



CIGNA HEALTHCARE COVERAGE POSITION

Subject Ambulatory Blood Pressure Monitoring with Automatic Portable Monitors

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INSTRUCTIONS FOR USE

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Coverage Position

CIGNA HealthCare covers ambulatory blood pressure monitoring (ABPM) over a 24-hour period as medically necessary when ANY of the following criteria are met:

- suspected white coat hypertension (WCH) (three in-office blood pressure [BP] readings of > 140/90 mm Hg and two out-of-office BP readings of < 140/90) with no evidence of end organ damage
- resistant hypertension in patients who are being treated with three or more medications
- episodic hypertension suspected when office BP measurements are normal and symptoms (excessive sweating, palpitations, apprehension) suggest episodic hypertension secondary to an existing condition
- hypertensive patients with hypotensive symptoms thought to be related to antihypertensive medications or neurological syndromes
- suspected masked hypertension
- suspected nocturnal hypertension (i.e., nondippers)
- when there is a large discrepancy between clinic and home BP measurements
- management of isolated systolic hypertension in patients age 60 or older

General Background

Elevated blood pressure (BP), also termed hypertension, is a risk factor for cardiovascular diseases (CVD) and kidney disease. The National Heart, Lung, and Blood Institute's (NHLBI) Joint National

Committee (JNC) on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure defines hypertension as: stage one, systolic pressure of 140–159 mm Hg or diastolic pressure of 90–99 mm Hg; or stage two, systolic pressure greater than or equal to 160 mm Hg, or diastolic pressure greater than or equal to 100 mg Hg (NHLBI, 2004).

BP is characterized by a clear circadian pattern. BP values tend to peak during the daytime hours and then fall after midnight. In the early morning hours, BP sharply increases, with daytime levels being reached within a relatively short period. Activity of subjects at the time of BP recording is an important determinant of the level of BP and may affect hypertensive disease (Chobanian, et al., 2003).

BP as recorded in the office setting is the standard technique recommended for the measurement of BP in routine medical care. The standard technique for the auscultatory method of BP measurement in the office setting requires: a properly calibrated and validated instrument; the patient seated quietly for at least five minutes in a chair rather than on the examination table, with feet on the floor and arm supported at heart level. At least two measurements should be made on each of two or more office visits. The mean of those readings should be recorded and given to the patient along with the goals for BP management. Clinic BP measurements have limitations even when measured by established guidelines. One limitation is that BP measured in the clinic may not be the same as BP outside the clinic setting. When BP rises in the clinic setting in response to the observer and/or other aspects of the medical environment, it is known as “white coat” hypertension (WCH). The difference between measurements obtained in- and outside the clinic setting can lead to confusion about the diagnosis of hypertension and the need to start or modify therapy. ABPM allows for the identification of those patients whose nocturnal BP does not fall, so called “nondippers.” It is reported that these patients have a higher risk of developing complications from their hypertension. More recently, another type of hypertension has been recognized on ambulatory monitoring, so-called “masked hypertension” where values are consistently higher at home than in the physician’s office (Treadway, 2007; Ohkubo, et al., 2005).

Ambulatory Blood Pressure Monitoring (ABPM)

ABPM differs from self-BP monitoring. Self-BP monitoring is performed by a patient using standard BP monitoring equipment (may be manual or digital) and is performed at determined times. ABPM is a noninvasive technique by which multiple indirect BP readings can be obtained automatically over a 24-hour period. Usually, the heart rate (HR) and BP will be measured at 15- to 30-minute periods during the day and every 30 minutes to one hour at night. The total number of readings varies between 50 and 100. ABPM devices consist of an inflatable cuff with pressure regulators and valves to measure BP, a cuff microphone or sound transducer and microprocessor to detect and interpret BP sounds, mechanisms for programming and recording BP readings, and an inflation bulb for semiautomatic devices. There are several types of devices including: fully automated, which inflate at pre-programmed intervals; semi-automated, which are patient-activated; and trans-telephonic, which allow the use of telephones to transmit measured automatic digital readings to a computer-assisted receiver. The devices are lightweight and quiet and use auscultatory or oscillometric methods, or both. The monitors can be attached by a trained technician. A series of calibration readings are taken with a mercury sphygmomanometer to ensure the device is giving accurate readings (Pickering, et al., 2005; Hayes, 2004; Ernst, et al., 2002).

U.S. Food and Drug Administration (FDA)

Both semiautomated and fully-automated ABPM monitors are categorized as Class II devices. The FDA has published guidelines regarding the 510(k) approval of noninvasive BP monitors (NIBP). The guidelines apply to monitors covered by the American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI) for electronic or automated sphygmomanometers (SP10 standard). Included in the SP10 standard are automated NIBP monitors that measure pressure at the arm, finger, or wrist using a standard oscillometric measurement method (FDA, 2006).

Literature Review

In a cohort study, Boggia et al. (2007) investigated the prognostic significance of the ABPM during night and day and of the night-to-day BP ratio. A total of 7458 patients in six population-based cohorts from three continents received 24-hour BP monitoring. Median follow-up was 9.6 years. The authors reported that the predictive accuracy of the daytime and night-time BPs and the night-to-day BP ratio depended on the outcome under study. For fatal endpoints, the night-time BP did better than the daytime BP, and the

night-to-day ratio predicted total, cardiovascular, and non-cardiovascular mortality. In contrast, for fatal combined with non-fatal outcomes, the daytime BP did equally well as the night-time BP, and the night-to-day ratio lost its prognostic accuracy in all participants and in those who were untreated. The authors report that their finding suggest that a less pronounced dip in BP might be a marker of pre-existing or concurrent disease, leading to a lower daytime BP, or might be the result of the intake of drugs to lower BP during daytime. The worse prognosis for participants with higher night-time than daytime BP was not associated with shorter life expectancy. The authors reported that their findings support recording the ambulatory BP during the whole day. The authors reported numerous limitations to their study.

In a multicenter prospective study, Dawes et al. (2006) assessed the prognostic value of daytime ABPM compared to routine clinic BP measurement in determining mortality. The study took place in two hypertensive clinics and a primary care cohort consisting of 48 general practices. A cohort of 10,129 patients was followed for a median of 8.2 years. Patients were selected for ABPM by practitioners who determined that, for clinical reasons, they required monitoring. The main reasons for monitoring a patient included variable or borderline clinic BP (this was not defined by the authors), established hypertension resistant to treatment, and isolated high clinic BP. The mean of the previous three BP readings at different visits within the six months of ABPM was defined as clinic BP. The clinical presentation was based on the World Health Organization-International Society of Hypertension classification: normal (< 130 mm Hg), high normal (130–139 mm Hg), Grade 1 (140–159 mm Hg), Grade 2 (160–179 mm Hg), Grade 3 (\geq 180 mm Hg).

Nine hundred and one deaths were recorded (8.9%), corresponding to a mortality rate per 1000 years of follow-up of 10.8 (99% CI 9.9–11.8). Comparing the highest quartile for systolic ambulatory BP with the lowest (\geq 160 versus < 135 mm Hg) gives an estimated age sex-adjusted hazard ratio for mortality of 1.51 (95% CI 1.25–1.83, $p < 0.001$). The corresponding comparison for clinic systolic BP (\geq 174 versus < 148 mm Hg) results in a hazard ratio of 1.02 (95% CI 0.84–1.24, $p = 0.9$). Comparing ambulatory versus clinic systolic BP (10 mm Hg groupings) using nested statistical modeling, removal of the ambulatory BP term from the baseline Cox model (nine 10 mm Hg categories) resulted in a highly significant likelihood ratio test statistic of 52.5 (df=8, $p < 0.0001$). The corresponding result for removal of the clinic BP term was 18.1 (df=8, $p = 0.02$), thus reinforcing the finding that ABPM has greater prognostic significance. Ambulatory BP was also a better predictor of all-cause mortality, both in patients taking medication and those not taking medication at the time of monitoring. The authors stated that subsequent controlled trials are needed to test the benefit of interventions at different thresholds of ambulatory BP.

In a prospective cohort study, Agarwal et al. (2006) investigated the role of ABPM in predicting end-stage renal disease (ESRD) and death in patients with chronic kidney disease (CKD). A total of 217 patients with CKD had their BP measured by ABPM and in the clinic. Twenty-four hour ambulatory BP was 133.5 +/- 16.6/73.1 +/- 11.1 mm Hg, and clinic BP was 155.2 +/- 25.6/84.7 +/- 14.2 mm Hg. The composite renal end point of ESRD or death over a median follow-up of 3.5 years occurred in 75 patients (34.5%); death occurred in 52 patients (24.0%), and ESRD in 36/178 patients (20.2%). Thirty-nine patients died before reaching ESRD. One standard deviation increase in systolic BP increased the risk of composite outcome to 1.69 (95% CI 1.32–2.17) for standard clinic measurement and to 1.88 (95% CI 1.48–2.39) for 24-hour ambulatory BP recording. One standard deviation increase in 24-hour ambulatory systolic BP increased the risk of ESRD to 3.04 (95% CI 2.13–4.35) and to 2.20 (95% CI 1.43–3.39) when adjusted for standard clinic systolic BP. Nondipping was associated with increased risk of total mortality and composite end point. The authors concluded that in patients with CKD, BPs obtained by ambulatory monitoring are a stronger predictor of ESRD or death compared to BPs obtained in the clinic. Systolic ambulatory BP and nondipping are independent predictors for ESRD after adjusting for clinic BP. The authors stated that adjustment for other risk factors for CKD progression removes the independent prognostic value of ambulatory BP. This study was limited to older men with concomitant illnesses and to a single center. There is no data that shows superior clinical outcomes when ambulatory BPs, rather than clinic BPs, are used to guide therapy.

In a prospective cohort study, Paoletti et al. (2006) evaluated the prevalence and clinical correlates of arterial hypertension assessed by means of 24-hour ABPM in patients with nondiabetic CKD at their first referral to a nephrologist. Each patient had BP measured by 24-hour ABPM, creatinine clearance estimated according to the Cockcroft-Gault formula, and Hgb concentration, serum lipids, iPTH, daily urinary protein and sodium excretion assessed using routine methods. A total of 210 patients were

included in this single-center study. According to ABPM data analysis, 81 patients were normotensives, 78 were stable hypertensives, 26 had daytime hypertension, and 59 had nocturnal hypertension. Analysis of variance showed both lower creatinine clearance ($p=0.0033$) and higher urinary protein ($p<0.0001$) in stable and nighttime hypertensives as compared with normotensives and daytime hypertensives. In the whole group, each set of both systolic BP and pulse pressure (PP) readings was directly associated with both age and urinary protein ($p<0.05$), and inversely with both creatinine clearance and Hgb ($p<0.05$). In multivariate analysis, however, urinary protein emerged among modifiable risk factors as the most significant predictor of both systolic BP and PP; the strength of this association was in the order nighttime PP > nighttime systolic BP > 24-hour PP > daytime PP > daytime systolic BP > 24-hour systolic BP. The authors concluded that in CKD patients, proteinuria is the strongest correlate of arterial hypertension and particularly of increased nocturnal PP, possibly as an expression of vascular damage. The authors stated that on the basis of these results, ABPM appears to be the most reliable tool for detecting the associations between raised BP (particularly nighttime hypertension) and renal damage in CKD patients not yet on renal replacement therapy. Reported limitations of this study are that it was a single-center study, and outcome results are missing. Additionally, no information on the effectiveness of antihypertensive therapy was reported, since the BP profile of CKD patients was evaluated after pharmacological wash-out.

In a prospective cohort study, Niiranen et al. (2006) compared home and ambulatory BP in the adjustment of antihypertensive treatment. After a four-week washout period, patients whose untreated daytime diastolic ambulatory BP averaged ≥ 85 mm Hg were randomized to be treated according to their ambulatory or home BP. Antihypertensive treatment was adjusted at six-week intervals according to the mean daytime ambulatory diastolic BP or the mean home diastolic BP, depending on the patient's randomization group. If the diastolic BP stayed above 80 mm Hg, the physician blinded to randomization intensified hypertensive treatment. Ninety-eight patients completed the study. During the 24-week follow-up period, both systolic and diastolic BP decreased significantly within both groups ($p<0.001$). At the end of the study, the systolic/diastolic differences between ambulatory ($n=46$) and home ($n=52$) BP groups in home, daytime ambulatory, night-time ambulatory, and 24-hour ambulatory BP changes averaged 2.6/2.6 mm Hg, 0.6/1.7 mm Hg, 1.0/1.4 mm Hg, and 0.6/1.5 mm Hg, respectively (p range 0.06–0.75). A nonsignificant trend to more intensive drug therapy in the ambulatory BP group and a nonsignificant trend to a larger share of patients reaching (57.7% versus 43.5%, $p=0.16$) the target pressure in the home BP group was observed due to the 3.8 mm Hg difference in ambulatory and home diastolic BP at randomization. The authors concluded that the adjustment of antihypertensive treatment based on either ambulatory or home BP measurement led to good BP control. No significant between group differences in BP changes were seen at the end of the study. The authors stated that because of the relatively small number of patients in their study, larger long-term prospective studies are needed to validate their results and to determine the prognostic, diagnostic, and treatment thresholds for home-measured BP.

Ingelsson et al. (2006) studied 24-hour ambulatory BP characteristics as predictors of CHF incidence and investigated whether altered diurnal BP patterns confer any additional risk information beyond that provided by conventional office BP measurements. This prospective, community-based, observational cohort in study included 951 elderly men free of CHF, valvular disease, and left ventricular hypertrophy. The study took place between 1990 and 1995 with follow-up until the end of 2002. Twenty-four hour ABPM was performed at baseline, and the BP variables were analyzed as predictors of subsequent CHF. The main outcome measure was first hospitalization for CHF. Seventy men developed heart failure during follow-up, with an incidence rate of 8.6 per 1000 person-years at risk. In multivariable Cox proportional hazards models adjusted for antihypertensive treatment and established risk factors for CHF (myocardial infarction, diabetes, smoking, body mass index, and serum cholesterol level), a one standard deviation (9 mm Hg) increase in nighttime ambulatory diastolic BP (hazard ratio HR, 1.26; 95% CI, 1.02–1.55) and the presence of nondipping BP (night-day ambulatory BP ratio ≥ 1 ; HR, 2.29; 95% CI, 1.16–4.52) were associated with an increased risk of CHF. After adjusting for office-measured systolic and diastolic BPs, nondipping BP remained a significant predictor of CHF (HR, 2.21; 95% CI, 1.12–4.36 versus normal night-day pattern). Nighttime ambulatory diastolic BP and nondipping BP were also significant predictors of CHF after exclusion of all participants who had an acute myocardial infarction before baseline or during follow-up.

In an observational study, Ohkubo et al. (2005) investigated the prognosis of patients with WCH and masked hypertension (MHT), in which BP is lower in clinical measurements than during 24-hour

ambulatory monitoring. Twenty-four hour ambulatory BP and casual BP (i.e., obtained in clinic) was obtained in 1332 participants. Survival and stroke morbidity were followed up for a mean duration of ten years. Risk of cardiovascular mortality and stroke morbidity for individuals with WCH was no different from risk for individuals with sustained normal BP. However, risk was significantly higher for individuals with MHT or sustained hypertension than for subjects with sustained normal BP.

Goyal et al. (2005) conducted a systematic review of the literature to evaluate the role of ABPM in heart failure. The authors report ABPM has established its use in the definition of WCH and monitoring of essential hypertension; however, more prospective controlled studies in patients with CHF need to be conducted to define the impact of treatments on circadian BP profile.

Bobrie et al. (2004) assessed the prognostic value of home versus office BP measurement by general practitioners of elderly patients (n=4939) being treated for uncontrolled hypertension. The threshold BP was 140/90 in the office and 135/85 in the home. The main outcome measure at 3.2 years was cardiac mortality. Secondary end-points were total mortality and the combination of cardiovascular mortality and nonfatal myocardial infarction, stroke, transient ischemic attack, hospitalization for angina or heart failure, angioplasty or coronary artery bypass. For BP measurement at home, each 10 mm Hg increase in systolic BP increased the risk of a cardiovascular event by 17.2%. For the same increase in BP using office measurement, there was no significant increase in the risk of cardiovascular event. The findings suggest that home BP measurement has a better prognostic value than office BP measurement.

Staessen et al. (2004) conducted a randomized controlled study comparing the use of home, office, and ambulatory BP measurements (n=400). Study results suggested that both home and ambulatory BP measurements might provide a more accurate estimate of the severity of hypertension than estimates obtained with an office measurement. It was reported that home and ABPMs led to less intensive drug treatment and lower costs than office-based BP measurement.

Clement et al. (2003) conducted a prospective study (n=2232) to assess the association between ABPM in treated patients and subsequent cardiovascular events during follow-up. The findings suggested that ABPM can have predictive value for cardiovascular events and adds to the predictive value of office BP measurements.

In a double-blind placebo-controlled study, Staessen et al. (1999) compared the prognostic significance of conventional and ambulatory BP measurement in older patients with isolated systolic hypertension (n=808). The age of the participants was ≥ 60 years of age. The authors reported that in older patients with isolated systolic hypertension, ambulatory systolic BP was a significant predictor of cardiovascular complications over conventional systolic BP.

Hansen et al. (2007) conducted a meta-analysis to investigate the multivariate-adjusted predictive value of systolic and diastolic BPs on conventional and daytime (10–20 hour) ABPM. The meta-analysis included only randomized studies which had information on the conventional and ambulatory BPs and cardiovascular risk factors available at baseline, and the subsequent follow-up included fatal and nonfatal outcomes. Four studies were included in this meta-analysis. The authors reported that individual subject data included over 7000 people randomly recruited from four populations and covered approximately 10 years of follow-up with more than 800 new cardiovascular endpoints. The key finding was that ABPM was by far superior to conventional BP measurement in the prediction of cardiovascular events and risk stratification.

The National Institute for Excellence (NICE) clinical guideline on management of hypertension in adults in primary care advises to identify hypertension (persistent raised BP above 140/90 mmHg), the patient must return for at least two subsequent clinic visits where their BP is assessed from two readings using the best conditions available. The routine use of automated ABPM or home monitoring devices in primary care is not currently recommended because their value has not been adequately established; appropriate use in primary care remains an issue for further research (NICE, 2006).

The Institute for Clinical Systems Improvement (ICSI) guideline on hypertension diagnosis and treatment states, “standardized BP measurement techniques, including out of office or home BP measurements,

should be employed when confirming an initially elevated BP and for all subsequent measures during follow-up and treatment for hypertension” (ICSI, 2006).

Bergel et al. (2002) reported in a Cochrane review of ambulatory versus conventional method for monitoring BP during pregnancy. No randomized controlled trials provided evidence to support the use of ABPM during pregnancy.

Professional Societies/Organizations

The American Heart Association (AHA) Scientific Statement recommendations for BP measurement states 24-hour ambulatory monitoring gives a better prediction of risk than office measurements and is useful for diagnosing WCH. Other potential applications of ABPM include the identification of individuals with a nondipping BP pattern (e.g., in diabetes), refractory hypertension with little target organ damage, suspected autonomic neuropathy, and patients in whom there is a large discrepancy between clinic and home measurements (Pickering, et al., 2005).

Practice guidelines of the European Society of Hypertension for clinic, ambulatory and self-BP measurement accepted clinical indications for ABPM include: suspected WCH, nocturnal hypertension and masked hypertension; to establish dipper status, resistant hypertension, and hypertension of pregnancy. Potential indications for ABPM include: elderly patient; as a guide to antihypertensive drug treatment; type I diabetes; evaluation of symptoms suggesting orthostatic hypotension; autonomic failure (O'Brien, et al., 2005).

The NHLBI JNC on Detection, Evaluation, and Treatment of High Blood Pressure states in its seventh report that APBM is warranted for the evaluation of WCH in the absence of target organ injury. APBM is also helpful to assess patients with apparent drug resistance, hypotensive symptoms with antihypertensive medications, episodic hypertension, and autonomic dysfunction. ABPM also provides a measure of the percentage of BP readings that are elevated, overall BP load, and the extent of BP reduction during sleep. BP in most individuals decreases by 10%–20% during the night. There is an increased risk for cardiovascular events for those individuals who do not have a decrease in BP at night (NHLBI, 2004).

In a statement by the U.S. Preventive Services Task Force (USPSTF) summarizing recommendations on screening for high BP, ABPM was found to be a better predictor of clinical cardiovascular outcome than clinic-based approaches. The USPSTF states, “due to the limitations in the reliability of BP measurements, experts commonly recommend that clinicians diagnose hypertension only after obtaining two or more elevated readings at two or more office visits at intervals of one to several weeks.” This statement has not been updated since 2003 (USPSTF, 2003).

The Hypertensive Disease Committee of the American College of Cardiology (ACC) recommends ABPM as a clinically applicable technology for the management of selected hypertensive patients. This guideline has not been updated since 1993 (ACC, 1993).

Summary

Ambulatory blood pressure monitoring (ABPM) provides information about blood pressure (BP) during daily activities and sleep. ABPM can have predictive value for cardiovascular events and adds to the predictive value of office BP measurements. Professional organizations and evidence in the peer-reviewed medical literature suggests that ABPM is indicated for the management of a selected subset of patients. ABPM is indicated for the evaluation of white-coat hypertension (WCH) in the absence of target-organ injury. ABPM is used to assess patients with hypotensive symptoms with antihypertensive medications, resistant hypertension, episodic hypertension and autonomic dysfunction, suspected masked hypertension, suspected nocturnal hypertension, when there is a large discrepancy between clinic and home BP measurements, and for the management of isolated systolic hypertension in patients age 60 or older.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT^{®*} Codes	Description
93784	Ambulatory blood pressure monitoring utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer, including recording, scanning analysis, interpretation and report.
93786	Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; recording only
93788	Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; scanning analysis with report
93790	Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; physician review with interpretation and report

HCPCS Codes	Description
	No specific codes

ICD-9-CM Diagnosis Codes	Description
401.0-405.99	Hypertensive disease
458.0	Orthostatic hypotension
780.2	Syncope and collapse
796.2	Elevated blood pressure reading without diagnosis of hypertension

***Current Procedural Terminology (CPT[®]) © 2007 American Medical Association: Chicago, IL.**

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