1.01.02	Automated Ambulatory Blood Pressure Monitoring for Diagnosis of Hypertension in Patients with Elevated Office Blood Pressure		
Original Policy Date:	July 18, 1973	**Effective Date:**	September 1, 2023
Section:	1.0 Durable Medical Equipment	**Page:**	Page 1 of 16

Policy Statement

I. Automated ambulatory blood pressure (BP) monitoring over a 24-hour period may be considered **medically necessary** for individuals with elevated office BP when performed 1 time to differentiate between "white coat hypertension" and true hypertension, and when the following conditions are met (see Policy Guidelines section for considerations in pediatric patients):
   A. Office BP elevation is in the mild-to-moderate range (less than 180/110 mm Hg), not requiring immediate treatment with medications
   B. There is an absence of hypertensive end-organ damage on physical examination and laboratory testing

II. All other uses of ambulatory BP monitoring for individuals with elevated office BP are considered **investigational**, including but not limited to repeated testing in individuals with persistently elevated office BP and monitoring of treatment effectiveness.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

For pediatric patients, the principles of ambulatory blood pressure monitoring used to confirm a diagnosis of hypertension are the same as in adults, with the following special considerations per 2022 American Heart Association guidelines on ambulatory blood pressure monitoring in children and adolescents:

- A device should be selected that is appropriate for use in pediatric patients, including the 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 the classification of hypertension in pediatric patients using clinic and ambulatory blood pressure, which are given in Table PG1
- Additional considerations from the American Heart Association for the pediatric population are detailed in Supplemental Information

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

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	<95th percentile OR adolescent cut points[a]	<125/75 mm Hg over 24-h AND <130/80 mm Hg while awake AND <110/65 mm Hg while asleep
White coat hypertension	≥95th percentile	≥130/80		
Masked hypertension	<95th percentile	<130/80	≥95th percentile OR adolescent cut points[a]	≥125/75 mm Hg over 24-h OR ≥130/80 mm Hg while awake OR ≥110/65 mm Hg while asleep
Ambulatory hypertension	≥95th percentile	≥130/80		

Adapted from Flynn et al (2022). [Hypertension. 2022;79(7):e114-e124.]
BP: blood pressure.
[a] Including 24 h, wake, and sleep 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.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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."[2,]

FDA product code: DXN.

Rationale

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,]

Ambulatory blood pressure monitoring 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.

Literature Review

This review was informed by a TEC Assessment (1999)[3,] and a subsequent 2001 reanalysis of this report conducted by the Centers for Medicare & Medicaid Services.[4,]

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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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 individuals who have elevated office BP is to confirm a diagnosis of hypertension and to initiate an appropriate treatment regimen.

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.

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.[5,6,] 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.[7,8,]

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.[9,] Their recommendations are summarized in Table 1. Subsequent studies have identified racial and ethnic variations in ABPM results,[10,] but the impact of these differences on clinical management may be minimal.[11,]

Table 1. Adult Ambulatory Blood Pressure Monitoring 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).[9,]

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 (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.[16,] 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.[17,] 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.[18,] 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.[19,] 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).[20,]

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.[21,] 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.[22,] 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.[23,] 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 (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."[24,] 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.[25,]

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.[25,] 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 (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=.16) and cardiovascular events (2 vs. 6; p=.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 to 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.[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 that 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 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.

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.[26,] Table 2 lists the 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.[27,] Table 3 lists the 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
"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; BP: blood pressure; 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 American Heart Association updated its 2014 recommendations[28,] on routine ambulatory blood pressure monitoring (ABPM) in children and adolescents, which included the following:[29,]

- "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 sleep-disordered 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 BP monitoring in humans that provides an overview of BP measurement overall.[30,] 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, NICE updated its 2019 guidance on the diagnosis and management of hypertension in adults.[31,] 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.[32,33,34,] 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.[34,]

In 2021, the USPSTF issued updated recommendations for high BP screening in children and adolescents.[35,] 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.[36,]

Medicare National Coverage

Medicare considers ABPM eligible for coverage as follows as of 2019:[37,]

"...ABPM is reasonable and necessary for the diagnosis of hypertension in Medicare beneficiaries under the following circumstances:

1. 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.
2. 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."

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
Ongoing			
NCT04826250	The Effect of Timing of Antihypertensive Medication on Diurnal Fluctuations in Blood Pressure Using a Wearable Sensor With Continuous Monitoring (ABPM)	150	Jun 2022 (unknown)
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 (ongoing)
NCT02804074	MASked-unconTrolled hypERtension Management Based on Office BP or on Out-of-office (Ambulatory) BP Measurement (MASTER Study)	1240	Dec 2023 (recruiting)
Unpublished			
NCT04726761	Frequent Cuff Inflations May Disrupt the Accuracy of 24-hour Ambulatory Blood Pressure Monitoring	171	Jun2022 (completed)

NCT: national clinical trial.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation report including:
  - Documentation reflecting blood pressure elevation
  - Documentation of absence of end-organ damage
  - Laboratory testing results
  - Reason for 24 hour automated ambulatory blood pressure monitoring

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	93784	Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; including recording, scanning analysis, interpretation and report
	93786	Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; recording only
	93788	Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; scanning analysis with report
	93790	Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; review with interpretation and report
	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
HCPCS	A4670	Automatic blood pressure monitor

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/18/1973	New policy.
03/20/1999	Annual review.
04/01/2001	Administrative update.
10/01/2004	Annual review.
03/01/2005	Administrative update.
07/02/2007	Annual review.
09/25/2009	Annual review. Policy statement, guidelines and literature updated. Policy title changed from Ambulatory Blood Pressure Monitoring to Automated Ambulatory Blood Pressure Monitoring.
10/31/2012	Annual review. Policy statement, guidelines and literature updated.
01/04/2013	Annual review. Policy statement, guidelines and literature updated.
01/11/2013	Annual review. Policy statement, guidelines and literature updated.
07/14/2014	Annual review. Policy statement, guidelines and literature updated. Policy title changed from Ambulatory Blood Pressure Monitoring to Automated Ambulatory Blood Pressure Monitoring for the Diagnosis of Hypertension in Patients With Elevated Office Blood Pressure.
05/29/2015	Annual review. Policy statement, guidelines and literature updated. Coding Update.
09/01/2016	Annual review. Policy statement, guidelines and literature updated. Policy title changed from Ambulatory Blood Pressure Monitoring to Automated Ambulatory Blood Pressure Monitoring for Diagnosis of Hypertension in Patients With Elevated Office Blood Pressure.
08/01/2017	Annual review. Policy statement, guidelines and literature updated.
08/01/2018	Annual review. Policy statement, guidelines and literature updated.
08/01/2019	Annual review. Policy statement, guidelines and literature updated.
03/01/2020	Coding Update.
09/01/2023	Policy reactivated. Previously archived from 06/01/2020 to 08/31/2023.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished

at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
Reactivated Policy **Policy Statement:** N/A	**Automated Ambulatory Blood Pressure Monitoring for Diagnosis of Hypertension in Patients with Elevated Office Blood Pressure 1.01.02** **Policy Statement:** I. Automated ambulatory blood pressure (BP) monitoring over a 24-hour period may be considered **medically necessary** for individuals with elevated office BP when performed 1 time to differentiate between "white coat hypertension" and true hypertension, and when the following conditions are met (see Policy Guidelines section for considerations in pediatric patients): A. Office BP elevation is in the mild-to-moderate range (less than 180/110 mm Hg), not requiring immediate treatment with medications B. There is an absence of hypertensive end-organ damage on physical examination and laboratory testing II. All other uses of ambulatory BP monitoring for individuals with elevated office BP are considered **investigational**, including but not limited to repeated testing in individuals with persistently elevated office BP and monitoring of treatment effectiveness.