹⁶ Four were rated high-quality and three3 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%.

A systematic review and meta-analysis by Panagiotakos et al (2024) evaluated prospective cohort studies that explored the role of ABPM and home BP measurements on cardiovascular disease risk prediction.^{17.} The review included 8 studies and the number of participants per study ranged from 150 to 2000. Systolic blood pressure (SBP) readings were significantly positively associated with CVD risk for ABPM (combined hazard ratio [HR] per 1 standard deviation SBP, 1.32; 95% CI, 1.19 to 1.45) and for home measurements (combined HR per 1 standard deviation SBP, 1.30; 95% CI, 1.11 to 1.49). For systolic ABPM measurements, there was no significant heterogeneity reported (I²=79.1%;p<.001).

Numerous other studies have directly compared ABPM with office BP and/or home selfmeasured 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 ten studies identified, seven compared ABPM with office BP measurements and three 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 over-diagnosis and over-treatment.

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 two2 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

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 base for children and adolescents is smaller but generally consistent with the evidence in adults. A representative sample of studies identified 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 2002 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 in pediatric patients.

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, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary 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 (e.g., 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 RCTs 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 six baseline clinic BP readings (two readings obtained with the patient seated at each of three baseline visits at least one month apart). Participants were classified into three groups based on ABPM readings: nonsustained hypertension (i.e., 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=0.16) and cardiovascular events (2 vs. 6, p=0.17), i.e., 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 (i.e., 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). ABPM was significantly associated with cardiovascular endpoints, even when conventional BP was taken into account.⁹

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.¹⁶ Six studies were rated good quality and five 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 blood pressure (BP) who receive 24-hour automated ambulatory blood pressure monitoring (ABPM), the evidence includes RCTs, cohort studies, and studies of diagnostic accuracy. The 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 over diagnosis 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 gualitatively that the technology results in a meaningful improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06198855	Automated Measurement of Blood Pressure in Waiting Appointment Versus 24-h Ambulatory Measurements	500	Jun 2025
Unpublished			
NCT04726761	Frequent Cuff Inflations May Disrupt the Accuracy of 24-hour Ambulatory Blood Pressure Monitoring	154	Aug 2022
NCT03480217	Assessing the Effectiveness of a Multifaceted Implementation Strategy to Increase the Uptake of the USPSTF Hypertension Screening Recommendations in an Ambulatory Care Network: a Cluster Randomized Trial	2000	Jul 2022

Table 4. Summary of Key Trials

NCT: national clinical trial.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Pediatrics

The American Academy of Pediatrics (2017) published a clinical practice guideline for the screening and management of high blood pressure in children and adolescents.²⁷ Table 2 lists the following recommendations.

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 clinical visits."		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."	В	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."	С	Moderate
"Children and adolescents with suspected WCH should undergo ABPM."	В	Strong

BP: blood pressure; DBP: diastolic blood pressure; HTN: hypertension; LOE: level of evidence; SBP: systolic blood pressure; SOR: strength of recommendation; WCH: white coat hypertension.

American College of Cardiology et al

The American College of Cardiology, with 10 other medical specialty societies, published guidelines for the prevention, detection, evaluation, and management of high blood pressure in adults in 2017.²⁸

Table 3 lists the following recommendations.

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"	lla	B-NR
"In adults with white coat hypertension, periodic monitoring with either ABPM or HBPM is reasonable to detect transition to sustained hypertension"	lla	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"	lla	C-LD
"In adults with untreated office BPs that are consistently between 120 mm Hg and 129 mm Hg for SBP between 75 mm Hg and 79 mm Hg for DBP, screening for masked hypertension with HBPM (or ABPM) is reasonable"	lla	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)"	llb	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 2022, the AHA updated its 2014 recommendations on routine ABPM in children and adolescents, which included the following:^{29,30}

- "To confirm the diagnosis of hypertension in a patient with hypertension on the basis of clinic BP measurements:
 - Distinguish between ambulatory hypertension and WCH [white coat hypertension].
- To better assess BP in a patient with clinic BP persistently in the elevated but not hypertensive range.
- To evaluate for possible masked hypertension when there is a clinical suspicion of hypertension, but clinic BP readings are normal or in the elevated BP range.
- To evaluate for possible masked hypertension when there is clinical suspicion of hypertension, but clinic BP readings are normal or in the elevated BP range.
- To assess BP patterns in high-risk patients:
 - Assess for abnormal circadian variation in BP, such as abnormal dipping, or isolated nocturnal hypertension in patients with diabetes, CKD [chronic kidney disease], solid-organ transplant, and severe obesity with or without sleepdisordered breathing.
 - Assess the severity and persistence of BP elevation in patients at high risk for hypertensive TOD [target organ damage].
- To optimize drug therapy for hypertension:
 - Confirm BP control in treated patients
 - Evaluate for pseudo-resistant hypertension
 - Determine if symptoms suggestive of hypotension can be confirmed as such.
- An ABPM device suitable for use in children should be selected:
 - Only oscillometric or auscultatory ABP devices that have been validated according to American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)/International Organization for Standardization (ISO) should be used. The British Hypertension standard is acceptable for devices marketed before publication of the ANSI/AAMI/ISO standards.
 - Appropriate cuff sizes as recommended in the 2017 CPG [clinical practice guideline] must be available for the device selected."

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.³¹ 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 2022, the National Institute for Health and Care Excellence (NICE) updated its 2019 guidance on the diagnosis and management of hypertension in adults.³² For diagnosing hypertension, the NICE made the following recommendations for ambulatory blood pressure monitoring (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

The U.S. Preventive Services Task Force (USPSTF) (2021) issued a systematic review and affirmed its prior 2015 recommendations on screening for hypertension in adults.³³⁻³⁵ 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.³⁵

In 2021, the USPSTF issued updated recommendations for high BP screening in children and adolescents.^{36,} 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.^{37,}

Government Regulations National:

NCD 20.19, Ambulatory Blood Pressure Monitoring, Effective date 07/02/2019.³⁸ Ambulatory blood pressure monitoring (ABPM) involves the use of a non-invasive device used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted by the physician.

Indications and Limitations of Coverage

For dates of service on and after July 2, 2019, the Centers for Medicare & Medicaid Services (CMS) believes that the evidence is sufficient to determine that ABPM is reasonable and necessary for the diagnosis of hypertension in Medicare beneficiaries under the following circumstances:

 For beneficiaries with suspected white coat hypertension, which is defined as average office BP of systolic BP > 130 mm Hg but < 160 mm Hg, or diastolic BP > 80 mm Hg but < 100 mm Hg on two separate clinic/office visits with at least two separate measurements made at each visit, and with at least two BP measurements taken outside the office which are < 130/80 mm Hg. For beneficiaries with suspected masked hypertension, which is defined as average office BP between 120 mm Hg and 129 mm Hg for systolic BP, or between 75 mm HG and 79 mm Hg for diastolic BP on two separate clinic/office visits with at least two separate measurements made at each visit, and at least two BP measurements taken outside the office which are ≥ 130/80 mm Hg.

ABPM devices must be:

- capable of producing standardized plots of BP measurements for 24 hours with daytime and night-time windows and normal BP bands demarcated; and,
- provided to patients with oral and written instructions and a test run in the physician's office must be performed; and,
- interpreted by the treating physician or treating non-physician practitioner.

For eligible patients, ABPM is covered once per year.

Local:

No LCD on this topic

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 2024, the date the research was completed.

Policy BCBSM BCN Comments Effective Date Signature Date Signature Date 4/1/03 4/6/03 4/1/03 Joint policy established 11/18/03 11/18/03 11/18/03 Policy retired 5/1/16 2/16/16 2/24/16 Policy unretired. Updated rationale, references and policy statement. Added "screening and diagnosis of hypertension" to title. End-stage organ failure added to exclusions. 11/1/16 9/23/16 9/23/16 Routine policy maintenance. 11/1/17 8/15/17 8/15/17 Updated rationale section. Added #14, 56 and 57 to references. Policy status unchanged. 11/1/18 8/21/18 8/21/18 Routine policy maintenance. Added reference 26 and 27. Policy statement unchanged. 11/1/19 8/20/19 Routine policy maintenance. No change in policy status. 11/1/20 8/18/20 Routine maintenance 11/1/21 8/17/21 Routine policy maintenance. No change in policy status. 11/1/22 Updated rationale section, AHA 8/16/22 guidelines for adults and children. No change in policy status. 11/1/23 8/15/23 Updated rationale section, added references 1, 29 and 34. No change in policy status. 11/1/24 8/20/24 Routine policy maintenance, added reference #17. No change in status. Vendor managed: N/A (ds)

Joint BCBSM/BCN Medical Policy History

Next Review Date: 3rd Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE POLICY: AMBULATORY BLOOD PRESSURE MONITORING FOR SCREENING AND DIAGNOSIS OF HYPERTENSION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, policy guidelines apply.
BCNA (Medicare Advantage)	Covered, policy guidelines apply under Government Regulation.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.