Protocol

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

(10102)

Medical Benefit		**Effective Date**: 07/01/14	**Next Review Date**: 03/19
Preauthorization	No	**Review Dates**: 01/08, 11/08, 09/09, 09/10, 07/11, 07/12, 03/13, 03/14, 03/15, 03/16, 03/17, 03/18	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With elevated office blood pressure	Interventions of interest are: • 24-hour automated ambulatory blood pressure monitoring	Comparators of interest are: • Office blood pressure measurement • Home blood pressure measurement	Relevant outcomes include: • Test accuracy • Other test performance measures • Morbid events • Medication use

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 protocol 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.

Summary of Evidence

For individuals with elevated office BP who receive 24-hour automated ambulatory blood pressure monitoring (ABPM), the evidence includes randomized controlled trials, cohort studies, and studies of diagnostic accuracy. Relevant outcomes are test accuracy, other test performance measures, morbid events, and medication use. Data from large prospective cohort studies have established that ABPM correlates more strongly with cardiovascular outcomes than with other methods of BP measurement. Compared directly with 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 of overdiagnosis and overtreatment based on office BP measurements alone. Use of ABPM in these patients will improve outcomes by eliminating unnecessary pharmacologic treatment and avoiding adverse

events in patients not expected to benefit. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Policy

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

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

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

Policy Guidelines

For pediatric patients, the principles of ABPM used to confirm a diagnosis of hypertension are the same as in adults, with the following special considerations (Flynn et al, 2014):

- A device should be selected that is appropriate for use in pediatric patients, including use of a cuff size appropriate to the child's size.
- Threshold levels for the diagnosis of hypertension should be based on pediatric normative data, which use gender-and-height-specific values derived from large pediatric populations.
- Recommendations from American Heart Association (AHA) concerning the classification of hypertension in pediatric patients using clinic and ambulatory BP are given in Table 1:

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

Classification	Clinic BP	Mean Ambulatory SBP	SBP Load[a]
Normal BP	< 95th percentile	< 95th percentile	< 25%
White coat hypertension	> 95th percentile	< 95th percentile	< 25%
Masked hypertension	< 95th percentile	> 95th percentile	> 25
Pre hypertension	> 95th percentile	< 95th percentile	25-50%
Ambulatory hypertension	> 95th percentile	> 95th percentile	25-50%
Severe Ambulatory hypertension	> 95th percentile	> 95th percentile	> 50%

BP: blood pressure; SBP: systolic blood pressure

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

Medicare Advantage

ABPM must be performed for at least 24 hours to meet guideline criteria.

ABPM is only **medically necessary** for those patients with suspected white coat hypertension. Suspected white coat hypertension is defined as:

1. Office blood pressure greater than 140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit;

2. At least two documented blood pressure measurements taken outside the office which are less than 140/90 mm Hg; and
3. No evidence of end-organ damage.

ABPM is considered **investigational** for all other indications.

Medicare Advantage Policy Guidelines

In the rare circumstance that ABPM needs to be performed more than once in a patient, the medical criteria described above must be met for each subsequent ABPM test.

The information obtained by ABPM is medically necessary when it is used to determine the appropriate management of the patient.

Background

Typically done over a 24-hour period with a fully automated device, ABPM provides more detailed 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.

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 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 WCH are not at increased risk for cardiovascular events and would not benefit from antihypertensive treatment.

This protocol 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. 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.

Regulatory Status

Many ambulatory blood pressure monitors have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. As an example of an FDA 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."[1]

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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