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

Medical Benefit | Effective Date: 06/01/21 | Next Review Date: 03/23
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, 03/19, 03/20, 03/21, 03/22

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.

RELATED PROTOCOL
None

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

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.

SUMMARY OF EVIDENCE
For individuals with elevated office BP who receive 24-hour automated 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. 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 automated 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 an 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 repeated 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:

- 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 (AHA) concerning the classification of hypertension in pediatric patients using clinic and ambulatory BP are given in Table 1:

Table 1. Classification of Ambulatory BP Levels in Children

<table>
<thead>
<tr>
<th>Classification</th>
<th>Clinic BP</th>
<th>Mean Ambulatory SBP</th>
<th>SBP Loada</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal BP</td>
<td>&lt;95th percentile</td>
<td>&lt;95th percentile</td>
<td>&lt;25%</td>
</tr>
<tr>
<td>White coat hypertension</td>
<td>&gt;95th percentile</td>
<td>&lt;95th percentile</td>
<td>&lt;25%</td>
</tr>
<tr>
<td>Masked hypertension</td>
<td>&lt;95th percentile</td>
<td>&gt;95th percentile</td>
<td>&gt;25%</td>
</tr>
<tr>
<td>Prehypertension</td>
<td>&gt;95th percentile</td>
<td>&lt;95th percentile</td>
<td>25-50%</td>
</tr>
<tr>
<td>Ambulatory hypertension</td>
<td>&gt;95th percentile</td>
<td>&gt;95th percentile</td>
<td>25-50%</td>
</tr>
<tr>
<td>Severe Ambulatory hypertension</td>
<td>&gt;95th percentile</td>
<td>&gt;95th percentile</td>
<td>&gt;50%</td>
</tr>
</tbody>
</table>

Adapted from Flynn et al (2014). BP: blood pressure; SBP: systolic blood pressure

a Percent of SBP readings that are above 95th percentile for gender and height.
MEDICARE ADVANTAGE

For Medicare Advantage, ABPM may be considered medically necessary for the diagnosis of hypertension under the following circumstances:

1. For patients with suspected white coat hypertension. Suspected white coat hypertension is defined as:
   a. An average office blood pressure (BP) of systolic BP greater than 130 mm Hg but less than 160 mm Hg, OR a diastolic BP greater than 80 mm Hg but less than 100 mm Hg; AND
   b. On two separate clinic/office visits with at least two separate measurements made at each visit; AND
   c. With at least two BP measurements taken outside the office which are <130/80 mm Hg.

2. For patients with suspected masked hypertension. Suspected masked hypertension is defined as:
   a. An 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; AND
   b. On two separate clinic/office visits with at least two separate measurements made at each visit; AND
   c. At least two BP measurements taken outside the office which are ≥130/80 mm Hg.

ABPM is considered not medically necessary when the above criteria is not met.

MEDICARE ADVANTAGE POLICY GUIDELINES

ABPM devices must be:

1. Capable of producing standardized plots of BP measurements for 24 hours with daytime and night-time windows and normal BP bands demarcated; AND

2. Provided to patients with oral and written instructions and a test run in the physician’s office must be performed; AND

3. Interpreted by the treating physician or treating non-physician practitioner.

For eligible patients, ABPM may be considered medically necessary once per year.

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.3

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.

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.”

FDA product code: DXN.

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

4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). 24-hour ambulatory blood pressure monitoring for the evaluation of patients with elevated office blood pressure. TEC Assessments. 1999; Volume 14:Tab 8.


