AUTOMATED AMBULATORY BLOOD PRESSURE MONITOR (ABPM)
DME104.011

COVERAGE:

Automated ambulatory blood pressure monitors ARE NOT ELIGIBLE FOR COVERAGE, as they are considered investigational.

DESCRIPTION:

Ambulatory blood pressure monitors (i.e., 24-hour sphygmomanometers) are portable devices that record blood pressure while the patient is involved in daily activities. There are several types of monitors, which include:

• intra-arterial, which are used exclusively as research tools due to risk of infection or arterial damage and tissue necrosis;

• fully automated, which inflate at preprogrammed intervals;

• semi-automated, which are patient activated; or

• transtelephonic, which allow use of the telephone to transmit measured automatic digital readings to a computer-assisted receiver.

The use of ABPM’s provides the physician with a more comprehensive perspective on blood pressure, compared to the more typical casual office readings that are not representative of the normal circadian rhythm of blood pressure. The use of AMPM has been researched most extensively in two clinical contexts:

1. Borderline hypertension
2. White coat hypertension.

White coat hypertension is defined as a transient elevation of blood pressure in the physician’s office, presumably due to anxiety.

RATIONALE:

This policy is based on a 1999 TEC assessment that focused on the use of ABPM in untreated patients with borderline hypertension or “white coat” hypertension. The assessment offered the following conclusions:

• Direct evidence to determine the health outcomes associated with ambulatory blood pressure monitoring would consist of a clinical trial of patients who are diagnosed and subsequently treated based on ABPM compared to a control group of patients who are diagnosed and treated based on office blood pressure measurement. The ideal outcomes for such a study would be measures of cardiovascular morbidity and mortality associated with hypertension. A well-controlled prospective cohort study could also provide adequate evidence. No such evidence exists.

• In the absence of direct evidence, indirect evidence was evaluated; i.e.
evidence suggesting ABPM leads to changes in the management of the patient which in turn results in clinically significant outcomes.

- While the evidence permits the conclusion that ABPM can more accurately classify patients as hypertensive or normotensive, it is not possible to conclude that this increased precision leads to clinically significant health outcome benefits. The effect on health outcomes depends on the balance between potential overtreatment of hypertension using office-based measurements of blood pressure and undertreatment based on ambulatory monitoring.

This policy contrasts with various recommendations made by the American College of Physicians, the American College of Cardiology, and the National High Blood Pressure Education Program. These policy statements are reviewed below.

National High Blood Pressure Education Program:

This 1990 document outlines a variety of situations in which ambulatory measurements of blood pressure may be useful.

- In patients with borderline hypertension with evidence of target organ damage (i.e., left ventricular hypertrophy, hypertensive retinopathy), ambulatory pressure reading may be used to confirm or refute high blood pressure as the etiology.

- Resistant hypertension is diagnosed when multiple antihypertensive medications fail to control high blood pressure. Ambulatory recording can be used to determine if the office reading is representative.

- Episodic hypertension raises the possibility of pheochromocytoma or anxiety syndromes, both of which may be best evaluated with a 24-hr recording of blood pressure.

- Transient hypotension from antihypertensive drug therapy may be difficult to diagnose in the office; ambulatory recordings may allow recognition of overtreatment.

- The possibility of “white coat hypertension” in patients with borderline hypertension presents a treatment dilemma. Normal ambulatory blood pressure readings is an objective method of evaluation of these patients.

The statement also points out that ABPM is not necessary or clinically appropriate for most patients with hypertension, particularly when target organ damage is already apparent (these patients are clear candidates for antihypertensive therapy) or when other risk factors are present, i.e., strong family history or diabetes.

It should be noted that these recommendations do not appear to be evidence based and that definitive data documenting improved health outcomes associated with the clinical use of these devices is not presented, particularly in comparison with other methods of measuring blood pressure, i.e., serial measurements by a nonphysician in the office setting or patient self-measurement at home. In addition, the policy statement also points out that several technical issues remain unresolved; i.e., a standardized approach to data analysis. Furthermore, most of the data that link blood pressure to
cardiovascular risk, and clinical trials of antihypertension agents have primarily been based on episodic office readings. It is unclear how 24-hour ambulatory readings should be extrapolated to office settings.

**American College of Physicians:**

The American College of Physicians position paper consists of an evidence-based literature review followed by a policy statement derived from the literature review.

The literature review also identified technical issues, similar to those identified by the National High Blood Pressure Education Program; i.e., lack of standardization of data analysis. In addition, limitations of the published literature were carefully considered, i.e., the varying number of blood pressure readings, the variety of personnel performing the readings, small sample size, and representativeness of study samples. The literature review concludes that the published data suggest, but do not establish, the clinical utility of ABPM. The authors recommend that either patient self-monitoring or ambulatory blood pressure monitoring be considered in those patients with mild hypertension (diastolic pressure between 90-99mm Hg) without end organ damage, in whom the results of the measurements would help determine the necessity of antihypertensive medications.

The actual position paper derived from the literature review states as follows:

“Self measured blood pressure and automated APBM devices may, in theory, have a specific role in the diagnosis, prognosis, and management of hypertension. The evidence supporting the role of automated ambulatory blood pressure measurement in the diagnosis and treatment of hypertension is, for the most part, indirect. The major studies showing the benefits of treatment in decreasing the morbidity and mortality risks associated with hypertension have used office-based blood pressure measurements to make diagnoses and to treat and follow patients. Similar studies comparing treatment guided by self-measured blood pressures or automated ambulatory blood pressures to treatment guided by office based blood pressures are required but have not been conducted. Therefore, the available evidence does not warrant widespread dissemination or routine use of automated ambulatory blood pressure measurement at this time. On the other hand, we support a more circumspect use of such devices for research and for the care of subgroups of hypertensive patients with specific clinical problems.

Unfortunately, the position paper does not further define the targeted subgroup of patients.

**American College of Cardiology:**

In 1990 the American College of Cardiology issued a policy statement on ABPM that identified the technology as “investigational” in part based on technical concerns regarding the accuracy of the devices. The position statement was revised in 1994, stating that the previous concerns had been addressed. Specifically, manufacturing standards had been developed, leading the American College of Cardiology to conclude that “ABPM has become a mature, clinically applicable technology...” However, the policy statement does not appear to be evidence-based; there is no detailed discussion of the literature.
A separate indication for ABPM is its use to titrate drug therapy in patients already diagnosed with hypertension. In 1997, a randomized controlled trial was published, which addressed this issue. Antihypertensive drug therapy was adjusted in a stepwise fashion based on either the average daytime diastolic blood pressure, as calculated from ambulatory blood pressure monitoring, or on the average of three readings performed in the office. At the end of the study, a significantly higher percentage of patients in the ambulatory blood pressure group were able to discontinue drug therapy compared to those in the conventionally measured blood pressure group. As pointed out in an accompanying editorial, patient self-monitoring may obtain the same results.

The American College of Cardiology in 1994 revised its 1990 investigational policy statement regarding these devices to state, "ABPM has become a mature, clinically applicable technology..." However, the policy statement does not appear to be evidence-based; there is no detailed discussion of the literature.

The recommendations made by the National High Blood Pressure Education Program do not appear to be evidence based and definitive data documenting improved health outcomes associated with the clinical use of these devices is not presented. The policy statement also points out that several technical issues remain unresolved.

PRICING:

None

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member's contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically. HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.