Clinical Policy Title: Ambulatory blood pressure monitoring

Clinical Policy Number: 04.01.03

Effective Date: October 1, 2014
Initial Review Date: May 21, 2014
Most Recent Review Date: May 18, 2016
Next Review Date: May 2017

Related policies:

CP# 04.01.05  Implantable cardiac loop recorder
CP# 04.01.01  Real-time outpatient cardiac monitoring

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of 24-hour ambulatory blood pressure monitoring (ABPM) to be clinically proven and, therefore, medically necessary to assist in the diagnosis of white coat hypertension (WCH) when all of the following medical necessity criteria and quality criteria are met:

- Medical necessity criteria:
  - No definitive diagnosis of hypertension (HTN) has been established.
  - Patient has suspected WCH defined as either:
    - Office reading of mildly elevated HTN ≥ 140/90 mm Hg in adults.
    - Greater than 95th percentile for age, gender and height in children on at least three separate physician office visits with two separate measurements taken at each visit.
  - At least two documented separate blood pressure (BP) measurements taken outside of the physician’s office are < 140/90 mm Hg.
  - No evidence of end-organ damage.
  - The information obtained by ABPM is necessary to determine appropriate patient management.
• Quality criteria:
  o ABPM must be performed for at least 24 hours.
  o ABPM automatic readings must be set at ≤ 30-minute intervals.
  o ABPM must be performed using an FDA-approved device that has been validated according to international, standardized protocols prior to use.

Limitations:

• All other uses of ABPM are not medically necessary.
• Repeat ABPM may be obtained if the first examination has less than 70 percent of the expected values due to a high number of artifacts.
• Routine repeat ABPM is not clinically proven and, therefore, not considered medically necessary.
• In a circumstance when ABPM needs to be performed more than once on a patient, the medical necessity and quality criteria described above must be met for each subsequent ABPM test.

Note: The following CPT/HCPCS codes are not listed in the Pennsylvania Medicaid fee schedule:

93784 - ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; including recording, scanning analysis, interpretation and report
93786 - ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; recording only.
93788 - ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; scanning analysis with report.
93790 - ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; physician review with interpretation and report.

Alternative covered services:

• Office/clinic blood pressure measurement.

Background

HTN is a common chronic health condition in the United States. The prevalence of HTN is estimated to be approximately 30 percent in adults (age 18 and older) and 3 – 4 percent in children (Gillespie, 2013; NHLBI, 2005). HTN is a major risk factor for heart disease and stroke, and blood pressure (BP) control among those with HTN can reduce the risk of subsequent cardiovascular diseases (Chobanian, 2003). Primary (essential) HTN is now identifiable in children and adolescents and is often associated with a positive family history of HTN or cardiovascular disease, obesity and lifestyle factors (NHLBI, 2005; Flynn, 2014).

Accurate BP measurement is essential to classify individuals, ascertain BP-related risk and guide management. To date, office BP measurements define the relationship between BP and risk (Pickering, 2005; NHLBI, 2005). BP fluctuates substantially throughout a typical day, from day to day and over longer periods of time. Multiple factors contribute to these fluctuations, including WCH, which may be present in 20 to 35 percent of patients diagnosed with HTN. Therefore, a diagnosis of HTN requires repeated
measurements to minimize misclassification of individuals as hypertensive or normotensive (Pickering, 2005).

ABPM:

ABPM is a noninvasive method of obtaining multiple BP readings at regular intervals over a 24-hour (or sometimes 48-hour) period in the person's own living environment. ABPM collects data during daily activities and sleep, ostensibly representing a true reflection of the individual's BP. The rationale for using ABPM within carefully selected populations is to provide more precise and accurate BP data that will help simplify or eliminate drug therapy and reduce medication consumption and related complications, resulting in improved outcomes and overall cost savings. The purported clinical advantages of ABPM are to (Pickering, 2005):

- Detect masked HTN or WCH.
- Determine the presence or absence of normal nocturnal dipping status.
- Assess the adequacy of BP control in persons taking complex antihypertensive medication regimens.
- Provide detailed information on BP patterns in persons with episodic HTN, chronic kidney disease, diabetes and autonomic dysfunction.
- Identify persons with apparently refractory HTN but relatively little to no target organ damage.
- Confirm HTN in patients in whom there is a large discrepancy between clinic and home measurements.

In the United States, ABPM is used most commonly to determine the presence or absence of WCH and offered only by centers that specialize in HTN or cardiovascular medicine (Bloch, 2011). Several ABPM monitors have been cleared for marketing via the 510(k) process (FDA, 2014). However, monitors that have not undergone validation testing or FDA clearance can be sold in the United States, and few have been formally validated in children (Flynn, 2014).

Table 1 illustrates the lack of consensus among guidelines regarding the definition of HTN in adult populations according to ABPM. Instead, guidelines use thresholds based on a definition of HTN (BP > 140/90 mm Hg) obtained in an office setting from clinical trials that examined the benefits of treating HTN. Less robust data exist to support treatment guidelines using ABPM (Meyers, 2011).

Table 1. Diagnostic thresholds for HTN using ABPM in adults

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<tr>
<td>24-hour</td>
<td>&gt; 135/85</td>
<td>≥ 130/80</td>
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<tr>
<td>Daytime</td>
<td>&gt; 135/85</td>
<td>&gt; 140/90</td>
<td>≥ 135/85</td>
<td>≥ 135/85</td>
<td>≥ 135/85</td>
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<tr>
<td>Nighttime</td>
<td>&gt; 120/75</td>
<td>&gt; 125/75</td>
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<td>≥ 120/70</td>
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In pediatric populations, an AHA consensus statement defines HTN as a mean ambulatory systolic blood pressure (SBP) or diastolic blood pressure (DBP), or both, > 95th percentile with an elevated SBP or DBP load ≥ 25 percent (Flynn, 2014). However, they acknowledge deficiencies in the research of HTN.
management in pediatric populations, particularly using ABPM. The AHA stresses the urgent need for more comprehensive normative ABPM data across sexes, races and ages; devices that can measure DBP more accurately; and robust data linking ABPM patterns to target organ damage (Flynn, 2014).

**Searches**

Keystone First searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on April 13, 2016. Search terms were: “blood pressure monitoring, ambulatory [MeSH]” and “Hypertension/diagnosis [MeSH].”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

For this policy, we included only studies published since 2000 to reflect the most current research in the United States context. Keystone First identified six systematic reviews and one health technology assessment that addressed the diagnostic accuracy, prognostic value and cost-effectiveness of ABPM in managing adults with HTN. No systematic reviews addressed ABPM in pediatric populations. The overall quality of the evidence comparing ABPM to clinic BP measurement or home measurement consisted of three randomized controlled trials (RCTs), multiple cross-sectional studies and multiple prospective observational studies of generally poor to moderate quality. Heterogeneity in study designs limited comparison of results across studies.

There is sufficient evidence to support the safety, efficacy and cost-effectiveness of ABPM to confirm the presence or absence of WCH in persons with elevated BP measured by office-based screening. More recent evidence-based guidelines are notably consistent in defining suspected WCH as > 140/90 mm Hg in the clinic and < 135/85 mm Hg outside the clinic (NICE, 2011; Mancia, 2013; CHEP, 2014). Evidence suggests an association between WCH and intermediate harmful health outcomes (left ventricular hypertrophy, nephropathy, retinopathy) in persons with normal BP and persons with sustained HTN. Therefore, WCH may not necessarily be a benign condition. Patients with WCH should be identified for close monitoring and instituting lifestyle improvements early, where necessary. Additional research is needed to better define WCH and low-risk patients. Insufficient evidence exists to support other routine uses of ABPM in persons with HTN.
Policy update:

Keystone First identified one additional systematic review for the United States Preventive Services Task Force (USPSTF) that updated a 2007 systematic review on the benefits and harms of screening for HTN in adults and summarized evidence on rescreening intervals and diagnostic and predictive accuracy for cardiovascular events of different BP methods (Piper, 2015). The USPSTF and CHEP now recommend using ABPM to confirm initially elevated BP measured by office-based screening methods to avoid potential over-diagnosis of isolated clinic HTN and harms of unnecessary treatment (Siu, 2015; Cloutier, 2015). These results do not change earlier findings; therefore, no changes to the current policy are warranted.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Piper (2015) for Agency for Healthcare Research and Quality (AHRQ)</td>
<td>Key points:</td>
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<tr>
<td>Screening for high BP in adults, rescreening intervals and diagnostic/predictive accuracy of BP methods for cardiovascular events</td>
<td>• Systematic review of multiple studies, including 11 studies (8,458 total participants) of the predictive value of ABPM methods for long-term cardiovascular events, after adjustment for office-based BP measurement.</td>
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<tr>
<td></td>
<td>• Overall quality: Fair to good.</td>
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<td>• ABPM predicted long-term cardiovascular outcomes independently of office BP (hazard ratio [HR] range, 1.28 to 1.40).</td>
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<td>• Persons with BP in the high-normal range, older persons, those with an above-normal body mass index and African Americans are at higher risk for HTN on rescreening within six years than are persons without these risk factors.</td>
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<td>• For patients who undergo ABPM and have an ambulatory blood pressure of &lt; 135/85 with no evidence of end-organ damage, their cardiovascular risk is likely similar to that of normotensives.</td>
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<td>Health Quality Ontario (2012)</td>
<td>Key points:</td>
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<tr>
<td>ABPM versus clinic BP in persons with uncomplicated HTN</td>
<td>• Systematic review of three large RCTs (n = 1,882) comparing ABPM to clinic BP in persons with uncomplicated HTN.</td>
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<td></td>
<td>• Overall quality of evidence — Very low to moderate and conflicting.</td>
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<td></td>
<td>• Incorporating ABPM in the diagnostic algorithm for persons with uncomplicated hypertension arterial (HTA) results in lower and less intensive antihypertensive medication consumption and improved BP control.</td>
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<td>• Over the long term, patients managed with ABPM had fewer fatal and non-fatal cardiovascular events (RR 1.76, 95% CI 1.03 to 3.02), but conventionally managed patients were more likely to have control of BP (RR 0.90, 95% CI 0.81 to 0.99). No difference between groups in the number of patients who began multi-drug therapy or risk for a drug-related adverse event.</td>
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<tr>
<td>Health Quality Ontario (2012)</td>
<td>Key points:</td>
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<tr>
<td>Carotid Endarterectomy (CEA) of conventional BP monitoring versus ABPM</td>
<td>• A systematic review of two economic evaluations and one primary CEA compared conventional and ambulatory monitoring for uncomplicated HTN. Overall quality: variable.</td>
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<td>• One United States study reported savings for diagnosis and treatment with ABPM ranging from $85,000 to $153,000 per 1,000 patients based on 20% and 5% of patients with WCH confirmed to be hypertensive, respectively (Krakoff, 2006).</td>
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<td>• One study in the UK reported incremental cost-effectiveness ratios (ICER) of £3,000 to £26,000 per quality-adjusted life-year (QALY) for ABPM versus conventional monitoring (Lovibond, 2011).</td>
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<tr>
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<td>• Canadian perspective: ABPM would save the health system $19 million (Cdn) over five years, with a borderline dominant effect (ICER: $30 per QALY).</td>
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<td>Hodgkinson (2011)</td>
<td>Key points:</td>
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<tr>
<td>Clinical or home</td>
<td>• Systematic review of 20 eligible studies, of which only seven studies (clinic) and three studies...</td>
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<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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| BP monitoring (HBPM) versus ABPM in adults | (home) could be directly compared with ABPM.  
- Neither clinic nor home measurement had sufficient sensitivity or specificity to be recommended as a single diagnostic test.  
- ABPM before the start of lifelong drug treatment might lead to more appropriate targeting of treatment, particularly around the diagnostic threshold.  
- CEAs are needed before wholesale changes to the diagnosis of HTN can be recommended. |
| Conen (2008) Predicting cardiovascular risk using 24-h SBP | Key points:  
- Systematic review of nine cohort studies (n = 9,299 with 881 outcome events) of association between 24-h SBP and a combined cardiovascular endpoint.  
- Overall quality — Low to moderate, follow-up 11.1 years.  
- 24-h SBP is a strong predictor of cardiovascular events, providing prognostic information independent of conventional in-office BP readings. |
| Hayes (2004) ABPM vs. office BP measurement in adults | Key points:  
- Systematic review of multiple prospective studies of treated and untreated hypertensive patients and normotensive patients.  
- Overall quality — Low to moderate. Heterogeneous study designs limited data interpretation.  
- ABPM can distinguish between normotensive patients, patients with WCH and patients with sustained HTN. Insufficient evidence for assessing BP in patients with evidence of severe HTN who require hospital admission for appropriate diagnosis and treatment.  
- ABPM provides independent prognostic information for cardiovascular risk, but impact on health outcomes is lacking: |
| Appel (2002) for AHRQ ABPM versus HBPM versus clinic BP monitoring | Key points:  
- Systematic review of 18 studies of various designs.  
- Overall quality — Low to moderate.  
- For both SBP and DBP, clinic BP measurement exceeded HBPM and ABPM; few studies compared HBPM and ABPM.  
- ABPM levels and ABPM patterns were associated with BP-related target organ damage; lower risk in individuals with WCH than in those with sustained HTN.  
- In aggregate, ABPM appears useful in evaluating prognosis. Insufficient evidence to determine whether risks associated with WCH are sufficiently low to consider withholding drug therapy in this large subgroup of patients with HTN. |
| CMS (2001) Impact of ABPM on management and outcomes | Key points:  
- Building on a 2001 Blue Cross Blue Shield Technology Evaluation Center (BCBSA TEC) report, systematic review of two RCTs, three cohorts, seven case series and one case control study of persons with suspected WCH.  
- Quality of evidence — Moderate.  
- Persons with WCH have intermediate harmful health outcomes (left ventricular hypertrophy, nephropathy, retinopathy) compared with normotensive people.  
- ABPM may help diagnose WCH as part of a risk assessment, but insufficient evidence to support use of ABPM for other indications.  
- More research needed to better define WCH in low-risk patients. |
| BCBSA TEC (1999/2001) ABPM in adults | Key points:  
- Systematic review and update of 18 cross-sectional studies of ABPM in adults.  
- Overall quality of evidence: Poor to moderate and only for evaluation of WCH.  
- ABPM can identify a group of patients with WCH who have an intermediate risk profile, partially dependent on the definition.  
- The effect of ABPM on treatment decisions or patient outcomes is uncertain. |
**Glossary**

**Ambulatory blood pressure monitoring (ABPM)** — A noninvasive method of obtaining BP readings at regular intervals over 24 hours while the individual is in his or her own environment, representing a true reflection of the individual’s BP.

**Dipping status** — Describes decreases in an individual’s BP during nighttime hours or when sleeping.

**Hypertension** — Persistently high systemic arterial BP based on multiple readings (NHLBI, 2005):
- **Prehypertension** — SBP of 120 – 139 mm Hg and DBP of 80 – 89 mm Hg.
- **Stage 1 hypertension** — In adults, SBP of 140 – 159 mm Hg and DBP of 90 – 99 mm Hg; in children, an average BP level from the 95th percentile to 5 mm Hg above the 99th percentile.
- **Stage 2 hypertension** — SBP of ≥ 160 mm Hg or DBP of ≥ 100 mm Hg; in children, an average BP that exceeds 5 mm Hg above the 99th percentile.

**Masked hypertension** — Normal BP in the office and elevated BP outside of the medical setting.

**Sustained hypertension** — Hypertension displayed by both clinic BP and ABPM.

**White coat hypertension (WCH)** — BP that is persistently elevated in the presence of a health care worker, yet is not elevated when measured elsewhere (e.g., outside of the medical setting), in patients not taking antihypertensive medications. This phenomenon occurs in approximately 15 percent – 20 percent of patients with Stage 1 HTN.

**References**

**Professional society guidelines/other**


Peer-reviewed references:


Clinical trials:

Searched www.clinicaltrials.gov on April 14, 2016 using terms Open Studies | ambulatory blood pressure monitoring. 71 studies found, one relevant.


CMS National Coverage Determinations (NCDs):


Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.
Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>93784</td>
<td>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.</td>
<td>For ICD-9 796.2 and ICD-10 R03.0 codes only.</td>
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<tr>
<td>93786</td>
<td>Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; recording only.</td>
<td>For ICD-9 796.2 and ICD-10 R03.0 codes only.</td>
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<tr>
<td>93788</td>
<td>Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; scanning analysis with report.</td>
<td>For ICD-9 796.2 and ICD-10 R03.0 codes only.</td>
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<tr>
<td>93790</td>
<td>Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; review with interpretation and report.</td>
<td>For ICD-9 796.2 and ICD-10 R03.0 codes only.</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
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<tr>
<td>R03.0</td>
<td>Elevated blood pressure reading without diagnosis of hypertension.</td>
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